BRACE
Law Firm

November 2019

DIGEST
of regulation of the Russian pharmaceutical industry

December 11, 2019

Dear Colleagues!

We are glad to propose to your attention the Digest of legal regulation of the Russian pharmaceutical industry for November 2019, prepared by BRACE Law Firm. November of 2019 was marked by significant legislative activity, as well as the adoption of legal acts that have a significant impact on the functioning of the turnover of medicines.

The most important legal news are:

- The Board of the Eurasian Economic Commission approved the Guidelines for Preclinical Safety Studies for the purpose of conducting clinical trials and drug registration in order to develop a unified order of clinical trials on the territory of the EAEU.
- The Russian government approved a new procedure for including drugs into civilian circulation. Now, before the drug is included into the civil circulation, it is necessary to submit to the automated information system of the Federal Service for Surveillance in Healthcare a certificate of the manufacturer of the drug certifying the compliance of the imported drug with the requirements of the pharmacopeia article. Other conditions have also been established for the introduction of drugs into civilian circulation.
- The Federal Service for Surveillance in Healthcare of Russia approved a form for authorizing the introduction into civil circulation in the Russian Federation of a series or a batch of an immunobiological drug produced in the Russian Federation or imported into the Russian Federation.
- The Federal Antimonopoly Service of Russia is empowered to conduct test purchases in order to verify the rules for dispensing drugs by pharmaceutical retailers.
- Until July 1, 2020, it is proposed to extend the implementation of the labeling procedure for drugs.
- The Ministry of Health of Russia has developed a draft Regulation on the Commission for the Settlement of Conflicts of Interest in the Implementation of Medical and Pharmaceutical Activities, which regulates the commission’s work and decision-making regarding the cases of a conflict of interest.
- It is proposed that the Ministry of Health of Russia be obligated to directly register special medicines used in the treatment of diseases resulting from exposure to weapons.

In this digest, we suggest that you familiarize yourself with the above and other equally important changes in the current legislation in more detail.

Sincerely yours,

BRACE Law Firm

1. Laws, by-laws, legal news

1.1. The Eurasian Economic Commission approved the Guidelines for preclinical studies of drug safety for conducting clinical trials and registering them.

The decision of the Board of the Eurasian Economic Commission dated November 26, 2019 N 202 "On approval of the Guidelines for preclinical safety studies for the purpose of conducting clinical trials and drug registration"

The management found that clinical trials should be expanded if results are obtained confirming the sufficient safety of the drug in a previous clinical trial, as well as in the presence of additional data from preclinical safety studies that become available as the clinical development progresses.

Before starting clinical trials, it is necessary to evaluate the metabolic profile and the degree of binding to plasma proteins in animals and humans in vitro, as well as analyze the data on systemic exposure obtained in studies on animal species used to study toxicity with repeated (repeated) administration of the active substance of a drug, in accordance with the guidelines for the study of toxicokinetics and assessment of systemic effects in toxicological studies adopted by the Eurasian economic commission.

The basic set of pharmacological safety studies includes an assessment of the effects on the cardiovascular, central nervous and respiratory systems, which should be carried out before the start of clinical development in accordance with the guidelines for the study of the pharmacological safety of medicinal products for medical use.

The toxicity data for a single administration of a drug are traditionally obtained in toxicity studies with the introduction of two types of mammals using the parenteral route of administration and route of administration specified in the draft general characteristics of the drug. New drugs for medical use are being evaluated to confirm the presence of immunotoxic potential

When determining the recommended initial dose of a drug for humans, all relevant preclinical studies should be considered, including the dose-effect pharmacological relationship, pharmacological (toxicological) profile, and pharmacokinetics.

The purpose of the Guide is to establish a unified procedure for preclinical studies of the safety of drugs for their subsequent registration within the Eurasian Economic Union (hereinafter - the EAEU).

The specified document shall enter into force on May 29, 2020.

