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Competition Issues in the Health Sector and Pharmaceuticals

Contribution by The Russian Federation

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Questionnaire to Member States to support the discussion on competition issues in the health sector and pharmaceuticals

1. Abuse of market dominant position in the pharmaceutical markets

Getting the optimal balance between intellectual property rights and protection of competition is the most important issue related to the development of innovative medicines and the welfare of the population.

Exclusive rights to the results of intellectual activity may provide a market participant with a certain market power. In 2017-2018, a case on violation of antimonopoly legislation by the "Novartis Pharma" was initiated and considered according to the Paragraph 1 Part 1 Article 10 of the Law on Protection of Competition. The company increased prices for an oncological medicine that was under patent protection for almost 35% per package (more than 500 EUR).

Commission of the FAS Russia concluded that "Novartis Pharma" as a dominant player in the commodity market of the medicine with INN "Lapatinib" in the Russian Federation established a monopolistically high price for the medicine through commercially unjustified inclusion of bonuses (discounts) in the price of the medicine for their distributors. Commission of the FAS Russia made a decision to issue an order to eliminate identified violation, but the judicial system of the Russian Federation did not support this decision.

In the process of consideration, the FAS Russia established that defendant's active substance is also patented, although it does not differ significantly from the applicant's patent. Possibility and validity of registration of the second patent is the source of the problem that is now being resolved in court and a definite solution to the problem has not yet been found.

In addition, it can be mentioned that the FAS Russia is currently dealing with the increased number of cases in which defendants, including multinational companies, are trying to justify their anticompetitive actions by citing antitrust "immunities" for intellectual property. Such "immunities" are described in Paragraph 4 Article 10 and Paragraph 9 Article 11 of the Federal Law "On Protection of Competition". It is noted there that norms of these articles, which prohibit economic entities from abuse of dominance in the market and agreements that restrict competition, do not apply to exclusive rights to the results of intellectual activity.

The case of 2013-2015 related to TEVA (Israel) may serve as an example as it violated Paragraph 5 Part 1 Article 10 of the Federal Law "On Protection of Competition". In 2010, a 5-year agreement was signed between "Biotek" and TEVA for the supply of the medicine "Copaxone" (included in the list of vital and essential medicines and used to treat multiple sclerosis), its storage, secondary package, distribution and promotion within the Russian Federation. In 2012, TEVA branched out its office in the Russian Federation, through which it began to independently participate in state procurement, ignoring the orders of "Biotek" and not disclosing the reason for avoiding conclusion of supply agreements. After considering the complaint of the "Biotek", the FAS Russia decided that TEVA was responsible for the violation of the Russian antimonopoly legislation due to refusal to supply "Copaxone" medicine. In its defense TEVA referred to antimonopoly "immunities", namely to Paragraph 4 Article 10 of the Federal Law "On Protection of Competition". However, the Supreme Court of the Russian Federation also supported the decision of the FAS Russia.

In response to the described problems, the FAS Russia plans to exclude "immunities" for intellectual property from antimonopoly legislation - all the provisions provided to ensure the interests of the right holder are governed by civil law and a number of special laws, so that the exclusive rights to the results of intellectual activity will not be reduced if "immunities" are canceled.

At the same time, together with the increase in the risk of abuse of dominance by rights holder, expressed in establishing and maintaining commercially unjustified high prices, as well as refusing to produce or supply necessary medicines and medical devices to the Russian Federation, the FAS Russia developed a draft law on compulsory licensing. Such mechanism would limit intellectual property rights for the public benefit.

After the draft law enters into force, the Government of the Russian Federation for the purpose of state security and the life of citizens will be able to transfer to the domestic testing laboratory a formula of a medicinal product in order to produce it within the country with subsequent remuneration to the rights holder. It is worth noting that such legal mechanism should be applied only in exceptional circumstances that may endanger national defence and security, including the life and health of citizens of the Russian Federation.

2. Concentration in hospital markets

In its work, the FAS Russia regularly deals with the increase in economic concentration in the health care market. In general, the economic concentration in a given market

within the Russian Federation arises not due to the organic growth of a medical organization, but due to a merger. More detailed information on evaluation of mergers by the FAS Russia and specific examples of economic concentration deals in the health care markets will be given in the next section.

In terms of economic concentration in hospitals market, it is important to note that recently the FAS Russia raised an important issue of medical licensing - it was found that in the Russian Federation there is no uniform system of requirements for license applicants and licensees. Moreover, licensing authorities of the subjects of the Russian Federation and supervisory authorities specify requirements for medical organizations at their own discretion, which leads to competition restriction.

