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Roundtable "Designing Publicly Funded Healthcare Markets"
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The FAS Russia is working to solve the main existing problems in the field of healthcare that have a significant impact on competition, such as issues of substitutability of medicines and medical products, the lack of specialized regulatory legal acts regulating the market of medical products, the distribution of the volume of medical care provided under the compulsory medical insurance program between medical organizations.

In the field of circulation of medicines

The most acute problem of the development of competition in the commodity market of medicines continues to be the question of the substitutability of medicines.

The Russian Ministry of Health has not yet adopted the act of equivalence of medicinal forms of medicines, which allows unfair state and municipal customers to specify the requirements for the supply of specific medicinal forms of medicines, rejecting the therapeutic effects equivalent to pharmaceutical forms.

Moreover, in 2016-2017, despite the current Order of the Ministry of Health dated July 27, 2016 No. 538n "On establishment of the List of names of medicinal forms of medicines for medical use", the Ministry continued to register medicines in pharmaceutical forms that are not included in the established list. So, starting from September 1, 2016, about 30 medicinal products were registered in pharmaceutical forms that do not correspond to the Order of the Ministry of Health dated July 27, 2016 No. 538n.

At the same time, since 2018, state and municipal customers are beginning to use the informational analytical system for monitoring and controlling the procurement of medicines. The lack of information on the equivalence of pharmaceutical forms and dosages in the State Register of Medicines, as well as in a single directory of medicines for monitoring and controlling the procurement of medicines leads to monopolization of the pharmaceutical markets, as it allows customers to choose any parameters at their discretion without availability of equivalent medicines, and also prevents the implementation of correct calculations of reference prices for the formation of objective initial (maximum) prices of contracts by customers.

As part of the work on the analysis of the commodity markets of medicines, the FAS

Russia issued guidelines[1] on creating documentation for procurement for state and municipal needs in relation to medicines with the following international non-proprietary names: Trastuzumab, Rituximab, Peginterferon alpha-2b and Cepeginterferon alpha-2b, Paclitaxel, as well as for medicines with the group name "Vaccine for tick-borne encephalitis prevention".

Based on the information specified in the established instructions on the medical use of medicines, assessments of experts and the Russian Ministry of Health, the FAS Russia made a conclusions about the equivalence of these medicines for certain groups of patients[2].

In addition, at the request of business entities, guidelines were issued to establish the period of useful medicine's life remaining purchased for state and municipal needs. Issued guidelines on the substitutability of syringes packaged in "poly-bag" and "blister" (or in other packaging that ensures the quality, effectiveness and safety of the medical product itself).

The results of the analysis of the registration dossier on medicines with the INN Peginterferon alfa-2b and Cepeginterferon alpha-2b formed the basis of these guidelines that these medicines in the pharmaceutical form of “lyophilisate for preparing a solution for subcutaneous administration” and “solution for subcutaneous administration", despite the different INN, contain the same active substance" pegylated interferon alpha-2b "and can be used to treat patients over 18 years old as part of combination therapy for hepatitis C[3]. In this regard, customers need to ensure the possibility of simultaneous participation in such a purchase of suppliers of equivalent medicines with the INN Peginterferon alfa-2b and Cepeginterferon alpha-2b.

Guided by the position set forth in the guidelines, when considering complaints from R-Pharm and RUSMEDCOM companies about the actions of the Russian Ministry of Health when reviewing applications for participation in electronic auctions[4] for the supply of a medicinal product with INN Cepeginterferon alpha-2b, expressed in the rejection of participation in which the medicine with the INN Peginterferon alfa-

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[1] The FAS Guidelines of 24.05.2017 “On creating documentation for procurement for state and municipal needs in relation to medicines with the international non-proprietary names Peginterferon alpha-2b and Cepeginterferon alpha-2b” (Russian version only): https://fas.gov.ru/documents/-33a7f27a-8440-4d11-855e-4342e6ae914f

[2] The FAS press-release of 28.06.2017 “Substitutability of Hepatitis C drugs, established by FAS, saved more than 18 million RUB to the budget”: http://en.fas.gov.ru/press-center/news/detail.html?id=50657

[3] The FAS Guidelines of 27.02.2017 “On the procurement of medicines with INN Peginterferon alpha-2b and Cepeginterferon alpha-2b” (Russian version only): https://fas.gov.ru/documents/-ec33125a-3010-4d8d-8775-465b3daa48c4

[4] № 0195100000217000142, 0195100000217000148, 0195100000217000147, 0195100000217000141

2b was offered for delivery, the FAS Russia recognized the complaints as justified and issued prescriptions[5] to the Russian Ministry of Health to eliminate the violations. According to the results of the repeated procurement procedure of the medicinal product with the INN Cepeginterferon alpha-2b in a competitive environment and taking into account the guidelines of the FAS Russia, the reduction from the initial (maximum) price of contracts ranged from 44 to 60%[6].

