BRACE
Law Firm

December 2019

DIGEST
of regulation of the Russian pharmaceutical industry

January 15, 2020

Dear Colleagues!

We are glad to propose to your attention the Digest of legal regulation of the Russian pharmaceutical industry for December 2019, prepared by BRACE Law Firm. A significant number of important legal acts were adopted in the field of drug circulation. The most important include the following:

- The Eurasian Economic Commission approved the Guidelines for the selection of unexplored drugs to conduct clinical trials of drugs. The document establishes that a medicinal product is unexplored if its use in the course of a clinical trial is not the direct objective of this clinical research, and also determines the criteria for the selection of unexplored medicinal products during clinical trials.
- The Federal Service for Surveillance in Healthcare approved the Procedure for assessing the volume of tests for the quality of immunobiological drugs.
- Important amendments have been made to the Federal Law “On the Circulation of Medicines” and the Federal Law “On Amendments to the Federal Law “On the Circulation of Medicines”, affecting the determination of bioequivalence of drugs, as well as allowing the import into Russia of a specific consignment of unregistered drugs containing narcotic drugs or psychotropic substances for the provision of health care for medical reasons.
- In terms of re-registering the maximum selling prices for medicines included in the list of vital and essential medicines, the Russian Government empowered the Ministry of Health and the Federal Antimonopoly Service to make an independent decision on the mandatory re-registration of the maximum selling prices for medicines.

We suggest that you familiarize yourself with the above and other equally important changes in the current legislation in this digest.

Sincerely yours,

BRACE Law Firm

1. Laws, by-laws, legal news

1.1. The Eurasian Economic Commission approved the Guidelines for the selection of unexplored drugs for the purpose of conducting clinical trials of drugs.

Recommendation of the Board of the Eurasian Economic Commission dated December 17, 2019 N 42 "On the Guidelines for the selection of unstudied drugs to conduct clinical trials of drugs"

The Recommendation defines the term "unexplored medicinal product". It is established that a medicinal product is unexplored if its use in the process of a clinical trial is not the immediate goal of this clinical trial.

The document also defines the criteria for the selection of unstudied drugs during clinical trials of drugs, the amount of information about unstudied drugs presented in the dossier for obtaining permission to conduct clinical trials.

The most commonly used unexplored drugs are drugs registered under the Rules of Registration and Expertise or registered in any of the Member States where it is planned to conduct a clinical trial, under acts included in the law of the Eurasian Economic Union.

If it is intended to use a drug that is not registered in the Eurasian Economic Union or the Member States as an unexplored drug, make sure that such a drug is manufactured in accordance with these Rules.

Such categories of unexplored medicinal products are established as emergency medicine (rescue therapy); unexplored drugs used to evaluate endpoints (results) in a clinical trial; simultaneously used unexplored drugs systematically prescribed to the subjects of the study.

The guidance is effective on June 19, 2020.

1.2. The Eurasian Economic Commission amended the Rules for the registration and examination of medicines for medical use.

Order of the Board of the Economic Commission for Europe dated December 17, 2019 N 202 "On the draft decision of the Council of the Eurasian Economic Commission "On amendments to the Rules for the registration and examination of medicines for medical use""

The document added that after bringing the registration dossier in accordance with the requirements of the EAEU, the manufacture and import of a medicinal product with a registration certificate issued in accordance with the legislation of the EAEU Member State is allowed within 180 calendar days from the date of bringing the registration dossier in accordance with the requirements EAEU.

The simultaneous sale of a medicinal product is allowed until the expiration date in the package and with instructions for medical use ,relevant documents and information from the registration dossier, approved in accordance with the legislation of the EAEU member states, and the registration dossier brought into line with the EAEU requirements.

1.3. The Russian Government has approved the rules for providing subsidies to stimulate demand and increase the competitiveness of Russian industrial products.

