

Risks in the Drug Procurement System: Current Issues

Riesgos en el sistema de compra de medicamentos: problemas actuales

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Abstract

The public procurement segment is one of the components of the pharmaceutical market in Russia. Procurement of medicines and medical devices is the top sector of public procurement, both in terms of their number and the amount of contracts concluded. The procedure for concluding state contracts itself is spelled out in sufficient detail in the regulatory documents, but, despite this, risks may arise when concluding a state contract both for a potential applicant for a state order and for a state customer. The purpose of the study is to determine the possible risks when concluding a state contract of a healthcare institution for medicines and medical devices and ways to reduce them.

Keywords: risk, state contract, medicines (drugs), public procurement system, procurement procedures, compliance control, pharmaceutical companies

Resumen

El segmento de contratación pública es uno de los componentes del mercado farmacéutico en Rusia. La adquisición de medicamentos y dispositivos médicos es el principal sector de la contratación pública, tanto por su número como por la cantidad de contratos celebrados. El procedimiento para concluir contratos estatales en sí mismo se detalla con suficiente detalle en los documentos reglamentarios, pero, a pesar de esto, pueden surgir riesgos al concluir un contrato estatal tanto para un solicitante potencial de una orden estatal como para un cliente estatal. El propósito del estudio es determinar los posibles riesgos al concluir un contrato estatal de una institución de salud para medicamentos y dispositivos médicos y las formas de reducirlos.

Palabras clave: riesgo, contrato estatal, medicamentos (medicamentos), sistema de contratación pública, procedimientos de contratación, control de cumplimiento, empresas farmacéuticas

Introduction

The pharmaceutical market for the production and sale of medicines in the Russian Federation has its own characteristics. State and municipal purchases of medicines are allocated to a rather specific industry, which has a narrow profile. In this market, there are a relatively small number of companies with their own specialized assortment, such as cancer drugs, insulins, hospital antibiotics, etc., and other dealers do not work with this assortment.

One of the most stable sources of income for the pharmaceutical market is the state order, which includes hospital purchases and preferential drug provision. In 2019, suppliers, as well as performers and contractors, including those registered in the Unified Register of Procurement Participants, submitted 773 applications for participation in procurement under the national project "Healthcare". The State program "Development of Healthcare" ranks second after the state program "Development of the Transport system" in terms of the total cost of concluded contracts. In 2019, 180,737 contracts were concluded, for a total amount of 621,132,793,960 rubles, including 9,119 contracts were concluded within the framework of the national project "Healthcare", for the amount of 96,978,686,273 rubles. (<https://minfins.gov.ru/ru/performance>).

Since medicines are a specific product that has a number of features that affect the state of health and quality of life of people, this type of state contracts is particularly close attention. Moreover, in this case, we are talking about budget organizations, and economic risks are also added to the risks associated with the implementation of socio-economic tasks.

Methods

The study used the following methods: analysis of the problem and the subject of the study, a holistic approach to the study of public procurement management in the field of medicine, the study of sources, and methods of empirical research: analysis and synthesis, methods of systematization and classification of theoretical and practical data.

Results

Any risk is associated with a significant number of factors that influence the decisions made by the participants of public procurement. And, despite the fact that the procedure for concluding state contracts is spelled out in sufficient detail in the regulatory documents, risks in concluding a state contract may arise both for a potential applicant for a state order and for a state customer.

Among the risks at the conclusion of a state contract, two main groups can be distinguished: risks before the conclusion of the contract and possible risks at the stage of contract execution (Table 1).

Table 1. Classification of risks at the conclusion of a government contract

Before signing the contract	During the execution of the contract
liquidity risk in the case of signing the contract with the insolvent or incompetent contractor	the risk of reducing the profitability of the transaction or the occurrence of unforeseen expenses
the risk of nonperformance of the contract, after award of the contract, the counterparty waives its execution	the risk of additional losses, both direct and indirect
the risk of unfair competition	the risk of various disagreements between the partners during the implementation of the transaction
	the risk of invalidity of the concluded contract
	short supply as a risk
	the delivery delay as a risk or a premature delivery
	financial or foreign exchange risk
	the risk of inflation
	non-payment by the customer of the delivery or late payment as a possible risk

In addition, all types of risks that may arise both at the stage of concluding and implementing government contracts can be classified into groups:

1. From the state of the customer's risks include the following possible situation: the counterparty is insolvent partner, after the auctions, from signing of the contract refuses counterparty, the failure by the counterparty of its contractual obligations, or they are incomplete or improperly performed the obligation, the possible ways overestimation of the initial contract price not specified partner with the additional costs of performing its contractual obligations;

2. On the part of the supplier or the contractor of the order, the following risks occur: the financing was made within a different time frame than specified in the contract; the market situation changed in an unfavorable direction; erroneous or incorrect interpretation of the provisions of the tender documentation;

3. Both the state customer and the contractor also have certain risks, namely: first of all, it is a corporate risk; the risk of corruption; in the bidding process, there may be such a risk as the use of unfair competition by bidders, as well as harm or possible damage to third parties, as a risk.