The attention of the FAS Russia was drawn by the Order No. 121n issued by the Ministry of Health of the Russian Federation in 2013, which, in the opinion of the FAS Russia, violated medical licensing regulation as it did not contain any licensing requirements for works and services constituting medical activities. In 2016, the FAS Russia sent a warning to the Ministry of Health, and in 2017 initiated a case. Following the consideration of the case, the Ministry of Health was ordered to establish the requirements for medical licensing for each medical work (service). Ministry of Health of the Russian Federation did not agree with this decision and went to court.

On November 29, 2018, the Moscow District Arbitration Court (cassation instance) rejected a claim of the Ministry of Health of the Russian Federation and Roszdravnadzor (Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation) to cancel the decisions and the order of the FAS Russia. The court also upheld a ruling of the court of the first instance and the ruling of the appeals instance, which had previously recognized as lawful the decision and order of the FAS Russia.

3. Merger Review in health markets

The FAS Russia quite often reviews mergers in the health care market. In examining such transactions, a lot of attention is paid to investigation of the following aspects:

1) study of the product boundaries of the commodity market by identifying characteristics of goods (services) that determine buyer’s choice and potentially interchangeable goods (services) for the given goods (services); definitions of interchangeable goods (services). When establishing the interchangeable goods (services), the competition authority pays great attention to study consumer-

oriented, technical and quality characteristics of the goods (services), application of such goods (services), its functional use and price;

2) definition of the geographical boundaries of the commodity market (territory boundaries in which the buyer of the medical service (the patient) obtains or has an economic, technical or other opportunity to obtain the goods (service) and does not have such an opportunity beyond this boundaries). When determining the geographical boundaries of the commodity market, the competition authority determines the territories included in the geographical boundaries of the commodity market in question. The commodity market can cover the territory of the Russian Federation or go beyond it (federal market), cover the territory of several subjects of the Russian Federation (interregional market), not go beyond the borders of the subject of the Russian Federation (regional market), not go beyond the borders of the municipal unit (local market);

3) definition of the composition of economic entities operating in the commodity market within established geographical boundaries, calculation of the commodity market size and the shares of economic entities in this market as well as determination of the level of concentration in such commodity market.

Example of state control over economic concentration in the health care markets could be a deal between "Ranbaxy" and "Biosintez". In December 2016, the FAS Russia with an order approved the request of "Ranbaxy" (a subsidiary of one of the largest Indian pharmaceutical companies Sun Pharmaceutical Industries) to acquire up to 100% of the voting shares of the medicine company "Biosintez".

It was identified that within the territory of the Russian Federation the company "Biosintez" solely manufactured certain medicines that were registered and authorized for medical use. Thus, the company occupied a dominant position in each commodity market of the corresponding medicinal product. The FAS Russia concluded that due to this transaction, "Ranbaxy" would be able to set out general terms of circulation of these medicines in the relevant product markets, which could restrict market access.

According to the order issued by the FAS Russia, "Ranbaxy" had to perform all the contracts previously concluded by "Biosintez" with counterparties and should not reduce the output or supply of medicines, if this is not economically or technologically justified measure. In addition, the company had to develop and place on its official website a document specifying interaction of the "Ranbaxy" with counterparties in order to ensure the transparency of the conditions.

Another example could be the case of the FAS Russia that was considered in 2014. "Rigla" pharmacy chain filed an application to the FAS Russia for the acquisition of "Central Pharmacies". During the consideration of this transaction, it was established that within the geographic boundaries of the Yaroslavl region such merger will strengthen the dominant position of "Rigla", whose share in this market in the Yaroslavl region will be 50.61%. In this regard, the FAS Russia refused to satisfy the petition.

4. Horizontal and vertical conduct by practitioner groups

With regard to the impact on competition, antimonopoly legislation in Russia does not provide for any provisions that separately regulate the behavior of doctors. At the same time, upon an initiative of the FAS Russia in order to govern competitive relations, provisions that regulate behavior of medical and pharmaceutical workers in their professional activities were introduced in Russian legislation in the field of health care.