Based on the long-term experience of the control activities of the FAS Russia and taking into account the existing enforcement and judicial practice, the FAS Russia has formulated the most typical examples of restricting competition in the procurement of medicines, and also summarized all the guidelines on public procurement of medicines.

These materials were used as the basis for the Resolution of the Government of the Russian Federation of November 15, 2017 No. 1380 "On the features of the description of medicinal products for medical use, which are the subject of procurement for state and municipal needs".

Thanks to the adopted document, prohibitions and restrictions have been established with regard to the description of the technical characteristics of the purchased medicines, in terms of indicating therapeutically insignificant characteristics by the customers, corresponding to specific brand names of the medicines, leading to restriction of competition in the bidding.

Compliance by customers with the provisions of this decree should help:

- increasing the availability of medicines for citizens of the Russian Federation and the effectiveness of budget expenditures on medical provision through the reduction of prices for medicines at auctions;

- suppression of actions of unfair customers and cartelization among procurement participants;

- significant budget savings, which can be additionally directed to medical provision of citizens.

The Act adopted by the Government of the Russian Federation received the highest rating at the world level. In 2017, the FAS Russia won the nomination "Creating markets for private sector development" of the international competition advocacy award held annually by the World Bank in conjunction with the International Competition Network, presenting its experience in this regard.

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[5] The FAS press-release of 26.07.2017 "Arbitration supported the FAS decision to purchase the anti-tuberculosis medicine" (Russian version only): https://fas.gov.ru/news/1431

[6] The FAS press-release of 24.10.2017 "The appeal confirmed the lawfulness of the FAS decisions and prescriptions for the purchase of the anti-tuberculosis medicine" (Russian version only): https://fas.gov.ru/news/23307

In addition, in order to improve the regulatory framework in the field of medicines' procurement for state and municipal needs, the FAS Russia has developed a draft Decree of the Government of the Russian Federation aimed at prohibiting the unification of services for the supply, storage and distribution of medicines for state and municipal procurement.

In the field of circulation of medical devices

The market for medical devices and related markets of consumables and maintenance (repair) are highly concentrated due to the behavior of market participants, as well as the lack of systemic legal regulation.

The development of competition in the markets of medical devices, including spare parts and accessories, special software, in the markets of consumables, as well as maintenance and repair, is hampered by the massive transition of medical device manufacturers to the use of special software and hardware tools aimed at restricting the use of alternative equivalent consumables (reagents).

The absence of information about the medical device (instructions for use, technical characteristics) in open sources results in the situation when the procurement participants provide different sets of documents confirming the technical and functional characteristics of the product, the completeness and accuracy of which cannot be assessed by the customer.

The issue of substitutability of medical devices also remains the most acute problem of developing competition among manufacturers of medical devices, suppliers of medical devices for state and municipal needs, prevents a reduction in prices for medical devices, leads to unreasonable expenditures of budget funds and reduction of availability of medical devices for patients.

The market for maintenance and repair of medical devices remains closed even among business entities that have the appropriate license for this type of activity, as the suppliers of medical devices do not provide the necessary information, keys and passwords not only to third-party contractors for the necessary technical maintenance and repair, but also to buyers themselves - medical organizations that are the owners of the relevant medical devices.

Thus, the owners depend on the suppliers, at whose discretion price conditions, terms of performance of works, provision of services, and the list of executors for the repair and maintenance of medical products are formed.

In order to eliminate these problems, the FAS Russia proposes to legally fix the obligation for the manufacturer (supplier) of a medical device to transfer together with the medical device the information, keys, passwords, etc. necessary for its repair and maintenance, thereby ensuring the owner - the medical organization - the

right to fully own, use and dispose of their property - a medical device.