Decree of the Government of the Russian Federation of December 27, 2019 N 1908 "On approval of the Rules for the provision of subsidies from the federal budget to stimulate demand and increase the competitiveness of Russian industrial products and invalidate certain acts of the Government of the Russian Federation"

According to the said Rules, subsidies are granted to organizations included in the register of subsidy recipients, subject to the following conditions:

- a leasing agreement was concluded not earlier than January 1 of the current financial year for at least 12 months from the date of signing the acceptance certificate of industrial products manufactured not earlier than January 1 of the year preceding the year of receiving the subsidy for leasing;
- state support for the production and sale of a unit of industrial production is carried out once during the life of such a unit of production;
- the organization does not have an unfulfilled obligation to pay taxes, fees, insurance premiums, penalties, fines, interest payable in accordance with the legislation of the Russian Federation on taxes and fees, on the day no earlier than 30 calendar days before the day of application for participation in qualification selection;
- the organization has no overdue debts on the return to the federal budget of subsidies, budget investments provided, including in accordance with other legal acts, and other overdue debts to the federal budget on the day no earlier than 30 calendar days before the day of application for participation in qualification selection;
- the organization is not a foreign legal entity, as well as a Russian legal entity, in the authorized (joint-stock) capital of which the share of participation of foreign legal entities, the place of registration of which is the state or territory, is included in the list of states and territories that provide preferential taxation approved by the Ministry of Finance of the Russian Federation taxation regime and (or) not providing for the disclosure and provision of information during financial transactions (offshore zones) in aggregate more than 50 percent;
- the organization is not in the process of reorganization, liquidation, the bankruptcy procedure has not been introduced to it, its activity has not been suspended in the manner prescribed by the legislation of the Russian Federation;
- the organization has no overdue debts on monetary obligations to the Russian Federation.

It was established that the agreements (agreements) on the provision of subsidies concluded in accordance with the Decree of the Government of the Russian Federation of October 1, 2015 N 1047 “On approval of the Rules for the provision of subsidies from the federal budget to Russian organizations to compensate for part of the costs incurred in implementing projects for the organization of production of medicines and (or) pharmaceutical substances, under the subprogram “Development of the production of medicines” of the state program of the Russian Federation “Develop Pharmaceutical and medical industry activities “for 2013 – 2020”, are valid until the recipients of subsidies fulfill their obligations. At the same time, these Rules are declared invalid from January 12, 2020 (from the date of entry into force of the new Rules adopted by the Government of the Russian Federation).

1.4. The procedure for evaluating the volume of tests of the quality of immunobiological drugs by the Commission of the Federal Service for Surveillance in Healthcare on the quality of immunobiological drugs was approved.

Order of Federal Service for Surveillance in Healthcare dated December 17, 2019 N 9452 “On approval of the Procedure for assessing the volume of tests of the quality of immunobiological drugs by the Commission of the Federal Service for Surveillance in Healthcare on the quality of immunobiological drugs”

From January 12, 2020, the scope of the quality tests of immunobiological drugs is assessed to immunobiological drugs, data on which are entered in the State Register of Medicinal Products and

entered into civil circulation in the Russian Federation, information on which is contained in the automated information system of the Federal Service for Surveillance in Healthcare.

The decision to determine the scope of the quality tests of the immunobiological medicinal product of a specific name and manufacturer (taking into account the dosage form and dosage) is carried out by the Commission based on an analysis of the quality of such drugs, submitted to the Commission annually until March 1.

Based on the available information, the Commission annually, no later than April 1 of the year following the past, holds a meeting and decides to determine the scope of the quality tests of the immunobiological medicinal product of a specific name and manufacturer (taking into account the dosage form and dosage) and the frequency of immunobiological drug tests for all indicators of approved regulatory documentation.

The decision of the Commission to determine the scope of the quality tests of immunobiological drugs is mandatory signed by all members of the Commission present at the meeting.

The decision of the Commission to reduce the volume of quality tests of immunobiological drugs is taken in the absence of:

- information on the identification of non-compliance with the established quality requirements;
- information on serious adverse reactions that pose a potential threat to life, on cases of harm to the life and health of citizens, on cluster cases of insufficient therapeutic effectiveness;
- the results of a statistical analysis of the laws of quantitative data obtained as a result of tests of the quality of immunobiological drugs that go beyond reliability;
- gross violations of licensing requirements identified during the licensing control of pharmaceutical production activities, as well as critical discrepancies based on the results of the inspection for compliance with the requirements of the rules of the good manufacturing practice.