1.2. The Eurasian Economic Commission approved the classification of posts related to the circulation of drugs.

The decision of the Board of the Eurasian Economic Commission dated November 26, 2019 N 206 "On the classifier of positions of employees (in terms of posts related to the production and circulation of medicines)"

The use of classifier codes is mandatory for the implementation of common processes within the EAEU in the field of pharmaceuticals circulation. The classifier contains such positions as a pharmacist, pharmacologist, junior pharmacist. The document comes into force on February 2, 2020.

1.3. The Russian budget for 2020 has been approved.

Federal Law of December 2, 2019 N 380-FZ "On the Federal Budget for 2020 and for the Planning Period 2021 and 2022"

The budget line includes the allocation of funds for the implementation of the State Program of the Russian Federation “Development of the pharmaceutical and medical industries” and the subprogram “Development of the production of medicines”.

1.4. The Government of Russia approved the procedure for introducing drugs into civilian circulation.

Decree of the Government of the Russian Federation of November 26, 2019 N 1510 “On the procedure for introducing drugs into medical circulation for medical use” (together with the Rules for the submission of documents and information on pharmaceuticals for medical use introduced into civil circulation, the Rules for issuing test reports on the compliance of the first three series or batches of a medicinal product for medical use (except for an immunobiological medicinal product) first produced in the Russian Federation or the first ones imported into the Russian Federation, quality indicators provided for in normative documentation, the Rules for issuing permits for the introduction into civil circulation of a batch or batch of immunobiological medicinal products, the issuance of an opinion on the conformity of a batch or batch of immunobiological medicinal products to the requirements established during its state registration, the Rules for deciding on termination of civil circulation of a series or batch of a medicinal product for medical use)

Recall that the Federal Law of November 28, 2018, N 449-FZ “On Amending Certain Legislative Acts of the Russian Federation on the Issue of Introducing Medicines for Medical Use into the Civil Circulation” in the Federal Law of April 12, 2010 N 61-FZ “On the Circulation of Medicines”, article 52.1 has been introduced, according to which, with respect to medicines introduced into civil circulation after November 29, 2019, a submission to the Federal Service for Surveillance in Healthcare is required write a document of the manufacturer of the medicinal product confirming the quality of the medicinal product, and confirmation of the authorized person of the manufacturer of the medicinal product that the medicinal product meets the requirements established during its state registration. In fact, the indicated regulatory legal act abolished the mandatory certification of drugs.

The Decree of the Government of Russia, adopted in November of this year, specifies the provisions that a manufacturer submits a series or a batch of a medicinal product to the automated information system of the Federal Service for Surveillance in Healthcare through a personal account for each batch or each batch of a medicinal product: the manufacturer, confirming the quality of the drug confirmation of the authorized person of the manufacturer of compliance with the drug Foot drug requirements established under its state registration.

Before entering the drug into civil circulation, the importer submits to the automated information system of the Federal Service for Surveillance in Healthcare through the personal account for each series or each batch of the drug: a certificate of the manufacturer of the drug, certifying the compliance of the imported drug with the requirements of the pharmacopoeial article, and in case of absence pharmacopeia article requirements of regulatory documentation; confirmation of the representative of the importer, authorized by the foreign manufacturer of medicines, the compliance of the imported medicinal product with the requirements established during its state registration.

In case of failure to submit these documents, a decision is made to terminate the civil circulation, which is executed by order of the Federal Service for Surveillance in Healthcare within 5 business days after the receipt of information confirming the actual presence in the civil circulation of a series or batch of a medicinal product.

It is important to note that for the first three series or batches of a medicinal product introduced into civil circulation, it is necessary to submit a protocol of tests conducted by accredited in

accordance with the legislation of the Russian Federation on accreditation in the national accreditation system by federal state budgetary institutions subordinate to the Ministry of Health of the Russian Federation or the Federal Service for Surveillance in Healthcare. For these purposes, the interested person submits an application for the issuance of the test report on paper or in the form of an electronic document, which indicates the name of the applicant, his tax identification number, email address, main state registration number, name of the drug (trade name, international nonproprietary name medicinal product (group or chemical name), number and date of registration certificate of the medicinal product of the drug, details of the document confirming the payment of the test report. The document shall be accompanied by the document of the manufacturer of the drug, confirming that the quality of the series or batch of the drug meets the requirements established during its state registration, a copy of the regulatory documentation for the drug certified by the applicant.

