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# Current Issues of Improving the System of Public Procurement of Medicines

[1]Prodanova Natalia Alekseevna, [2]Zatsarinnaya Elena Ivanovna,
[3]Plaskova Nataliya Stepanovna, [4]Reshina Galina Alekseevna,
[5]Chumakova Natalya Valeryevna, [6]Mayorova Irina Albertovna

***Abstract*--***One of the main objects of state orders in the field of healthcare is medicines. They have a high social significance and have a direct impact on the human body. Despite the existence of a broad legal framework regulating the process of state and municipal procurement, there are many problems in this area at different stages of procurement, which the authors have tried to systematize in this article, as well as to outline measures that would contribute to improving the system of public procurement of medicines in general.*

***Key words*--***medicines(preparations), healthcare system, public procurement system, procurement procedures, efficiency*

## I. INTRODUCTION

Every year the state pays more and more attention to the social sphere of society, increasing the number of activities that contribute to maintaining the health and well-being of the population at a high level. For this reason, the development of such areas as health care is being carried out. At the same time, it is becoming more regulated and controlled. One of the areas of control is the implementation of state and municipal procurement. The main object of procurement for the healthcare sector is medicines. They have a high social significance and have a direct impact on the human body. Therefore, the purchase of such goods must be made taking into account their specifics, and for the correct conduct of procurement procedures for medicines, it is necessary to know the basics of legal regulation in this area and be able to apply them in

## II. LITERATURE REVIEW

Regulation of procurement in the healthcare sector is based on the application of a broad legal framework: from the Constitution of the Russian Federation, the Budget and Civil Code, to various Resolutions and Orders of the Government of the Russian Federation.

Despite the existence of a broad legal framework that regulates the process of state and municipal procurement in the field of health, taking into account its multiple features,there are still many problems in this issue. They occur at different stages of procurement and are associated with different factors. Some of the problems are directly related to the activities of the company and its way of organizing purchases and the

[1]*Plekhanov Russian University of Economics, Russian Federation, Email ID: prodanova-00@mail.ru*
[2]*Plekhanov Russian University of Economics, Russian Federation*
[3]*Plekhanov Russian University of Economics, Russian Federation*
[4]*Baltic International Academy, Riga, Latvia*
[5]*Azov-Black Sea Engineering Institute of Don State Agrarian University, Zernograd, Russian Federation*
[6]*Samara state technical University*

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Department that implements it, and some of them do not depend on the customer and arise due to external factors that one can not influence.

One of the significant problems that arise at the stage that precedes the direct implementation of competitive procedures is the high level of labor and time resources spent in the preparation of documentation for their implementation. First, for the direct implementation of the purchase, initially the employees of the Tender Department are required to collect information about the needs of all divisions of the organization. Secondly, when further drawing up the procurement documentation, it is necessary to take into account all legal norms related to medicines. The process of determining the initial minimum contract price (IMCC) for pharmaceutical products is considered particularly time-consuming, since it requires a large amount of information collection and processing. Initially, it is necessary to determine whether the purchased drug belongs to medicines from the list of vital and essential medicines (VEM), and then calculate the price simultaneously using three methods: tariff or comparable market prices, weighted average and reference prices. The tariff method involves market analysis, which requires a considerable amount of resources. A weighted average, in turn, requires careful examination of statistics, which takes a lot of time. Thus, in addition to the time spent on conducting procurement procedures directly, a large amount of resources is spent on the preparatory stage. This slows down the speed of procedures in general.

However, quite a large part of the time is spent not only on the preparatory stage, but also on the direct conduct of competitive procedures. When conducting procedures in compliance with all legal norms existing in the field of procurement, the duration of the procurement is significantly increased. This is a negative point, since it can complicate the treatment of patients in case of urgent need for specific medications.

Despite the fact that purchasing products from a single supplier significantly reduces the time needed to complete the purchase, the preparation of documentation requires time, which is estimated at several days, which is sometimes unacceptable. In addition, if there is a need for additional purchases that are not included in the schedule, changes must be made, which also causes additional difficulties in a situation where there is an urgent need for a medicine (https://goskontract.ru/podgotovka-k-tenderu/rezhim-povyshennoy-gotovnosti-v-zakupkakh-novye-pravila-iz-za-koronavirusa (accessed: 30.04.2020))

In addition, the process of purchasing pharmaceutical products is complicated due to the existence of a huge number of rules in the field of filling out purchasing documents. The state has developed many forms and acts that must be properly executed in order to recognize the procurement procedure as valid. The high level of bureaucracy is a negative point.