1.5. Significant changes have been made to the law on the circulation of medicines, which will enter into force in 2020.

Federal Law of December 27, 2019, N 475-FZ "On Amending the Federal Law "On the Circulation of Medicines" and the Federal Law "On Amending the Federal Law "On the Circulation of Medicines"

Federal Law of December 27, 2019, N 462-FZ "On Amendments to the Federal Law "On Circulation of Medicines" and the Federal Law "On Amendments to the Federal Law "On Circulation of Medicines"

Changes have been made regarding the disclosure of the meanings of the terms "generic drug" and "reference drug". The terminology pays special attention to equivalence. In particular, the term "bioequivalence" has been introduced, which means achieving comparable indicators of absorption rate, degree of delivery to the site of action, and rate of excretion of one or more active substances with pharmacological activity when using drugs for medical use that have one international non-patented (or chemical, or group) name, in equivalent dosages and with the same method of administration. A reference drug is a drug that is used to evaluate bioequivalence or therapeutic equivalence, quality, effectiveness and safety of a reproduced drug or bio-analog (biosimilar) drug (bio-analog). The original medicinal product is used as a reference medicinal product for medical use either, if the original medicinal product is not registered or is not in circulation in the Russian Federation and is not in circulation in foreign countries, the reproduced medicinal product or bio-analog (biosimilar) drug (bio-analog) which was first registered among those in circulation in the

Russian Federation, bioequivalence or therapeutic equivalent the relevance, quality, effectiveness and safety of which were evaluated in relation to the original medicinal product, as well as the quality, effectiveness, and safety of which are confirmed by the results of pharmacovigilance and checks of the conformity of drugs in civil circulation with the established requirements for their quality. As a reference medicinal product for veterinary use, a medicinal product for veterinary use, registered in the Russian Federation based on the results of preclinical studies of drugs and clinical studies of drugs confirming its quality, effectiveness, and safety, is used. A reproduced drug is a medicine for medical use that has a qualitative composition and quantitative composition of active substances in an equivalent dosage form equivalent to a reference medicine, or a medicine for veterinary use that has the same as a reference medicine, qualitative composition and quantitative composition of active substances in the same dosage form, bioequivalence or therapeutic whose equivalence to the corresponding reference medicinal product is confirmed by relevant studies.

Provisions are made for the import into Russia of a specific batch of unregistered drugs containing narcotic drugs or psychotropic substances to provide medical care according to the vital indications of a particular patient or group of patients if there is a decision of the medical commission of the medical organization on the inefficiency or impossibility of using other registered patients medicines, including those containing other active substances, and the need for the delivery of a certain unregistered medicinal product with an indication of its international non-proprietary (or chemical, or grouping) name, form of release and quantity. The list of diseases and conditions and related medications containing narcotic drugs and psychotropic substances, to import them in accordance with the requirements of this part, is approved by the authorized federal executive body.

These changes come into force on March 1, 2020.

On January 1, 2023, a decision to cancel the state registration of a medicinal product and its deletion from the state register of medicines is taken if the holder or holder of the registration certificate of the medicinal product for medical use has not been presented within six months from the date of suspension of the use of the medicinal product for medical use to the authorized body the documents (information in the documents) necessary for the examination of the registration dossier for a medicinal product in order to determine the interchangeability of a medicinal product for medical use, as well as if an application is not submitted to amend the documents contained in the registration dossiers for registered medicinal products for medical use, in relation to the information specified in the instructions for medical use the use of drugs, within forty business days from the date of placement by the authorized body of information on the need to make instructions th for medical use of the drug changes to the information about the indications and contraindications for use for applying medicament identified side effects, adverse reactions when applying a medicament.

The labeling of drugs used in a number of nosologies has been delayed. Medicinal products for medical use intended to provide persons with hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, malignant neoplasms of lymphoid, hematopoietic and related tissues, multiple sclerosis, persons after transplantation of organs and (or) tissues produced before December 31, 2019 years, as well as other medicinal products for medical use, produced before July 1, 2020, are subject to storage, transportation, leave, sale, transfer, use without application rest identification prior to the expiry of their validity.

1.6. Since 2021, a number of procedures for submitting documents for inclusion in the state register of medicines of a pharmaceutical substance have been simplified.