The specified document establishes that permission to enter into civil circulation in the Russian Federation a series or a batch of an immunobiological medicinal product manufactured in the Russian Federation or imported into the Russian Federation is issued on the basis of an opinion issued by the Federal Service for Surveillance in Healthcare. There is no charge for issuing such a permit.

1.5. The Russian Government has approved the procedure for providing subsidies for the production of competitive medicines.

Decree of the Government of the Russian Federation of November 16, 2019 N 1464 "On the approval of the Rules for the provision of subsidies from the federal budget to Russian organizations for the financial provision of a part of the costs of implementing projects to develop modern technologies, organizing the production and implementation of competitive medicines on their basis, and declaring certain acts invalid Government of the Russian Federation"

Subsidies are provided in order to support Russian organizations – manufacturers of industrial products registered in the Russian Federation and engaged in the development of modern technologies, organization of production and sale of competitive medicines on their basis

Subsidies are granted to manufacturing organizations that have passed competitive selection for the right to receive subsidies

The amount of the subsidy may not exceed 70 percent of the costs of manufacturing organizations aimed at implementing the project and the maximum amount of the subsidy established within each modern technology.

In order to ensure equal access for manufacturers to receive subsidies, the Ministry of Industry and Trade of the Russian Federation creates an interdepartmental commission to formulate proposals for modern technologies and evaluate the implementation of projects to develop modern technologies, organize production and sales of competitive medicines on their basis

The Ministry of Industry and Trade of the Russian Federation holds a competition for each modern technology in accordance with the list of modern technologies no more than 1 time per quarter within the budget allocation.

The document comes into force on January 1 of the following year.

1.6. The Federal Service for Surveillance in Healthcare of Russia has given explanations regarding the new procedure for introducing drugs into civilian circulation.

Letter of Federal Service for Surveillance in Healthcare dated November 28, 2019, N 01I-2906/19 "On Entering into Civil Turnover"

Starting November 29, 2019, organizations that manufacture drugs in the Russian Federation or import drugs into the Russian Federation enter information into the personal account of the external information resource of the automated information system of Service for Supervision of Healthcare.

If the applicant already has a personal account in the automated information system of Service for Supervision of Healthcare, then additional registration is not required.

In order to obtain permission to introduce an immunobiological medicinal product into civilian circulation, it is necessary to fill out an electronic application form for obtaining a public service using the Unified Identification and Authentication System, located in the Personal Account on the main page of the official website of the Federal Service for Surveillance in Healthcare.

For pharmaceutical substances, data entry is maintained in the amount provided for by the Order of Federal Service for Surveillance in Healthcare of August 7, 2015 N 5539.

A number of requirements are established for an authorized representative of a distributor of medicines. The letter says that at present there are no requirements for the education and length of service of the specified representative of the distributor. However, from the nature of the work carried out by him and the imposed responsibility, he must have the necessary information and be knowledgeable about the quality of medicines and the requirements for quality documentation. If there are clauses in a contract with a foreign manufacturer that determine the distributor's responsibility for making claims on the goods supplied, an organization order may appoint a person responsible for the set of established measures for the acceptance of goods and confirmation of their quality. A foreign manufacturer of medicine can directly authorize a specific representative of the importer (individual) or an organization importing a medicine in Russia, and the head of the importer locally issues a power of attorney to his employee.

1.7. The Federal Service for Surveillance in Healthcare in Russia approved the Regulation on the Commission for the Quality of Immunobiological Medicines, as well as the form for authorizing the introduction of a medicinal product produced in Russia or imported into the country into civilian traffic.