Another problem in the field of medicine procurement is the lack of a cost accounting system for procurement. Usually, these expenses include direct costs incurred by the customer. However, this does not take into account the time and additional labor costs required to complete procurement procedures. These include the involvement of experts in evaluating the quality of delivered medicines. In addition, one should consider such an item of expenditure as technical support for the Department. Despite the fact that a significant part of the costs is borne by the state, for example, ensuring the functioning and development of the unified information system (UIS) and other systems related to the purchase of medicines, customer is still responsible of some of them (Matveeva, 2018). All this leads to the fact that the calculated savings do not reflect the real picture achieved through the use of the procurement system, and creates an incorrect impression of the overall effectiveness of procurement.

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An equally important aspect that complicates the conduct of procurement procedures is the lack of coordination between the tender and other departments. In this case, it refers to the lack of coordination of departments, which is manifested in the interaction of doctors and other employees of medical institutions and non-clinical specialists (economists, employees of the tender Department), who actually implement the purchase. The doctor compiles information about the need for a particular medical device, drug, and then passes it to specialists in the field of procurement, who are engaged in purchasing the necessary products. Often, medical officials point out the particular position of the medicines that you want to purchase. In addition, specialists of the tender Department are already purchasing goods taking into account the specifics of the legislation in the field of procurement. As a result, there is a purchase of the wrong product that was required by medical workers, which is due to their lack of knowledge about the procurement rules.

This situation can be illustrated by a specific example: an employee of the neurosurgical Department of the hospital provides information about the need of purchasing suture materials with an antibacterial effect. It is assumed that the product will help to accelerate the patient's recovery by reducing the risk of developing surgical infections. However, some antibacterial substances are contraindicated for use in neurosurgery, for example, chlorhexidine. However, the specific antibacterial substances will lead to restriction of competition. As a result, the purchasing Department does not include restrictions on the antibacterial properties of the suture material in the purchase documentation in order to comply with antitrust laws. And as a result of purchasing procedures, the hospital acquires suture material that is unsuitable for the treatment of patients. Thus, the effectiveness of such a purchase is reduced to zero (http://mosapteki.ru/material/eksperty-o-problemax-v-sfere-zakupok-lekarstvennyx-sredstv-10148).

Often, procurement specialists do not have any information about the compatibility of a particular drug or medical device, and they make purchases based on the principles and rules of the contract system. And medical workers, in turn, submit information containing an incorrect description of their needs, because they are not aware of the procurement rules established by the contract system. As a result, insufficient efficiency in the interaction of medical staff and procurement specialists leads to damage from procurement procedures (Kuznetsova, 2012).

Also, at the moment, there is a widespread problem concerning low competitiveness indicators in the procurement of medicines. It manifests itself in the low number of applications submitted for participation in competitive procedures, as well as in the large volume of repeated procedures for the purchase of medicines. In other words, there is a problem of suppliers ' disinterest in participating in competitions and auctions related to the supply of medicinal products.

This is directly related to the level of the maximum starting price of contract set in the procurement documentation (https://www.katrenstyle.ru/articles/journal/news/nazvany_glavnye_problemy_goszakupok_lekarstv_v_2018_godu).

Thus, when calculating the maximum starting price of contract, the reference price method is actually a priority. According to statistics, it is used to generate contract prices for the purchase of medicines. However, most often they are significantly lower than the average prices currently available on the market, so suppliers consider it inappropriate to participate in the procedures due to the low level of benefit or no benefit at all. All this

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leads to the need for repeated procedures using other methods, which increases the time spent on purchasing products and reduces its effectiveness.