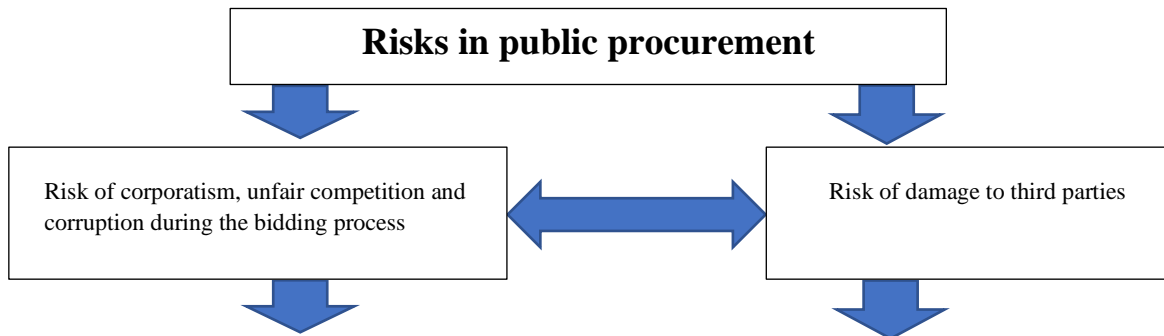


Figure 1. Main types of risks in public procurement

Government procurement remains one of the most attractive financial sources, but antitrust risks are becoming quite high. According to the Federal Antimonopoly Service (FAS), the number of cartel collusions and revealed facts of anti-competitive agreements for the supply of medical devices and medicines is in second place. The facts of collusion in the procurement of medicines and medical products were revealed in 82 regions. The fact that the healthcare sector ranks second in terms of government orders and uncovered anti-competitive agreements confirms the high antitrust risks. The risks of violating the antimonopoly legislation at the auction are very significant and can greatly shake the reputation of the company, lead to multimillion-dollar fines, but also contain clear risks of criminal prosecution.

The FAS of Russia is constantly working to identify violations in this area, regularly reporting on the introduction of new fines for participants in collusions, the initiation of criminal cases in the field of procurement of medicines and medical devices.

One of the largest fines, for example, was paid at the end of 2018 to LLC, the Russian pharmaceutical company "PHARM SKD", which is a distributor with its own logistics structure, in the amount of more than 85 million rubles. During the investigation, a cartel was revealed for the supply of medicines, medical devices, disinfectants and medical nutrition. Moreover, if, in accordance with Article 20.35 of the Code of the Russian Federation on Administrative Offenses, LLC "PHARM SKD" would not pay this fine on time, it would have to pay the amount in double amount.

As examples of successful cooperation between FAS Russia and the law enforcement authorities can consider the following:

- Investigative Committee of Russia in Samara region was indicted and sent to court a criminal case in which former Deputy Minister of health of the Samara region A. S. Navasardyan and others were charged with bid rigging and the commission of crime, provided by part 3 of article 30, part 2 - article 178, part 3 of article 204, part 1 of article 286 of the criminal code;

the inquiry by the Investigation Department of the MIA of Russia, a criminal case under part 4 of article 159 of the criminal code against the former Minister of health of the Republic of Dagestan I. T. Ibrahimova, the results of which revealed the fact of collusion with bidders for the purchase of medicines, medical equipment and medical products with embezzlement of budget funds;

- investigation Investigation Department of the MIA of Russia in Novosibirsk region criminal case under part 2 article 178 of the criminal code of the Russian Federation on the conclusion and implementation of LLC "Kompaniya Fitorodnik" and LLC "Terra Medica" conspiracy to participate in auction on delivery of medical products and medicines for the needs of the Federal State Budgetary Institution "National Medical Research Center named after academician Meshalkin". As a result, collusion was revealed when participating in 450 auctions, the results of which revealed the facts of illegal profit-making in the amount of more than 580 million rubles.

Analyzing such cases, the fact of antitrust risks that occur in the supply of medicines is

confirmed. As we can see, the defendants in such cases are not only officials, but also the chief doctors, the staff of medical institutions that in one way or another provide "services" to win the auction. Antimonopoly risks also apply to the heads of commercial organizations for organizing cartel collusions with customers or government agencies.