The order of Service for Supervision of Healthcare in Russia dated November 29, 2019 N 8967 "On the Commission of the Federal Service for Surveillance in Healthcare on the quality of immunobiological drugs" (together with the "Regulation on the Commission of the Federal Service for Supervision of Healthcare on the quality of immunobiological drugs")

The order of Federal Service for Surveillance in Healthcare dated November 29, 2019 N 8966 "On approval of the form for authorizing the introduction into civil circulation in the Russian Federation of a series or batch of an immunobiological drug produced in the Russian Federation or imported into the Russian Federation and the form of a conclusion on the conformity of a series or batch of an immunobiological drug to the requirements established by at its state registration"

The composition of the Commission for the Quality of Immunobiological Medicines (hereinafter - the Commission) is approved by the head of the Federal Service for Surveillance in Healthcare in the amount of at least 10 people. The Commission has the right: to involve independent experts in the field of production and quality control of immunobiological drugs; request and receive information necessary for work from federal executive bodies, organizations engaged in the production of immunobiological drugs in the Russian Federation, organizations importing immunobiological drugs into the Russian Federation, and other subjects of immunobiological drug circulation.

The decision to determine the scope of the quality tests of the immunobiological medicinal product of a particular name and manufacturer (taking into account the dosage form and dosage) is

carried out by the Commission in accordance with the procedure for assessing the volume of quality tests of immunobiological drugs

The Commission takes decisions by an open vote by a simple majority.

1.8. The Russian Ministry of Health and the Federal Medical and Biological Agency of Russia prepared a joint letter regarding the clinical and diagnostic aspects of mycoplasma infection in the foci.

Letter of the Federal Medical and Biological Agency of Russia dated November 5, 2019 N 32-024/758 "On the direction of recommendations" (together with the Information letter "Treatment, Prevention")

The letter notes that when choosing an antibiotic of a macrolide group, one must take into account its dosage form (often determined by the age of the child) and interaction with other drugs. Preference should be given to pediatric dosage forms (suspension) of azalide antibiotics (azithromycin) or to josamycin, roxithromycin, clarithromycin at the dosage indicated in the table in this document.

1.9. The powers of the Federal Service for Surveillance in Healthcare of Russia have been supplemented.

Decree of the Government of the Russian Federation of November 15, 2019 N 1459 "On Amending Certain Acts of the Government of the Russian Federation"

The Government of Russia has supplemented the Regulation on the Federal Service for Supervision of Healthcare, approved by Decree of the Government of the Russian Federation dated June 30, 2004 N 323 regarding the powers of the said authority to conduct control procurements in order to verify compliance by drug circulation entities engaged in retail sale of medicinal products for medical use, rules for dispensing medicines for medical use and (or) a ban on the sale of counterfeit medicines idents means substandard drugs and counterfeit drugs.

2. Drafts of regulatory legal acts

2.1. The Ministry of Health of Russia proposes to abolish the current rules of the wholesale trade in drugs.

Draft order of the Ministry of Health of Russia "order" On the recognition of the order of the Ministry of Health and Social Development of the Russian Federation dated December 28, 2010 N 1222n "On approval of the Rules for the wholesale trade of medicines for medical use"

Due to the fact that the current version of Article 54 of the Federal Law dated April 12, 2010 N 61-FZ "On the Circulation of Medicines" and subparagraph 5.2.163 of the Regulation on the Ministry of Health of the Russian Federation, approved by Decree of the Government of the Russian Federation dated June 19, 2012 N 608, The Ministry of Health of Russia is empowered to approve the rules of good distribution practice of medicines for medical use.

At the same time, with the participation of the Russian side, on December 23, 2014, an Agreement was reached on uniform principles and rules for the circulation of medicines within the EAEU, according to which the wholesale, transportation, and storage of medicines in the territories of the Member States is carried out in accordance with the Rules of Good Distribution Practice within EAEU approved by the Decision of the Council of the Eurasian Economic Commission of November 03, 2016 N 80.

In order to avoid duplication and correlation of overlapping norms

Taking into account the application of the provisions provided for by the Decision of the Council of the Eurasian Economic Commission, it is proposed to recognize the Order of December 28, 2010, N 1222n as null and void.

