Applying real-world data to justify requirements to purchased drugs in public procurement

Borzova M. A.
"Trubor" Law Firm, Russian Federation, Moscow

Abstract

The article describes the approaches of law enforcement practice in relation to the regulatory limits within which a medical institution may exercise its right to establish requirements for purchased drugs based on purchaser's clinical practice and its own clinical experience.

Keywords: real-world data; public procurement; regulatory practice

For citation: Borzova MA. Applying real-world data to justify requirements to purchased drugs in public procurement. *Real-World Data & Evidence.* 2021;1(1):13-17. https://doi.org/10.37489/2782-3784-myrwd-4

Received: September 02, 2021 **Accepted:** September 14, 2021 **Published online:** September 20, 2021

Introduction

According to clause 6 of part 1 of Article 33 of the Federal Law of April 05, 2013 No. 44-FZ "On the contract system in the field of procurement of goods, works, services to meet state and municipal needs" (hereinafter – Law No. 44-FZ), drugs are purchased in accordance with international nonproprietary names (in the absence – in accordance with chemical, grouping names) [1]. The exception is the procurement of drugs for medical reasons (individual intolerance, for health reasons) by decision of the medical commission and the procurement of drugs that are included in the list of drugs purchased in accordance with their trade names [2].

Additionally, the Decree of the Government of the Russian Federation of November 15, 2017 No. 1380 defines the features of the description of medicinal products for medical use, which are the object of procurement to meet state and municipal needs (hereinafter – Specifics of Drug Descriptions) [3]. According to the Specifics of Drug Descriptions, when forming the technical task, the customer indicates the dosage form, the dosage of the drug, the residual shelf life. Simultaneously, it is prohibited to include in the procurement documentation of many drug characteristics that indicate a single manufacturer and do not directly affect the therapeutic effect. Simultaneously, the customer has the right to justify the inclusion of certain characteristics of the purchased drug in the terms of reference, if there is no other way to describe the relevant requirements.

However, neither Law No. 44-FZ, nor the Specifics of Drug Descriptions contain indications of the possibility of forming requirements for a drug based on the experience of providing medical care in a specific medical institution or on the basis of real-world data (RWD). Simultaneously, law enforcement practice is formed more flexibly.

Materials and methods

Analysis of law enforcement practice is a painstaking process. It is necessary to track its development regularly to be able to assess the emergence and change of certain trends in the interpretation of existing norms. Additionally, decisions, as a rule, must be tracked manually using the register of complaints on the official website of the Unified Information System in the field of procurement for the complete coverage of the material and comparison of the texts of decisions directly with the procurement documentation. Simultaneously, this article presents the most indicative solutions from a practical viewpoint with detailed formulations of the law enforcement officer, which to the greatest extent allow analyzing and generalizing the regulatory experience. To demonstrate the continuity of approaches, this article considers examples from practice for 2019–2021. in relation to the procurement of medicines with various international nonproprietary names (INN).

Results

This study showed that there is no direct and formalized connection between the formation of practice in the field of state (municipal) procurement and the mechanisms for collecting and analyzing data from RWD. Nevertheless, the interpretations of the law enforcement officer demonstrate that the experience of using a drug in a particular medical institution can influence the formation of requirements for purchased drugs to ensure quality medical care for certain groups of patients. Simultaneously, the

legitimacy of the corresponding approach is confirmed by a number of decisions of the territorial departments of the Federal Antimonopoly Service and the courts. However, the relevant decisions are point-to-point, and no systematic study is being conducted to generalize and analyze the indicated practice. Nevertheless, this study shows that de facto the customer has non-formalized tools to consider his clinical experience in the formation of requirements for the procurement subject.

Analysis of the approaches of the law enforcement officer. To demonstrate how the law enforcement officer interprets the current legislation, examples from administrative and judicial practice will be described in detail and analyzed below.