Therefore, we see that the main antitrust risks encountered in the activities of pharmaceutical companies can be:

- cartels and anti-competitive agreements;
- various types of abuse of a dominant position, as a result of which unfavorable terms of transactions are imposed on counterparties;
- unreasonable from an economic point of view, the pricing;
- bidding in violation of antitrust laws;
- unfair competition;
- violation of the requirements and legislation in the field of advertising.

It is possible to significantly reduce such antitrust risks by introducing antitrust compliance in the organization, which consists in compliance with internal and external requirements, regulations and norms. Antimonopoly compliance is the most effective mechanism aimed at reducing antimonopoly risks and violations of legislation in this area, and in the event of cartel collusions, the risks of possible crimes are also reduced.

The main objectives of compliance are measures to identify, prevent and eliminate various risks through the tools of compliance control. Among the main tools of compliance control, we can distinguish such as: local regulatory acts regulating the compliance control system; a system for detecting violations of the law and informing about such violations; within the framework of compliance control, conducting training with this system and testing; in case of detection of violations of the law, conducting investigations of compliance procedures; this system provides both incentives and penalties in the event of violations, as well as the inclusion of mandatory clauses in contracts that are of an antitrust nature.

Compliance risks are possible if the following reasons are identified:

- ignorance of legal acts and prohibitions that lead to uncompetitive behavior;
- in the absence of rules for the clear selection of counterparties and further work with them;
- when the rules of working with contractors are violated;
- lack of coordination of actions for the release of advertising materials with legal services;
- the pricing system does not comply with the antimonopoly legislation.

Even if you are fully prepared to implement compliance control in the organization, you should pay very close attention to the development and implementation of this technology. The scope of compliance control tools is significant, it is necessary to know all the subtleties and requirements of the legislation, and a big mistake is made by companies that try to cope with such a volume of work on their own. It is important to know the stages and stages of implementation of a particular project, and ignorance can lead to additional costs and losses. If the organization does not have a compliance system, then additional costs may arise in the form of fines for violating the law.

Conclusions

The analysis of risks at the conclusion of state contracts shows that any economic activity, including the activities of budgetary institutions of the health system, is associated with certain types of risks. Tasks to prevent and minimize risks should be aimed at a more detailed study of existing and potential partners; monitoring prices at the stage of order formation; thorough study of all regulatory, tender and technical documentation, if necessary, the conclusion of contracts for legal support of the transaction; automation of order placement procedures, the use of electronic auctions, which makes procurement activities more open and transparent.

Pharmaceutical company, using a system of compliance control in their activities, in case of violation of norms of the Federal law "On protection of competition" dated 26.07.2006 No. 135-FZ "On combating corruption" dated 25.12.2008 No. 273, can avoid administrative and criminal

sanctions, both in terms of the organization and its employees to help protect business reputation of the organization to contractors and public authorities.

Of course, the choice between activities to minimize antitrust risks carried out by the structural divisions of the company itself or with the involvement of specialists in this field is made by the company's management, but ignoring antitrust risks is a rather risky path.

References

- Abdrahimov, D. (2015). Efficiency of the competitive procurement system: textbook. D. Abdrahimov. Arkhangelsk: publishing Lotsiya, 102s.
- Andreeva, L.V. (2015). About the specifics of procurement of medicines for the provision of state needs [Electronic resource]. All-Russian information-analytical weekly "Auction Bulletin" № 239 (04.189) Thursday, April 30, S.2.
- Baldin, K.V., & Vorobyov, S. N. (2005). Risk management: Textbook for university students studying in the fields of economics and management (060000). Moscow: UNITY-DANA,.
- Ruvinsky, V. (2017). Rating of conscientiousness of public procurement in healthcare [electronic resource]. Kommersant. Money. -28.01.2017 - URL: <https://www.kommersants.ru/docs/31961321>.
- Shavylina, Yu. A. (2015). Features of procurement of medicines included in the list of vital and essential medicines, Moscow, 57-68.
- Sokolova, S.V., Orlov, A.S., Rumyantseva, M.S. (2013). Pharmaceutical market: state procurement of medicines – - M. *Problems of Modern Economy*, 4 (48).
- Summary analytical report on the results of monitoring purchases, goods, and services for state and municipal needs in accordance with Federal Law No. 44-FZ of 05.04.2013 "On the Contract System in the field of procurement of goods, works, and services for State and Municipal needs" based on the results of 2019 - <https://minfins.gov.ru/ru/performance>
- Vinogradov, F.B. (2018). Workshop on participation in procurement in accordance with Federal Laws No. 44-FZ and No. 223-FZ. Journal "Financial Gazette: Finance, taxes, insurance, accounting" January-May, 1-5.