2.2. The Russian Ministry of Health proposes to approve the methodology for determining the size of fees for the provision of services for testing immunobiological drugs.

Draft order of the Ministry of Health of the Russian Federation "On approval of the Methodology for determining the amount of fees for the provision of services for testing a series or batch of immunobiological medicinal product for compliance with the requirements established during its state registration, and the maximum amount for fees for the provision of this service"

The draft order approves the Methodology, which establishes the procedure for determining the amount of fees for the provision by federal state budgetary institutions under the jurisdiction of the Ministry of Health of Russia and Federal Service for Surveillance in Healthcare accredited in accordance with the legislation of the Russian Federation with the national accreditation system for the quality of a series or batch of tests of the quality of an immunobiological medicinal product to the requirements regulatory documentation.

The methodology includes indicators such as the cost of analyzing the document of the manufacturer of the immunobiological drug, conducting a quality examination, purchasing consumables, and other indicators. Labor costs are estimated by the timing of the work of employees in the implementation of the rendered types of work.

The maximum fee for the provision of the above services is calculated on the basis of the maximum duration of the quality tests of the immunobiological medicinal product and the maximum amount of the document of the manufacturer of the immunobiological medicinal product confirming the conformity of quality.

2.3. The Ministry of Health has developed a methodology for determining the number of fees for the provision of services for testing the first three series or batches of a medicinal product for medical use (for the purpose of its introduction into civil circulation)

Draft order of the Ministry of Health of the Russian Federation "On approval of the methodology and determination of the fee for the provision of testing services on the compliance of the first three series or batches of a medicinal product for medical use (except for immunobiological medicinal product), first produced in the Russian Federation or first imported into the Russian Federation Federation, quality indicators stipulated by regulatory documentation"

The draft Order contains a Methodology for determining the amount of fees for the provision of testing services on the compliance of the first three series or batches of a medicinal product for medical use (with the exception of the immunobiological medicinal product), first produced in the Russian Federation or first imported into the Russian Federation, with quality indicators provided for by the normative documentation. The above methods are developed on the basis of an economically feasible fee in order to ensure a unified approach to determining the size of the fee for the provision of quality testing services.

The calculation method includes indicators such as the cost of conducting a quality examination, the purchase of consumables, etc. Labor costs are estimated by the timing of the work of employees in the implementation of the rendered types of work.

2.4. The Ministry of Industry and Trade of Russia proposes to amend the legislation on the circulation of medicines with regard to the importation of medicines into Russia.

Draft Federal Law "On Amending the Federal Law "On the Circulation of Medicines" dated April 12, 2010 N 61-FZ"

It is proposed to consider the issue of amending part 3 of article 47 of the Federal Law of April 12, 2010, N 61-FZ "On Circulation of Medicines" regarding the admission of the import into the Russian Federation of a specific consignment of registered and (or) unregistered medicines intended for laboratory tests samples (samples) taken during the pharmaceutical inspection of the production of medicines for medical use located outside the Russian Federation.

In support of the stated initiative, explanations are given that the draft law is being developed in order to bring the norms of Russian legislation in accordance with the Rules for conducting pharmaceutical inspections, approved by the Decision of the Council of the Eurasian Economic Commission dated November 03, 2016 N 83.

2.5. The Russian Ministry of Health proposes to consider the draft regulation on the Commission for the Settlement of Conflict of Interests in the implementation of medical and pharmaceutical activities.

Draft Order of the Ministry of Health of Russia "On Approving the Regulation "On the Commission for the Settlement of Conflict of Interests in the Implementation of Medical and Pharmaceutical Activities"

According to the proposed project, the commission will be entitled to make such decisions as:

- recognize that when an employee engages in professional activities, there is no conflict of interest;
- acknowledge that when an employee engages in professional activities, personal interest leads to or may lead to a conflict of interests, in this regard, the Commission recommends that the employee and (or) the head of the medical organization, the head of the pharmacy organization or individual entrepreneur take measures to resolve the conflict of interest or to prevent its occurrence;
- establish that the employee complied with the requirements for resolving a conflict of interest;
- establish that the employee did not comply with the requirements for the settlement of the conflict of interest, in this regard, the Commission recommends that the head of the medical organization, the head of the pharmacy organization or individual entrepreneur indicate to the employee the inadmissibility of violation of requirements for the settlement of the conflict of interest, or apply one of the disciplinary measures.