Federal Law of December 27, 2019 N 478-FZ "On Amending Certain Legislative Acts of the Russian Federation with Regarding the Implementation of the Registry Model for the Provision of Public Services for Licensing Certain Types of Activities"

From January 1, 2021, a number of documents submitted for inclusion of a pharmaceutical substance in the state register of medicines shall be submitted to the procedure of interagency information interaction. Namely, such a request should be made in case of failure to submit documents confirming the payment of the state duty in the state register of medicines of pharmaceutical substances, and in case of failure to submit documents confirming the payment of the state duty in the state register of medicines of pharmaceutical substances, copies of the license for the production of medicines or copies of the conclusion on the manufacturer's compliance In accordance with the requirements of the Rules of Good Manufacturing Practice issued by the authorized federal executive body, if the production of the medicine is carried out in Russia and if the production of the medicine is outside the Russian Federation, a copy of the document issued by the authorized body of the country of manufacture of the medicine and confirming the production permit medicinal product, and its certified translation into Russian, as well as a copy of the conclusion on compliance of the manufacturer of medicines with the requirements of the Rules of Good Manufacturing Practice issued by an authorized body, or a copy of the decision to conduct an inspection of the manufacturer of the medicine.

1.7. The Russian Ministry of Health has given explanations regarding the procurement of medicines that are necessary for prescribing to a patient if there are medical indications.

Letter of the Ministry of Health of Russia dated December 17, 2019 N 3175 / 25-2 "On the issues of the procurement of drugs"

In the presence of medical indications (individual intolerance, according to vital indications), by the decision of the medical commission, the prescription of drugs is carried out not according to the international nonproprietary name, but according to the trade name. The decision of the medical commission is drawn up in the protocol and entered into the medical documentation of the patient.

In this case, not only reference (original) drugs can be prescribed, but also reproduced drugs or bio-analog (biosimilar) drugs (bio-analogs) selected by the patient for health reasons.

When describing the procurement object, reference is also made to the trade names in relation to the medicines necessary for prescribing to the patient for health reasons.

The provisions of the Federal Law of 05.04.2013 No. 44-FZ "On the contract system of procurement of goods, work, services for the provision of state and municipal needs" in the procurement of medicines by trade names that are necessary for prescribing to a patient for health reasons, the following ways to determine the supplier:

- request for proposals, including request for proposals in electronic form;
- procurement from a single supplier (contractor, contractor).

The following conditions must be met:

- the subject of one contract may not be the drugs necessary for the appointment of two or more patients;
- the decision of the medical commission should be included simultaneously with the contract in the register of contracts.

In the case of determining the supplier by conducting a request for proposals, a notice on procurement should be posted on the website no later than 5 days before the date of such a request,

and when conducting a request for proposals in electronic form, no later than 5 working days before the date of such request. Moreover, the restriction on the initial (maximum) price of the contract is not provided.

In the case of purchasing from a single supplier (contractor, contractor), justification of the price of the contract is not required, however, the price of the contract with this method of determining the supplier should not exceed 1 million rubles. In this case, the volume of purchased drugs should not exceed the volume of such drugs required for the patient during the period necessary for the procurement of drugs. Notification of procurement is not required.majority.

1.8. The Rules for Mandatory Re-Registration in 2019 – 2020 of the registered maximum selling prices of manufacturers of medicines included in the list of vital and essential medicines were approved.

Decree of the Government of the Russian Federation of December 16, 2019 N 1683 "On amendments to some acts of the Government of the Russian Federation regarding state registration and re-registration of maximum selling prices for drugs included in the list of vital and essential drugs"

Mandatory re-registration of maximum selling prices for pharmaceuticals is carried out with the preservation of the last registered (re-registered) maximum selling prices for immunobiological pharmaceuticals, pharmaceuticals containing narcotic drugs and psychotropic substances, manufactured by the Member States of the Eurasian Economic Union, as well as pharmaceuticals in the price segment up to 100 rubles.

It is established that an application for mandatory re-registration in 2019-2020 of the registered maximum selling price of a manufacturer for a reference medicinal product included in the list of vital and essential medicines must be submitted by the holder or owner of the registration certificate of the reference medicinal product within 40 business days from the date of entry by virtue of the Decree of the Government of the Russian Federation of December 16, 2019 N 1683.