The FAS Russia in a letter of 15.11.2017 agreed on a draft Order of the Russian Ministry of Health “On Amendments to Annexes No. 1 and 2 of the Order of the Ministry of Health of the Russian Federation of October 15, 2015 No. 724n “On approval of a model contract for the supply of medical devices, and commissioning medical devices, training in the operation of experts who operate medical devices, and experts involved in the maintenance of medical devices”.

The draft Order contained an addition to clause 5.3 of the model contract with clause “g.1”, providing for the transfer of "information necessary to work with the Equipment, including the provision of keys, access passwords, programs and other information necessary for installation, commissioning, use, operation, maintenance of this type of equipment".

Considering the variety of medical devices represented on the Russian market, the antimonopoly body proposes to solve the issues of market access for maintenance through self-regulation.

At present, competition in the market of medical devices' servicing is limited due to the artificial monopolization of this activity by manufacturers of medical devices, including through the exclusive right to provide passwords, keys, codes, documentation for the necessary technical measures.

The FAS Russia believes that during the transition to a self-regulation system, one of the functions of self-regulating organizations for servicing medical devices will be monitoring compliance with internal rules and regulations by participants. The self-regulatory organization will be responsible for the activities of its members. In the event that the patient’s health is harmed by the use of a medical device that has become unusable as a result of a service that does not comply with the technical and operational documentation of the manufacturer, the damage shall be compensated by the self-regulating organization.

In addition, the rules adopted in a single self-regulatory organization for service maintenance of medical devices must be uniform with respect to economic entities entering into a self-regulatory organization with the same set of requirements for service maintenance of each type of medical devices.

Issues of operation and maintenance of a medical device are inextricably linked with the procurement and use of consumables for such a medical device. In this regard, the issue of disclosure of information on the requirements for consumables and reagents and on the prohibition of unreasonable restrictions by manufacturers of medical equipment on the possibility of using consumables and reagents from other manufacturers becomes most pressing.

In the field of medical services

The main problem in the development of competition in the provision of medical care under the program of compulsory medical insurance (hereafter - OMS) remains the lack of transparent mechanisms for distributing the volume of medical care among medical organizations.

In 2016, the FAS Commission considered an unprecedented case of violations of antimonopoly legislation, expressed in the creation of discriminatory conditions for the distribution of the volume of medical care in the framework of the regional OMS program.

During the consideration of the case by the FAS Commission, it was established that the Government of St. Petersburg did not ensure non-discriminatory conditions for the distribution of high-tech medical care within the framework of the free medical care program in the city, and the St. Petersburg OMS Commission created discriminatory conditions for medical organizations.

In order to ensure competition, the antimonopoly authority issued binding orders to the Government of St. Petersburg and the OMS Commission.

The Government of St. Petersburg and the OMS Commission of the city did not fulfill the requirements of the FAS Russia, but appealed the decision and prescriptions in court. However, the courts of three instances disagreed with the arguments of the applicants, supporting the position of the antimonopoly body.

In order to form a unified enforcement practice to prevent and suppress the creation of discriminatory conditions for the distribution of the volume of medical care provided in the framework of the regional OMS program, the position developed was communicated to the regional offices of the FAS Russia.

The proposals of the FAS of Russia on the development of competition in the field of healthcare are set forth in the Plan of Measures (“road map”) “Development of Competition in Healthcare”, approved by the Order of the Government of the Russian Federation No. 9-p dated January 12, 2017 and include the following measures.

In the pharmaceutical market:

- improvement of state registration of medicines;

- ensuring the functioning of the institute of substitutability of medicines;

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-improving the mechanism for regulating the prices of medicines included in the list of vital and essential medicines;

- improving the regulatory framework in the procurement of medicines for state and municipal needs;

- improvement of legal regulation in the field of intellectual property protection.

In the medical device markets:

- improving the regulatory framework in the field of circulation of medical devices;

- improvement of the regulatory framework in the field of procurement of medical devices for state and municipal needs.

In the markets of medical services:

- improvement of legislation in the field of health care in terms of determining the volumes and types of medical care provided within the framework of regional programs of state guarantees of free medical care to citizens, the annual update of the program of state guarantees of free medical care to citizens when introducing new medical technologies;

- approval and updating of clinical recommendations (treatment protocols);

- development of proposals for specifying the conditions under which state (municipal) medical organizations can provide paid medical services;

- preparation of proposals for improving the mechanism of distribution of medical care among the participants in the implementation of regional programs of state guarantees of free medical care to citizens.