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INTERACTIONS BETWEEN COMPETITION AUTHORITIES AND SECTOR REGULATORS – Contribution from Kazakhstan

- Session III -

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This contribution is submitted by Kazakhstan under Session III of the Global Forum on Competition to be held on 1-2 December 2022.

More documentation related to this discussion can be found at: oe.cd/icar.

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Interactions between Competition Authorities and Sector Regulators

- Contribution from Kazakhstan –

1. Introduction

1. Timely provision of medicines to the population directly affects the state of protection of the health and well-being of citizens, and its quality affects the level of national security.

2. The coronavirus infection pandemic in 2020 became an indicator that opened up problematic issues in the pharmaceutical industry in Kazakhstan, which led to speculation about increased prices for anti-covid drugs.

3. In this regard, for the purpose of more precise control over the regulation and approval of prices for medicines, the antimonopoly authority *(the Agency for Protection and Development of Competition of the Republic of Kazakhstan)* in 2020 became a co-regulator of marginal prices for medicines.

2. The work done by the Agency for Protection and Development of Competition

2.1. Work within the framework of price regulation

4. In a short period, the antimonopoly department employees took measures to revise the pricing procedure, which allowed reducing the negative consequences of the coronavirus pandemic, this is primarily:

- reduction of wholesale and retail prices for medicines by reducing unreasonable margins in the form of marketing costs from 50 to 30%;
- reduction of prices for medicines used in treatment protocols for coronavirus infection (marketing costs are excluded, in the amount of 30%, margins on a regressive scale are reduced in wholesale sales from 10-21% to 5-10.5%, in retail sales from 55% to 20%);
- the state regulation of prices for medical masks has been canceled (prices have been reduced by 56.7% from 60 to 26 tenge).
- prices for PCR tests for COVID-19 have been reduced (from 19,220 to 2,900 tenge).

5. In accordance with the instruction of the Head of State, the Ministry of Health of Kazakhstan, together with the Agency, is conducting step-by-step work on balanced regulation of prices for medicines and medical products with the suppression of anticompetitive actions of pharmaceutical market participants.

6. It is worth noting that currently, 7,705 trade names of medicines are registered in Kazakhstan, and the Agency double-checks and coordinates prices for each drug, while according to the analysis of drug price regulation conducted by Ernst&Young, countries such as the Russian Federation, Germany, Great Britain, China, Australia do not apply price control measures for all drugs.

7. In Kazakhstan, in order to prevent a sharp jump in prices for medicines, systematic work is being carried out in 3 stages of state regulation of prices:

- The first stage of 2022-2023 involves removing over-the-counter drugs that are available for free sale, homeopathic remedies, biologically active additives, vitamins, and medicines for the treatment of simple diseases from state regulation.
- The second stage 2023-2025 – prescription drugs in retail sales.
- The third stage 2025-2026 – prescription drugs in wholesale.

2.2. Regulatory changes to the legislation

8. As part of the ongoing work, in January 2022, amendments were made to the Code of the Republic of Kazakhstan "On the Health of the People and the Healthcare System" in terms of securing the authority to coordinate marginal prices for medicines with the antimonopoly authority, as well as to the Rules of Regulation, the formation of marginal prices and Margins for medicines, as well as medical products within the guaranteed volume free medical care and (or) in the system of compulsory social health insurance, in terms of the procedure for the formation and approval of the draft list of medicines, subject to price regulation for wholesale and retail sales. According to the new edits, regulation is subject to:

- prescription medicines;
- over-the-counter medicines having no more than 3 trade names of medicines within one international nonproprietary name and (or) having no more than 3 manufacturers of trade names of medicines within one international nonproprietary name;
- over-the-counter medicines included in the list of medicines and medical products purchased from a single distributor and (or) in the list of medicines and medical products for free and (or) preferential outpatient care for certain categories of citizens with certain diseases (conditions).

3. Problems of interaction with the industry regulator (Ministry of Health)

9. There are certain shortcomings in the interaction of the antimonopoly authority with the industry regulator represented by the Ministry of Health of the Republic of Kazakhstan. For example, an imperfect procedure for registering the manufacturer's price. When registering prices for medicines of foreign manufacturers, the prices of 16 reference countries (Azerbaijan, Belarus, Bulgaria, Hungary, Greece, Latvia, Lithuania, Poland, Russia, Romania, Slovakia, Slovenia, Turkey, Croatia, Czech Republic, and Estonia) determined by the Ministry of Health should be analyzed. However, information on prices is provided exclusively by the owners of trade licenses without researching alternative sources of information for the validity of the claimed data.

10. There is no possibility to double-check the actual costs (manufacturer's price, transport, customs costs) when registering the price of a medicinal product. The formation of prices for certain medicines takes into account customs costs, whereas the rate of import customs duty is set at 0%, and it is also not allowed to exceed the permissible amount of transport costs (no more than 15%) of the declared manufacturer's prices.

11. There are also regulatory gaps. So, in the rules of regulation, the formation of marginal prices, there is no detailing of costs for logistics/customs and other expenses. Thus, the antimonopoly authority assumes that this legislation allows the formation of marginal prices at artificially inflated costs.

12. Along with this, there are administrative barriers to the entry of new medicines into the commodity market:

- the complex procedure of submission for placement and approval of lists of medications (state register of registered medicines and medical devices, Kazakhstan national drug form, list of a single distributor, list of outpatient drug provision, list of marginal prices, protocol of treatment of diseases);
- non-compliance with deadlines for the approval of marginal costs;
- the absence of a methodology that allows the possibility of registering prices in a shorter time, etc.

4. Conclusions

13. Taking into account the risks of a possible increase in prices for deregulated medicines, the Agency, together with the Ministry of Health, has developed a Comprehensive Plan for implementing joint measures on drug pricing.

14. Within the framework of the Comprehensive Plan, measures are envisaged to track the prices of the purchase and import of medicines to Kazakhstan, obtain information on the cost and volume of sales of drugs, improve national legislation in terms of detailing the full name of the medicinal product in receipts, including the form, dosage, and other information, as well as shorten the registration/re-registration of medicines, the introduction of the principle of “openness” and much more.

15. These measures will allow timely identification of signs of violation of legislation in the field of competition protection and take appropriate response measures.