When references to experience with a drug help justify a claim. The decision of the Krasnodar OFAS dated August 04, 2021 in case No. 023/06/67-3767/2021 is one of the latest examples of a positive assessment of the reference to the experience of the customer's clinical practice as a justification for the requirements for the purchased drug. Thus, when holding an auction for the supply of a medicinal product with the INN "Paclitaxel" the customer established certain specific requirements for dosage and packaging. The procurement documentation indicated that the client has a need to treat patients with malignant neoplasms such as breast cancer. The customer's experience showed that sufficient patients with a body surface area of 1.6–1.7 m2 were treated. Simultaneously, according to the customer's experience, the packaging of the drug with the INN "Paclitaxel" is 6–16.7 mg/ml (100.2 ml) or 17 mg/ml (102 mg), 23 ml (138 mg) or 23.3 ml (139.8 mg), 46 ml (276 mg), 50 ml (300 mg) most closely matched the chemotherapy regimen in patients with this body surface area and other patients. The customer rejected the application of one of the market participants, in which the characteristics of the drug were proposed that did not correspond to the characteristics specified in the technical specifications. The antimonopoly body, in turn, recognized the rejection of the application as legitimate, and the customer's requirements justified.

The decision of the Leningrad OFAS dated December 15, 2020 in case No. 047/06/67-3288/2020 follows a similar approach. When holding an auction for the supply of a medicinal product with the INN "Oxaliplatin," the customer established a requirement for the dosage form and dosage: "lyophilisate for preparing solution for infusion, 150 mg or concentrate for preparing solution for infusion, 5 mg/ml, 30 ml or lyophilisate for preparation concentrate for the preparation of solution for infusion, 150 mg." A complaint was filed with the antimonopoly authority for the unlawful rejection of the application, in which, according to the complainant, a drug product with equivalent characteristics and similar therapeutic effect was proposed. The antimonopoly authority, in turn, noted that when assessing a similar therapeutic effect, one should be guided by the position of medical workers who directly interact with this drug. Additionally, the antimonopoly authority established that, considering many years of practice in conducting chemotherapeutic treatment, the customer developed the most optimal ratio of dosage and volume of filling of the drug with the INN "Oxaliplatin" in the dosage form "concentrate for the preparation of solution for infusion" (5 mg/ml in vials of 30 ml, which is similar to 150 mg of a solid). The use of a different dosage and a different volume of filling the bottle could interfere with the quality of the treatment process, significantly increase the harmful effect on employees and the amount of hazardous waste. Additionally, the customer purchased the drug in the appropriate quantity and dosage, considering statistical data:

1. according to the average needs of departments;
2. about possible treatment options.

Thus, with reference to the experience of using the drug and statistical data, the customer proved that the advantages of using the appropriate dosage and filling volume of the drug were:

1. no losses during dilution for the preparation of infusion solutions;
2. reduction in the time necessary for the preparation of infusion solutions and the in cost of accompanying medical devices;
3. no need to dispose of additional residues of the drug, which has high cytostatic toxicity and requires disinfection and neutralization;
4. minimization of the possible harmful effect of contact of medical personnel with a cytotoxic agent when preparing an infusion solution;
5. reduction of the customer's financial costs for treating patients.

A reference to the existing experience of providing medical care by specialists of a medical institution was also made in the Decision of the Krasnoyarsk OFAS dated April 10, 2020 No. 024/06/105-862/2020, which describes the following situation. The customer held an auction for the supply of a medicinal product with the INN "Cefotaxime + Sulbactam". A complaint was filed against the actions of the customer in connection with the unlawful, in the opinion of the complainant, formation of requirements for the purchased drug. The customer could justify the need to purchase the appropriate drug, including on the basis of the following. Based on the experience of the customer's medical personnel, it was found that, pursuant to the results of bacteriological cultures made at the customer's premises in 2018, the most common infectious agent was *E. coli,* which developed resistance to ceftriaxone/cefotaxime. "Cefo taxime + Sulbactam" was included by the customer in the purchase application for 2020 because the drug contains a beta-lactamase inhib-

itor – sulbactam, which expands its spectrum of action. Additionally, in the context of a rapid increase in antibiotic resistance of pathogens of infectious and inflammatory diseases (in particular, *E. coli*), the administration of the drug with the INN "Cefotaxime + Sulbactam" as an empirical therapy made it possible to reduce the need for prescribing reserve drugs and restrain the selection of carbapenem-resistant pathogens, including Pseudomonas aeruginosa.