2.6. The Russian Government proposes to establish cases where it is possible to use a patent without the consent of the patent holder.

Draft Federal Law "On Amending Article 1360 of the Civil Code of the Russian Federation"

According to the bill, in case of emergency, related to ensuring the defense and security of the state, protecting the life and health of citizens, the Government of the Russian Federation has the right to decide on the use of an invention, utility model or industrial design without the consent of the patent holder with notification of this as soon as possible and with the payment of proportional compensation to him.

In addition, it is proposed to establish that the methodology for determining the amount of compensation and the procedure for its payment is approved by the Government of the Russian Federation.

2.7. A bill was introduced to inspect pharmaceutical production for compliance with

GMP rules (EAEU)

Draft Federal Law "On Amending the Federal Law "On Licensing Certain Types of Activities" and the Federal Law "On the Circulation of Medicines"

The draft law assumes that with a positive result from the pharmaceutical inspection of the production of medicines for medical use, a certificate of compliance of the manufacturer with the requirements of the rules of good manufacturing practice of the EAEU will be issued.

At the same time, simultaneously with the decision to suspend the certificate of conformity of the manufacturer with the requirements of the rules of good manufacturing practice of the Eurasian Economic Union, the licensing authority decides to suspend the license for the period of suspension of the certificate of conformity of the manufacturer with the requirements of the rules of good manufacturing practice of the Eurasian Economic Union.

If the manufacturer of medicines refuses or does not provide the possibility of conducting a pharmaceutical inspection for compliance with the requirements of the rules of good manufacturing practice of the EAEU, the manufacturer of medicines for medical use is recognized as not complying with the rules of good manufacturing practice of the EAEU. In this case, the authorized body decides to terminate the previously issued certificate.

2.8. A Draft Federal Law to extend the implementation of the drug labeling system.

Draft Federal Law "On Amending Article 67 of the Federal Law "On Circulation of Medicines"

As noted in the explanatory note to the project, to guarantee the sustainability of the drug supply for the population, to prevent the supply of drugs for medical use being interrupted, it is advisable to gradually introduce the drug labeling system with a period until July 1, 2020.

The project provides that drugs of "high cost nosologies" introduced into civil circulation before October 1, 2019, as well as other drugs for medical use introduced into civil circulation before July 1, 2020, are subject to storage, transportation, dispensing, sale, transfer, use without identification means before the expiration date.

The draft federal law defines the obligation of legal entities and individual entrepreneurs engaged in the circulation of drugs for medical use to register in the system for monitoring the movement of drugs for medical use.

2.9. The State Duma has considered a bill banning the advertising of drugs through television and radio communications.

Draft Federal Law "On Amending Article 24 of the Federal Law "On Advertising".

At a meeting of the Council of the State Duma of the Russian Federation dated November 3, 2019, the consideration of the bill, which proposes to prohibit the advertising of medicines in television and radio programs, was postponed again. The next consideration of the bill is scheduled for December this year.

2.10. In the first reading, the State Duma of the Russian Federation adopted a bill that proposes to entrust the Ministry of Defense of the country with the function of registering the drugs necessary for use in diseases resulting from exposure to weapons

The draft federal law "On Amending the Federal Law "On Defense" and Article 38 of the Federal Law "On the Basics of Protecting Citizens' Health"

The bill provides for the operational use of special drugs and medical devices that are intended for use by units, units and organizations of the Armed Forces of the Russian Federation. It is planned

that the Ministry of Defense will register medicines and medical devices for the prevention and treatment of diseases and injuries resulting from exposure to weapons.