As for legal regulation, despite its wide application, there are also shortcomings that cause difficulties in making state and municipal purchases in the field of healthcare (Ovsipyan, 2017). For example, the legal documentation regulating the organization and conduct of auctions contains a vague requirement for the rules for assigning codes to products according to the product classifier Russian Classification of Products by Economic Activities 2. The lack of a clear procedure for determining the code of the purchased product sometimes leads to violations when making a purchase, because the goods are purchased under the wrong codes (https://tpprf.ru/ru/news/bolezni-goszakupok-v-sfere-zdravookhraneniya-vliyayut-na-zdorove-vsey-natsii-i194185). In addition, there are many exceptions in the health sector related to the specifics of the items purchased, but they are contained in various legal documents. The lack of systematization of data on the specifics of purchasing medicines and medical products makes the procurement process more complex. Contract service employees need more time to collect all available information in the field of drug procurement regulation, since there is no single information source, this directly reduces the effectiveness of procurement.

There are also problems related to the specifics of the purchased drugs. One of them is the problem of therapeutic equivalence of medicines. To date, the purchase of medicines is based on their international non-proprietary name and the main factors are the active substance, dosage and shelf life. With the same active substance, several hundred drugs of different manufacturers with different product quality can be registered. (https://rg.ru/2018/10/08/institut-vzaimozameniaemosti-lekarstv-otorvan-ot-sistemy-zakupok.html). In addition, it should be borne in mind that not always equivalence indicates interchangeability, i.e. not always the same active substance gives the same therapeutic effect, since different auxiliary substances, which are secondary, to varying degrees contribute to the disclosure of certain properties of drugs. Therefore, to improve the quality of treatment, it is sometimes necessary to take into account the effect of a specific medicine, and not the active pharmaceutical substance (Bartanova, 2017).

Also, the focus on the active substance in the purchase of medicines explains the existence of a huge number of generics-medicines containing an active chemical that is identical to the patented company-the original developer of the drug. At the same time, such drugs do not actually always pass clinical studies that confirm their medical effectiveness and safety (https://gmpnews.ru/terminologiya/generic/).

However, since these products are not patented, their cost is significantly reduced in comparison with patented products, and as a result of bidding, such products are purchased, despite the fact that the actual use of such drugs cannot guarantee the effectiveness of patient treatment (https://moodle.imisamara.ru/pluginfile.php/43453/mod_resource/content/0/Макаров%20Д.А.%20ВКР.pdf). This reduces the usefulness of using the purchasing system in the health sector.

A negative aspect is also the lack of a complete system of control over all stages of procurement, which leads to an increase in the existing corruption risks. This problem concerns not only the purchase of medicines, but is of particular importance due to the increased risks of unfair procurement associated with the specific characteristics of the purchased products (Chulkov, 2017). In General, problems are observed at various stages of procurement procedures. They are of a diverse nature – some are related to the procurement process itself, others-

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to imperfect legislation, and others – to the specifics of the health sector. But all of them in one way or another reduce the effectiveness of the implementation of state and municipal procurement of medicines.

An equally acute problem that has been identified recently is a large number of violations on the part of customers when conducting public procurement in the health sector. Recently, there have been more and more situations in which customers violate the rules for preparing and directly conducting competitive procedures, and they do not take into account the specifics of purchasing medicines (Kaufova, 2017). Examples of such violations at the preparatory stage when drawing up procurement documentation are the inclusion of different types of medicines in one lot, as well as excessive specification of lots, which leads to restrictions on competition and contradicts the law. There are also cases in which the terms of reference and terms of performance of the contract are drawn up for a specific supplier. Some of the violations are related to the difficulty of interpreting the established legislation, and some are related to deliberate violations carried out by unscrupulous customers. However, what is common is that all this ultimately reduces the efficiency of using budget funds and reduces the potential savings that the use of the contract system provides (Bartanova, 2017).

Thus, the problems in the field of procurement of medicinal products have a very different orientation. Some of them can be solved by the customers on their own, others can be solved only with the assistance of government agencies. However, an important aspect is the timely resolution of these problems in order to improve the efficiency of the existing procurement system.

## III. MATERIALS AND METHODS

When writing the work, we used both General scientific research methods: analysis and synthesis, methods of systematization and classification of theoretical and practical data, and special methods: comparative legal method, method of analogy.

## IV. RESULTS

To improve the efficiency of state and municipal procurement of medicines, it is necessary to develop measures that will reduce the above-mentioned problems. It is necessary to develop a number of proposals for various stages of procurement procedures, some of which can be implemented by the customer independently, and some of which will be solved with the help of state participation.