In connection with the above, the antimonopoly authority indicated that the actions of the customer to purchase the relevant medicinal product in themselves could not be considered a violation of the requirements of Law No. 44-FZ, since:

1. the actions of the customer were aimed at the effective use of funding sources;
2. the actions of the customer were due to the actual need to resist the rapid growth of antibiotic resistance in conditions of objectively required antibiotic therapy in the provision of medical care to patients.

A similar logic can be seen in the Decision of the Novosibirsk OFAS dated September 13, 2019 on case No. 054/06/69-1774/2019, which describes the following approach to the procurement of a drug with the INN "Normal human immunoglobulin". The bid of a participant was found not to meet the requirements of the auction documentation because the indications for use of the proposed drug excluded the indicator "symptomatic hypogammaglobulinemia secondary to the underlying disease or treatment". In this regard, a complaint was filed with the antimonopoly authority. The customer explained that the establishment of the requirement for the presence of appropriate indications for use was primarily because the customer, as a medical institution, had a wealth of experience in the use of drugs with the INN "Normal human immunoglobulin". From the relevant experience, the customer made an unequivocal conclusion that the number of deaths is significantly lower in cases when a drug was used for treating patients, having, among the indications for use, "symptomatic hypogammaglobulinemia secondary to the underlying disease or treatment". The antimonopoly authority recognized the customer's arguments as reasonable.

References to the experience of using the drug are also contained in the Decision of the Arkhangelsk OFAS dated May 21, 2019 in case No. 121fz-19. Thus, when holding an auction for the supply of a drug with the INN "Enoxaparin sodium", the customer established a requirement for the form of drug release and the volume of filling the primary package. In connection with this formation of the requirements of procurement documentation, a complaint was filed with the antimonopoly authority. The customer explained that the purchased drug was intended for use in emergency and intensive care units, where patients are admitted and where they are in critical condition and need immediate medical attention. The customer noted that the drug with the INN "Enoxaparin sodium" was needed in the volume of filling the primary packaging of 0.400 ml due to many years of experience in using the drug in the indicated volume and in accordance with the patient's body weight. The customer noted that the use of a larger filling volume would lead to an overrun of the drug, since the drug remaining in the syringe after administration to one patient cannot be used for another patient. In turn, a smaller volume would increase the time spent on administering the required amount of the drug to a patient in critical condition, when it is extremely important not to waste time. Based on the relevant explanations, the antimonopoly authority recognized the customer's position as justified.

When the law enforcement officer says that the customer did not provide references to clinical practice. However, the customer does not always manage to convince the law enforcement officer of the validity of its position. Thus, the Decision of the Omsk OFAS dated November 22, 2019 in case No. 03–10.1/17–2019 contains the following approach to qualify the customer's actions.

A complaint was filed with the antimonopoly authority, according to which the customer unlawfully established a requirement to supply a drug with the INN "Cefepime" complete with a solvent, which corresponded to the characteristics of the only drug on the market. Simultaneously, the antimonopoly authority indicated that the auction documentation did not contain any documents and information justifying the establishment of the relevant characteristics. As noted by the antimonopoly authority, the customer did not provide in the procurement documentation references to clinical practice and the practice of using medicinal products by specialists of the medical institution. Considering that the customer did not provide for the possibility of supplying individual components and, simultaneously, the justification for the need to supply the drug complete with a solvent was absent in the procurement documentation, the antimonopoly authority concluded that the customer had violated the requirements of Law No. 44-FZ and the Specifics of the Drug Description. Simultaneously, it can be assumed that, in the case of proper justification with references to clinical practice and the practice of using the corresponding drug by specialists of the medical institution, the conclusion of the law enforcement officer could be different.

When the law enforcement officer requests to provide statistical information. Sometimes the law enforcement officer himself asks the state customer to provide statistical information and data from his clinical practice to justify the need. For example, the Decision of the OFAS in the Republic of Mari El dated May 13, 2021 in case No. 012/06/106-439/2021 describes the following approach. The customer held an auction for the supply of

a medicinal product with INN "Dalteparin sodium". The customer has established a requirement for the dosage form of the purchased drug: "solution for intravenous and subcutaneous administration". In the terms of reference, the customer indicated that the requirement was established "for the provision of full emergency medical care by the intensive care unit in the critical condition of the patient and in the postpartum period". A complaint was filed with the anti-monopoly authority about the provisions of the procurement documentation.