2.11. A bill has been submitted for consideration, which proposes the transfer of powers to organize the provision of medicines for people with two rare (orphan) diseases to the federal level.

Draft Federal Law "On Amending the Federal Law "On the Basics of Protecting Citizens' Health in the Russian Federation"

The bill proposes to amend the articles 14, 44 and 83 of the Federal Law "On the Basics of Protecting the Health of Citizens in the Russian Federation", aimed at transferring authority to organize the provision of medicines for people with aplastic anemia, unspecified, hereditary deficiency of factors II (fibrinogen), VII (labile), X (Stuart-Praer), Ministry of Health of Russia.

3. Judicial and other law enforcement practice

3.1. The Court of Appeal upheld the decision of the court of first instance on recognition by the cartel of Nizhny Novgorod pharmaceutical companies.

The determination of the First Arbitration Court of Appeal of December 2, 2019 in case N A43-18292/2019

As follows from the judicial act, from an analysis of the applications of LLC General Medical Systems and LLC Medicine and Diagnostics filed for bidding from January 01, 2016, it follows that the applications of LLC General Medical Systems and LLC Medicine and Diagnostics "have a similar design and are sent within the framework of a single procurement procedure, the applications of the named participants have one author to create and modify the file (which is established from the analysis of the" file properties "indicator). The supervisory authority concluded that these facts indicate that the actions to submit bids and price proposals at auctions were carried out by one person, which indicates joint preparation of participants for participation in auctions.

3.2. The Ministry of Health of the Russian Federation issued the first registration certificate prepared following Decision of the Council of the Eurasian Economic Commission dated November 3, 2016 N 78 "On the Rules for Registration and Expertise of Medicines for Medical Use".

According to the official website of the Ministry of Health of Russia, registration was made for the drug Granisetron (concentrate for the preparation of an infusion solution, 1 mg / ml manufactured by Ozon LLC, Russia). The registration certificate was prepared based on the procedure for bringing into compliance with the EAEU requirements the registration dossier of a medicinal product registered before the entry into force of the Agreement on Uniform Principles and Rules for the Circulation of Medicines within the EAEU of December 23, 2014 and until December 31, 2020.

3.3. The joint-stock company "R-Farm" has proved its non-involvement in the conclusion of anti-competitive agreements in the procurement of medicines in the Republic of Khakassia.

The decision of the Arbitration Court of the city of Moscow of October 29, 2019 in the case N A40-252379/18-94-2716

The court found that in addition to the applicant, other defendants in the antitrust case did not participate in the auction (in respect of which the audit was conducted). In addition to the Applicant,

only the company participated in the said auction, which was not charged with the Federal Antimonopoly Service of Russia to conclude a cartel agreement and which was not included in the list of defendants in the antitrust case. Also, according to the results of the analysis of the state of competition at the auction, the antimonopoly authority did not identify persons who evaded participation in the auction. Consequently, the auction was held in competition with an independent participant, and ended in victory for joint-stock company “R-Farm”. Under the circumstances, joint-stock company “R-Farm” had no objective reasons for concluding an anti-competitive agreement, since the only auction in which it participated was another organization that was not charged with the cartel. The absence of the second subject of the an anti-competitive agreement excludes the possibility of qualifying the company's actions as an anti-competitive agreement.

The court also considers that the coincidence of the actual / legal addresses of the companies and their IP addresses when entering the electronic platform does not in itself constitute evidence of an antimonopoly agreement. Thus, the investigation of the antimonopoly case carried out by the Federal Antimonopoly Service of Russia was incomplete, and the conclusion about the company's participation in the anti-competitive agreement does not correspond to the content of the evidence in the case.

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About us

BRACE Law Firm renders legal services to manufacturers and distributors of drugs, medical products, dietary supplements, and other healthcare organizations on issues of Russian and international law.

Our main industrial practice is “Health care and pharmaceutics”.

We provide legal assistance in the field of legal support of commercial activities, dispute resolution and litigation, antitrust law, public and corporate procurement, international trade law and some other areas.