One of the ways to improve the procurement system is to improve the regulatory framework in the field of procurement of pharmaceutical products. This measure should be implemented by the state through a number of procedures. First, it is necessary to systematize the information of legislative acts that are currently applied in order to regulate procurement procedures for medicines. Currently, there are a huge number of rules and regulations related to this area, and they are contained in various legislative acts. This dispersion of information is extremely inconvenient for customers and often leads to confusion and, as a result, difficulties and even violations in its application in practice.

Secondly, it is necessary to eliminate shortcomings in the existing legal framework. Sometimes some points of normative legal acts are not fully disclosed, which leads to disputes over their interpretation. Or the algorithm for applying regulatory norms is not always clear in practice, for example, the correlation of goods with their codes according to the all-Russian classification of products by type of economic activity (Russian

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Classification of Products by Economic Activities 2). In addition, sometimes legal acts may contain conflicting information, which also causes the customer difficulties in implementing purchases and justifying them. It is necessary to supplement the legislative base with information that fully describes the purchase of medicines.

Third, it is necessary to increase the transparency of legislation in terms of its perception. In some articles of normative legal acts, information is presented in difficult-to-understand language and requires special knowledge and experience to interpret it. However, in order to reduce the number of violations in the field of procurement of medicines, it is recommended to eliminate conflicting points and present the information in a language that is understandable to a wide range of people (http://duma.gov.ru/news/47851).

Another set of measures aimed at improving the efficiency of public procurement of medicines should address the issue of the time frame required for the implementation of procurement procedures. Earlier, it was considered that the deadlines set for the current day by the law are inappropriate in certain cases when it comes to urgent procurement. In general, the regulated duration of procurement of medicines using competitive methods is quite high. The existing time frame should be reviewed with a view to reducing it. In addition, it would be a good step to Supplement existing legislation with new rules for urgent procurement, which would allow the provision of documentation at the time of execution of the contract or at the end of its completion (Zemtsova, 2020).

It is also necessary to pay special attention to the issue of interchangeability of medicines. At the moment, the purchase of goods under an international non-proprietary name, depending on the volume of the active substance, sometimes leads to the purchase of cheaper, but lower-quality drugs. In order to avoid this situation, it is necessary to formulate more clearly information about which drugs can be considered interchangeable. It is necessary to take measures to improve the registration procedure for medicinal products, review the Institute of interchangeability, and strengthen the activities of pharmacovigilance. You can also develop a list of therapeutically equivalent medicines to help the customer. It will reflect information about medications that have an equivalent therapeutic effect. However, before including the drug in such a list, clinical studies will be conducted that will prove interchangeability for each drug from each manufacturer. So, the evidence will be based on evidence-based data. Then the decision to replace the drug will be carried out taking into account the medical specifics and will not harm the health of citizens, will not reduce the effectiveness of the prescribed treatment.

An important aspect is the development of measures that increase the competitiveness of procurement procedures. They can be divided into two groups: price and other. The price measures include measures in the field of formation of NMCC for pharmaceutical products. The low level of NMCC for medicines makes it unattractive for suppliers to participate in competitive procedures. Accordingly, it is necessary to review the procedure for generating this indicator, especially by using the reference price method, which will allow purchases to be made at prices commensurate with the current market situation.

There are several offers among non-price methods. You can attract suppliers of medicines by changing the terms of the contract, for example, making it possible to conclude long-term contracts. This will help to maintain a lower price for purchased medicines, but at the same time increase the interest of suppliers who will receive long-term guarantees (Chulkov, 2017). In addition, in some cases, it may be rational to use direct negotiations with the supplier. In Russia, this practice is not in demand, although, as foreign experience shows, in some cases it is an effective way to conclude contracts and settle prices for them, since it allows you to agree on terms that suit both parties (https://rg.ru/2019/10/14/sistema-goszakupok-lekarstv-budet-modernizirovana.html)

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Another technique can be risk-sharing of the drug supply system. This approach assumes that all purchased medications must justify the claimed therapeutic effect. Otherwise (i.e., if the medicines were ineffective in their use for the treatment of the patient), the suppliers of the specified pharmaceutical products return the money previously paid to them for the delivery of the goods back to the budget, since the actual purpose of concluding the contract was not achieved. This will increase the price of contracts, which will attract more procurement participants, and at the same time improve the quality of procurement and, consequently, their socio-economicefficiency(https://www.katrenstyle.ru/articles/journal/news/fas_nazvala_usloviya_dlya_zapuska_lekarstvennogo_risksheringa_v_rossii).