For drugs used in pediatric practice (for which the maximum selling price is not registered), the calculation of the maximum selling price is carried out in accordance with the requirements established for reference medicines. In this case, the maximum difference between the minimum registered maximum selling price of a medicinal product and the maximum selling price of a medicinal product submitted for state registration, calculated the basis of the unit cost of the active substance, may not exceed 90 percent.

Also, the Ministry of Health and the Federal Antimonopoly Service will now be empowered to make an independent decision on the mandatory re-registration of the maximum selling price for a drug.

1.9. The Ministry of Health has approved the procedure for determining the initial (maximum) price of a contract, the price of a contract concluded with a single supplier (contractor, contractor) in the procurement of medicines.

Order of the Ministry of Health of Russia dated December 19, 2019, N 1064н "On approval of the Procedure for determining the initial (maximum) price of a contract, the price of a contract concluded with a single supplier (contractor, contractor), the initial unit price of a product, work, service when purchasing medicines for medical use"

When applying the method of comparable market prices (market analysis), the customer must collect and analyze publicly available price information, as well as send requests for price information to suppliers.

To determine the weighted average price for the purchase of multicomponent (combined) drugs, which are a combination of 2 or more active substances, as well as sets of registered drugs, the customer has the right not to take into account the prices of units of drugs under the executed contracts for the supply of the corresponding single-component drugs, except if the completed contract for the supply of the relevant single-component drugs was concluded according to the results of the competitive procurement procedure for multicomponent (combined) drugs or sets of registered drugs. Also, now the customer has the right not to take into account the prices of delivered drugs with a residual shelf life of 20 percent or more different from the residual shelf life provided for by the customer in the description of the procurement object, for which the initial maximum price of the contract, the initial unit price of the drug, and under contracts for which the customer was charged with forfeits (fines, penalties) in connection with non-fulfillment or improper performance of obligations stipulated by the contracts.

When setting the unit price of a medicinal product, the reference price is not taken into account when determining the price for procurement from a single supplier under clause 28, part 1, article 93 of the Federal Law of April 05, 2013, N 44-FZ “On the contract system in the field of procurement of goods, works, services for the provision of state and municipal needs” by requesting offers and requesting proposals in electronic form, as well as the price of a drug that is not in civil circulation.

1.10. The Federal Service for Surveillance in Healthcare on the official website published a Guide for the Acceptance of Medicines in Connection with the Entry into Force on November 29, 2019, of a New Procedure for Putting Medicines into Civil Circulation

Leaflet on the acceptance of drugs in connection with the entry into force on November 29, 2019, of a new procedure for the introduction of drugs into civil circulation

The Federal Service for Surveillance in Healthcare of Russia explains that the legality of finding a series (batch) of a drug can be checked on the official website of the Federal Service for Surveillance in Health Care of Russia www.roszdravnadzor.ru.

To do this, on the website of the Federal Service for Surveillance in Healthcare of Russia, go to the section “Medicines” and in the section “Electronic Services” find the service: “Information about drugs received in civil circulation in the Russian Federation”.

The search is possible by several details, including the trade name, series number, manufacturer, country of manufacture.

Information on permissions of the Federal Service for Surveillance in Healthcare of Russia for the introduction into civil circulation of a series (batch) of immunobiological medicinal product is also posted on the website of the Federal Service for Surveillance in Healthcare of Russia under the heading “Electronic Services” / “Information on drugs received in the civilian turnover in the Russian Federation.”

If there is no information on the website of the Federal Service for Surveillance in Healthcare of Russia on the introduction of a series of a batch of a drug into civil circulation, you should contact the territorial body of the Federal Service for Surveillance in Healthcare of Russia to consider the need for control measures.

1.11. Amendments to the law on defense affecting the issue of circulation of drugs and medical devices developed on behalf of the Ministry of Defense of Russia

Federal Law of December 27, 2019, N 518-FZ “On Amending the Federal Law “On Defense” and Article 38 of the Federal Law “On the Basics of Protecting the Health of Citizens in the Russian Federation”

The Ministry of Defense of the Russian Federation establishes cases and procedures for the provision of medical assistance by personnel of medical (military-medical) organizations, units and medical (military-medical) units of the Armed Forces of the Russian Federation, other troops, military units and bodies during the deployment of these organizations, units and units outside the territory of the Russian Federation (including the procedure for the use of drugs and medical devices not registered in the Russian Federation).