Thus, Article 74 of the Federal Law No. 323 dated 21.11.2011 "On Fundamental Healthcare Principles in the Russian Federation" (hereinafter the Law on the Fundamental Healthcare Principles) defines a number of restrictions imposed on medical and pharmaceutical workers in their professional activities. In particular, in accordance with the Law on the Fundamental Healthcare Principles, medical workers and heads of medical organizations are not allowed to:

1) accept gifts, cash (with the exception of contract fees for conducting clinical trials of medicinal products, clinical trials of medical devices, and remuneration for pedagogical and (or) scientific activities), including payments for entertainment, recreation and associated travel costs from organizations engaged in the development, production and (or) disposal of medicines, medical devices, organizations that hold rights for the trade name of a medicine, wholesalers of medicines, pharmacy organizations (their representatives, other individuals and legal entities carrying out their activities on behalf of these organizations) (hereinafter respectively - the company, a representative of the company) as well as to participate in entertainment events held at the expense of companies, representatives of companies;

2) enter into agreements with the company, a representative of the company on the prescription or recommendation to patients of medicines or medical devices (with the exception of contracts for conducting clinical trials of medicinal products or clinical trials of medical devices);

3) receive from the company, a representative of the company, samples of medicinal products or medical devices for delivery to patients (with the exception of contracts for conducting clinical trials of medicinal products or clinical trials of medical devices);

4) provide inaccurate and (or) incomplete information about medicines or medical devices used when prescribing a course of treatment to a patient, including hiding information about the availability of similar medicines or medical devices;

5) accept representatives of companies, with the exception of contracts for conducting clinical trials of medicinal products or clinical trials of medical devices, participation according to the established procedure in meetings of medical workers and other events aimed at professional development or at providing information, related to the implementation of safety monitoring of medicines and medical devices;

6) issue prescriptions for medicinal products or medical devices on forms containing advertisement, as well as on forms on which the name of the medicinal product or medical device was printed in advance.

5. Policy developments in healthcare and pharmaceuticals

The FAS Russia developed a Road Map for developing competition in the healthcare sector, approved by the Decree of the Government of the Russian Federation No. 9-p dated January 12, 2017. The Road Map contains 47 activities for the development of competition in the healthcare sector and provides for measures to promote competition in the markets of medicines, medical products, medical services, as well as dietary supplements for the next four years. Key activities for developing competition include: improving procedures for state marketing authorization of medicine and dietary supplements; change in the mechanism for price regulation of the medicines included in the list of vital and essential medicines; ensuring the functioning of the institute of interchangeability of medicine and medical products; improvement of legislation in the field of procurement of medicine and medical products for state and municipal needs; settlement of intellectual property protection questions; development of competition between pharmacy organizations; development of measures aimed at reforming the legislation on compulsory health insurance and others.

It is important to note that the development of competition in the healthcare sector is also supported by the Decree of the Government of the Russian Federation No. 1380 dated November 15, 2017 "On the features of the description of medicines for medical use, which are the subject of procurement for state and municipal needs". By virtue of the adopted document, prohibitions and restrictions came into force in relation to the description of the technical characteristics of the purchased medicines in terms of indicating therapeutically insignificant characteristics by the customers that correspond to specific brand names of the medicines, which lead to restriction of competition in bidding. Adherence of customers to the provisions of this decree contributes to increased access to medicines and efficiency of budget expenditures on medicine provision through lowering medicine prices during procurement, as well as suppressing unfair practices of customers and cartelization among procurement participants. Due to entry into force of this decree, increase in competition among manufacturers and distributors of medicine is expected, decrease in the number of complaints regarding actions of public procurement authorities, as well as legitimization of clarifications made by the FAS Russia sent to market participants and control bodies within the framework of competition advocacy. It should be noted that the FAS Russia won Competition Advocacy Contest of the World Bank - International Competition Network in 2017-2018 for "Creating markets for private sector development".

In October 2018, the Decree of the Government of the Russian Federation No. 1207 dated 08.10.2018 came into force, which approved the new rules developed by the FAS Russia for registration (re-registration) of prices for medicines included in the list of vital and essential medicines as well as the method for their calculation. The new rules and methods have formed a transparent, objective, non-discriminatory and unhindered system to register the maximum selling prices for medicines included in the list of vital and essential medicines, preventing significant price increase for expensive medicines and unprofitable production of cheap medicines.

In addition, the Ministry of Health of the Russian Federation together with the FAS Russia developed a draft law aimed at improving the procedure for determining the interchangeability of medicines – its implementation can significantly increase the share of interchangeable medicines, contribute to the formation of equivalent groups of medicines, and, therefore, create a transparent and competitive system of central and local government procurement.