Also, a positive impact on this issue can be achieved by changing the conditions for allowing foreign suppliers to participate in competitive procedures. This method will expand the potential number of participants and reduce the level of contracts for which only one application was submitted that meets the requirements. In addition, increased competition will be a factor contributing to the increase in products offered by the national manufacturer. Thus, increasing the possibility of participation in purchases of foreign companies will contribute to a rational, competent solution of problems of low competition, and will also become an important factor in the development of the domestic market of medicinal products.

Special attention should be paid to the issue of bureaucracy. At the moment, conducting procurement procedures involves filling out a significant amount of documents and generating a large number of reports. In this case, in fact, there are situations where data from different documents duplicate each other. Such an example is the need to publish information about the performance of the contract and the report on the performance of the contract. This is not rational, since the provision of this information takes a considerable amount of time, and its duplication, in this case, is meaningless. Therefore, it is necessary to reduce the volume of reporting documents by reviewing documents containing the same data (Chulkov, 2017).

As another direction for improving the procedure for public procurement of medicines, we can highlight the development of measures that contribute to improving the quality of interaction between procurement specialists and medical staff. For example, this can be implemented by improving the skills of employees. Thus, for contract service employees working in the field of healthcare, several specialized employees can be identified, for whom the obligation to pass additional courses in the field of procurement of medicines will be introduced. At the same time, the frequency of such professional development should be directly associated with the appearance of significant changes and innovations in the legislative framework of the Russian Federation, and the focus – related to the specific direction of the organization in which the employee works. So, in addition to General information related to the contract system, employees will gain knowledge about the features that arise in a particular field of medicine, and will better understand the needs of doctors.

And among the medical staff in each Department, you can select an employee responsible for providing information about the existing needs. However, he will also be required to undergo refresher courses in procurement procedures, namely in the description of the object of procurement for the health sector. Such an employee will collect all the information from the Department's employees and transmit it in a well-formulated form to specialists in the field of procurement. This method will help reduce misunderstandings and eliminate the possibility of purchasing the wrong products (http://www.iblfrussia.org/upload/iblock/239/Improvement_of_public_procurement_procedures_ru.pdf).

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In order to reduce the number of violations by customers during public procurement, it is necessary to strengthen control over the procurement procedures. This can be facilitated, for example, by developing a single form of purchasing documentation and automating its completion. If customers need to describe the object of purchase by inserting information about the existing needs in the developed template, this will speed up the process of checking such documentation by regulatory authorities and reduce the number of violations. For example, if only one type of medicinal product can be selected automatically when forming a lot, and the requirements are filled in according to the established form (which eliminates the specification of lots), this will significantly reduce the number of violations in purchases.

The state can also develop additional customer support tools to improve the efficiency of state and municipal procurement in the health sector. For example, create an integrated information database for all drug supply programs for the treatment of various categories of patients, which will reflect all information about purchases (https://privetstudent.com/kursovyye/ekonomika-kursovyye/671-gosudarstvennye-zakupki-v-sisteme-upravleniya-finansami-v-rf-kursovaya-rabota.html). This will help other participants quickly find an example of a similar purchase if they have any questions and avoid violations. It is also possible to issue annual compilations dealing exclusively with purchases in the health sector, and to separate such a category of goods as medicines. A review of procurement practices that have already been implemented will help improve the literacy of specialists by increasing their understanding of how to conduct a purchase correctly. It will also be an effective step to issue journals that will review the main errors identified by regulatory authorities when purchasing medicines. This will allow other participants to avoid violations in difficult or insufficiently clear issues for them.

## V. CONCLUSION

Problems in the public procurement system in the health sector are multifaceted: the complexity of the preparatory stage of public procurement; the duration of procurement of medicines by competitive means; bureaucracy; incomplete accounting of expenditures during procurement; the problem of interaction between the tender Department and other structural divisions in the organization; low competitiveness indicators for the purchase of medicines; insufficient development of the regulatory framework in the field of procurement of medicinal products; the problem of therapeutic equivalence of medicines; the lack of a complete system of control over all stages of procurement, etc.

The state should devote special efforts to creating an effective system for purchasing medicines that functions in accordance with the current market situation. This area of regulation is crucial. It directly affects the level of well-being of the country's population.

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