Features of the circulation of drugs and medical devices developed on the instructions of the Ministry of Defense of the Russian Federation, federal executive bodies (bodies) authorized in the field of command and control of other troops, military units and bodies intended for use in wartime conditions and for conducting military (combat) operations fulfillment of combat (training), service and combat (operational) tasks in the field of defense by the Armed Forces of the Russian Federation, other troops, organizations, and bodies used to diagnose, prevent and treat diseases and injuries resulting from exposure to weapons, weapons and military equipment, adverse chemical, biological and radiation factors are established by the Government of the Russian Federation.

1.12. An amendment was made to the Government Decree approving the Lists of medical services and expensive types of treatment in medical institutions of the Russian Federation, medicines, the amount of payment of which at the expense of the taxpayer's funds is taken into account when determining the amount of social tax deduction.

Decree of the Government of the Russian Federation of December 20, 2019 N1740 "On Amending the Decree of the Government of the Russian Federation of March 19, 2001 N 201"

The List of medical services and expensive treatments in medical institutions of the Russian Federation, the amounts of which are paid at the expense of the taxpayer's funds are taken into account when determining the amount of social tax deduction, is recognized as invalid.

1.13. The government has included amendments to the law on the circulation of drugs and the law on the protection of public health in the legislative plan for 2020

Decree of the Government of the Russian Federation of December 26, 2019 N 3205-r "On approval of the plan of legislative activity of the Government of the Russian Federation for 2020"

In July 2020, it is planned to introduce into the State Duma of the Russian Federation draft laws on amendments to the Federal Law "On the Basics of Protecting the Health of Citizens in the Russian Federation" (regarding the systematization of mandatory requirements in the field of medical activity) and on amendments to the Federal Law "On circulation of medicines" (in terms of systematization of mandatory requirements in the field of circulation of medicines).

1.14. On December 1, the Decree of the Government of the Russian Federation dated May 17, 2019 N 667 "On Amending the Resolution of the Government of the Russian Federation dated December 29, 2007 N 964" came into force.

Decree of the Government of the Russian Federation of May 17, 2019 N 667 "On Amending the Decree of the Government of the Russian Federation of December 29, 2007 N 964"

To implement article 234 of the Criminal Code of the Russian Federation (illicit trafficking in potent or toxic substances for marketing purposes), the list of potent and poisonous substances for which trafficking in trafficking for criminal purposes is criminalized includes: pregabalin; tapentadol; tropicamide.

2. Drafts of regulatory legal acts

2.1. The Russian Ministry of Health proposes to amend the Regulation on the system for monitoring the movement of drugs for medical use.

Draft Decree of the Government of the Russian Federation "On Amending the Decree of the Government of the Russian Federation of December 14, 2018 N 1556 "On Approving the Regulation on the System for Monitoring the Movement of Medicinal Products for Medical Use"

Currently, the Decree of the Government of the Russian Federation dated December 14, 2018 N 1557 "On Establishing the Peculiarities of the Implementation of the Monitoring System for the Movement of Medicinal Products for Medical Use" has established the features of the implementation of the monitoring system, including the timing of its implementation, about medicines for medical use intended to provide individuals patients with hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, malignant neoplasms of lymphoid, hematopoietic and Rhodes their tissues, multiple sclerosis, persons after transplantation of organs and (or) tissues (hereinafter referred to as drugs for the treatment of high-cost nosologies).

For other medicinal products for medical use, the specifics of implementing a monitoring system, including the timing of its implementation, are not provided.

The project proposes to establish that the fee for the provision by the operator of the monitoring system of the service for the provision of marking codes will be charged from July 1, 2020.

Retail sale, vacation for free or at a discount on a prescription for a medicinal product or use in the provision of medical care of medicinal products manufactured from July 1, 2020, is allowed only if there is an identification tool on the primary packaging of the medicinal product (if secondary packaging is not provided) and on the secondary (consumer) packaging of the medicinal product, as well as the transfer to the monitoring system of information about their sale, vacation or use in the provision of medical care. These restrictions do not apply to medicines that, by the Regulations approved by this resolution and international treaties of the Russian Federation, are not subject to mandatory labeling using identification".