According to the customer's explanations, the requirement for the dosage form "solution for intravenous and subcutaneous administration" was established due to the need to administer the drug intravenously when providing emergency medical care to patients. To confirm this information, as part of the administrative proceedings, the antimonopoly authority requested from the customer statistical information on the intravenous use of the drug with the INN "Dalteparin sodium". However, the customer did not provide the required statistics, referring to the fact that the use of the medicinal product in accordance with a specific route of administration is not subject to statistical records and there is no mandatory requirement to maintain such statistics. Simultaneously, the customer provided information from which it followed that as of May 1, 2021, 361 packages of the drug were used in the form of "solution for intravenous and subcutaneous administration". Simultaneously, only 3 extracts from the medical history were presented, confirming the use of the drug intravenously. Thus, the antitrust authority established that the drug was used by the customer mainly for subcutaneous administration. Considering the above, the antimonopoly authority concluded that the customer had not justified the dosage form required for delivery. In this regard, the complaint was found to be well-founded. Simultaneously, it can be assumed that in the presence of detailed statistical data formed on the basis of the clinical practice of a medical institution, the conclusion of the law enforcement officer may be different.

The position of the judicial system corresponds to the approaches that have developed in administrative practice. At the level of the Supreme Court of the Russian Federation, there is a coherent confirmation in relation to the validity of references to the specific experience of using the drug by the medical institution. So, the determination of the Supreme Court of the Russian Federation of November 21, 2019 No. 309-ES19-18066 describes the following situation. The regional healthcare authority published a notice and documentation on the auction for the supply of a medicinal product with INN "Botulinum toxin type A-hemagglutinin complex" in a dosage of 500 units. A complaint was filed with the antimonopoly authority regarding the biased description of the procurement object, which was recognized as reasonable. However, the courts indicated that the customer, when setting the requirements for the characteristics of the purchased medicines, proceeded from the existing need for a drug with certain characteristics for prescribing to children with focal spasticity of the lower limb, and was purchased in a certain dosage and quantity based on doctors' prescriptions. Here, the list of patients was presented by the customer for review by the courts. Contrary to the arguments of the antimonopoly body, the courts considered that in the case under consideration, a certain requirement was established for the dosage of the drug, as a characteristic that was essential for the customer due to the methodology and experience of using the drug. The corresponding approach of the law enforcement officer can be indirectly traced in other court cases.

Conclusion

It will be a long time before the very concept of "real-world data" is integrated into the procurement legislation. Nevertheless, it is important to pay attention to the existence of interconnections between the practice of using medicines in medical institutions and the possibility of forming requirements for purchased medicines, considering the clinical practice of the customer. However, it is also important to remember that references to actual clinical practice data should not be used in bad faith to limit the pool of procurement participants since the indicated tool should serve two basic purposes:

1. to protect the interests of patients in receiving quality treatment;
2. for the optimal equipment of medical institutions and the provision of timely medical care in the required volume.

ADDITIONAL INFORMATION

Conflict of interest. The author declares no conflicts of interest in connection with this work.

Ethics committee approval. Review article did not require Ethics Committee approval.

ABOUT THE AUTHOR

Borzova Maria A. – Counsel, Trubor Law Firm, Russia, Moscow
e-mail: maria.borzova@gmail.com https://orcid.org/0000-0002-6448-6973

References

1. Federal Law of April 05, 2013 No. 44-FZ "On the contract system in the procurement of goods, works, services to meet state and municipal needs" (as amended on 02.07.2021). Available at https://fssp.gov.ru/2315090/ [Internet] (date accessed: 30.08.2021).
2. Decree of the Government of the Russian Federation of November 28, 2013 No. 1086 "On approval of the Rules for the formation of a list of medicines, the purchase of which is conducted in accordance with their trade names." Available at https://clck.ru/XJFmp [Internet] (date accessed: 30.08.2021).
3. Decree of the Government of the Russian Federation of November 15, 2017 No. 1380 "On the features of the description of drugs for medical use, which are the object of procurement to meet state and municipal needs." Available at http://static.government.ru/media/files/hoNXj8exUEVL8AfDVsYeQGms0l0oEeA5.pdf [Internet] (date accessed: 30.08.2021).