2.2. The Ministry of Health proposes to change the conditions for determining the compliance of a person who has received a pharmaceutical education with the requirements for the implementation of pharmaceutical activities

Draft order of the Ministry of Health of the Russian Federation "On amendments to the Regulation on the accreditation of specialists, approved by order of the Ministry of Health of the Russian Federation of June 2, 2016 N 334n"

It is proposed that the acquisition of a set of practical tasks to assess practical skills in simulated conditions and situational tasks in the framework of a professional exam should be carried out using information systems automatically from the database of a unified database of assessment tools.

The number of practical tasks and situational tasks within the framework of a professional exam is set separately for each pharmaceutical specialty in an amount of at least five.

One accredited person has 10 minutes to complete one practical task.

To solve one situational problem containing 12 questions, one accredited person is given 30 minutes.

The result of the professional exam is generated using information systems automatically based on the percentage of correctly completed practical actions of the total number of practical actions in practical tasks and the percentage of correct answers to questions contained in situational tasks.

Based on the result of the professional exam, the accreditation sub-committee evaluates the result of the accredited passing this stage of accreditation as:

- "passed the exam" with the result of 70% or more correctly performed practical actions of the total number of practical actions and with the result of 70% or more correct answers when solving situational tasks (provided that they are included in the professional exam);
- "not passed exam" with a result of 69% or less correctly performed practical actions of the total number of practical actions and (or) with a result of 69% or less correct answers when solving situational tasks.

2.3. The deadlines for considering the project on the remote delivery of medicines have been postponed.

Bill N 285949-7 "On Amendments to Certain Legislative Acts of the Russian Federation in the Field of Remote Retail Trade of Medicines"

The previously defined deadline for submitting amendments aimed at establishing an accounting procedure for prescription forms has been extended by verifying the authenticity of the recipe sent remotely by the buyer. It is also necessary to determine the identification procedure for persons representing prescription forms.

2.4. Federal Service for Surveillance in Healthcare posted draft standard forms of acts on the control purchase.

Draft order of Federal Service for Surveillance in Healthcare of Russia "On the approval of standard forms of acts on the control purchase of goods (work, services)"

The specified project in December 2019 underwent an anti-corruption examination. The draft order proposes to approve the standard form of the Act on the control purchase of goods (works, services) and the standard form of the Act on the remote control purchase of goods (works, services).

2.5. The Ministry of Health announced the creation of a unified register of recipients of preferential drugs.

The project aims to eliminate duplication of the provision of preferential categories of citizens from the federal budget and the budgets of the constituent entities of the Russian Federation. The project is planned for two to three years.

2.6. The Ministry of Education of the Russian Federation is making a shortening of the term for students in secondary vocational education in the pharmaceutical specialty.

Draft order of the Ministry of Education of the Russian Federation "On approval of the federal state educational standard of secondary vocational education in the specialty 33.02.01 Pharmacy"

The Ministry of Education of the Russian Federation is reducing in the time required for students to complete secondary vocational education in the specialty "Pharmacy". It is assumed that the duration of training based on basic general education (grades 5–9) will be 2 years 10 months, and based on secondary general education (grades 10–11) it will be 1 year 10 months.

3. Judicial and other law enforcement practice

3.1. The Federal State Unitary Enterprise Post of Russia launched the pilot project for the sale of medicines in post offices.

According to the official website of the organization, pharmacies are open based on three post offices in the Samara region. Four months later, a decision is planned on the advisability of expanding this practice in other regions.

3.2. Alkon Pharmaceuticals LLC managed to avoid administrative responsibility in connection with the fulfillment of the requirements of the Federal Antimonopoly Service of Russia.

The company complied with the requirements of the supervisory authority containing a warning about the need to terminate actions related to a violation of antitrust laws. Namely, she voluntarily eliminated the signs of violation of antitrust laws by carrying out maintenance work on the Allegretto excimer laser using a gas mixture of the customer's choice, while previously there was evidence of the imposition of the acquisition of a gas mixture of a particular manufacturer for servicing an excimer laser.

If you have any questions regarding this digest, please contact us:
✓ info@brace-lf.com
✓ +7(499)755-56-50

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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.

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