BRACE
Law Firm

October 2019

DIGEST
of regulation of the Russian pharmaceutical industry

November 22, 2019

Dear Colleagues!

We are glad to propose to your attention the Digest of legal regulation of the Russian pharmaceutical industry for October 2019, prepared by the BRACE Law Firm. October 2019 was marked by the adoption of significant number of legal acts affecting the functioning of the pharmaceutical market, high normative activity, as well as remarkable judicial practice:

- The Board of the Eurasian Economic Commission approved the passport of the Classifier of components of medicines altogether with the methodology for classification and coding of information and the procedure for maintaining the Classifier, as well as clarifications regarding the classification of the drug based on seedless aqueous substrates of metabolic products of microorganisms.
- The Government of Russia approved a list of vital drugs for 2020, a list of drugs prescribed by the decision of the medical commissions of medical organizations, a list of expensive drugs, and a minimum range of drugs needed to provide medical care.
- Federal Service for Surveillance in Healthcare (Roszdravnadzor) issued recommendations for participants in the experiment on labeling with identification and monitoring the circulation of certain types of drugs for medical use, as well as a list of the most frequent violations when sending mandatory information to be provided to Federal Service for Health Supervision.
- The Ministry of Health put forward such legislative initiatives as the creation of the Metrological Service at this ministry; Establishment of the maximum level of allowable expenses of a citizen for the payment of vital and essential medicines. In addition, the Ministry finalized the draft rules for mandatory re-registration in 2019-2020 of all previously registered by various methods, maximum selling prices for drugs included in the list of vital drugs, as well as the rules according to which the owners of registration certificates for drugs included in the List of Vital and Essential Drugs are obliged to reduce previously registered prices for medicines included in the List of Vital and Essential Drugs
- The Intellectual Property Rights Court confirmed the compulsory license of Nativa LLC to Sunitinib-native.
- The slogan “Cheap pharmacy. We’ll sell it cheaper if you name the competitor’s price” o on the sign of a pharmacy arbitration court ruled as an advertisement.

The above and other equally important changes in the current legislation, as well as legislative initiatives, can be found in this digest in more detail.

Sincerely yours,

BRACE Law Firm

1. Laws, by-laws, legal news

1.1. The Eurasian Economic Commission decided on the classifier of components of medicines, and also clarified the classification of the drug based on germ-free aqueous substrates of the metabolism products of microorganisms following the unified Commodity Nomenclature foreign economic activity of the Eurasian Economic Union

Decision of the Board of the Eurasian Economic Commission of October 08, 2019 N 171 "On the classifier of components of medicines"

Decision of the Board of the Eurasian Economic Commission of October 08, 2019 N 173 "On the classification of a drug based on seedless water substrates of metabolic products of microorganisms following the unified Commodity Nomenclature foreign economic activity of the Eurasian Economic Union"

By the decision of the Board of the Eurasian Economic Commission, the passport of the Classifier of components of medicines was approved along with the methodology for classification and coding of information and the procedure for maintaining the Classifier.

Information about the types of components for packaging drugs is classified by a hierarchical method.

The classification feature of the first step in the hierarchy is the category of pharmaceutical packaging components, with the following categories: administration devices; capping systems; unpacking devices; other types of components.

The classification feature of the second level of the hierarchy is the type of complementary means for packaging pharmaceuticals, determined in accordance with the Nomenclature of dosage forms approved by the Decision of the Board of the Eurasian Economic Commission dated December 11, 2015 N 172.

The classification object is information on the types of components included in the consumer packaging of drugs, which are indicated in the registration dossiers of drugs.

Also, it was determined by another Decision of the Board of the Eurasian Economic Commission that the preparation in liquid form in the form of a solution for oral administration containing, as active substances, germ-free aqueous substrates of metabolic products of microorganisms, as well as auxiliary substances, designed to restore and regulate the balance of normal intestinal microflora, enhance protective properties of the body, in accordance with the Basic Rule of Interpretation of the Commodity Nomenclature of Foreign Economic Activity 1 cl is codified in heading 2106 of the unified Commodity Nomenclature of Foreign Economic Activity of the EAEU.

When filling out a customs declaration for declaring a product as part of its movement within the borders of the Eurasian Economic Union, it is mandatory to indicate the product code for the product range of the EAEU's foreign economic activity. The correctness of the calculation of customs payments depends on the correct coding.

1.2. The government approved new lists of drugs for 2020, including a list of essential drugs, a list of drugs prescribed by the decision of the medical commission, and also approved the minimum range of drugs needed to provide medical care.

Decree of the Government of the Russian Federation of October 12, 2019, N 2406-r "On approval of the list of vital and essential medicines for 2020, as well as lists of medicines for medical use and the minimum range of medicines needed to provide medical care"

The specified document approved:

- a list of vital and essential medicines for medical use for 2020;

- a list of drugs for medical use, including drugs for medical use, prescribed by the decision of the medical commissions of medical organizations;
- a list of drugs intended to provide people with hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, malignant neoplasms of lymphoid, hematopoietic and related tissues, multiple sclerosis, hemolytic uremic syndrome, juvenile arthritis with the systemic origin, mucopolysaccharide and VI types, persons after transplantation of organs and (or) tissues;
- a minimum assortment of medications needed to provide medical care.

It is noteworthy that the List of Vital and Essential Drugs is supplemented by 24 new positions, and also Lornoxicam is excluded from this list.

The so-called List of expensive drugs has been supplemented with drugs intended for the treatment of hemolytic uremic syndrome, juvenile arthritis with systemic onset, mucopolysaccharidosis of types I, II and VI (taking into account the fact that the nosology replenished the list in 2019).

Another 23 new positions were added to the List of drugs for medical use, prescribed by the decision of the medical commissions of medical organizations.

1.3. The Federal Service for Surveillance in Healthcare (Roszdravnadzor) made recommendations to participants in the experiment on labeling with identification tools and monitoring the turnover of certain types of drugs for medical use.

Recommendations for the participants of the Labeling Experiment on the labeling by means of identification and monitoring of the circulation of certain types of drugs for medical use (together with “Characteristics of identification tools, requirements for the structure and format, including the procedure for obtaining and using labeling codes and generating group codes”, “Requirements for the information provided by the state information systems of federal executive bodies to the monitoring system, as well as to the information transmitted from the monitoring system”), approved by Federal Service for Surveillance in Healthcare (Roszdravnadzor) on October 2, 2019

The specified document established that the participants in the experiment on labeling with identification mean and monitoring the turnover of certain types of drugs for medical use by drug circulation entities is determined on the basis of voluntary registration in the monitoring system.

As part of the information interaction, the monitoring system exchanges information with state information systems of interested executive bodies, including through the infrastructure that provides information and technological interaction of information systems used to provide state and municipal services and perform state and municipal functions in electronic form. The monitoring system interacts with the following information systems: a single register of licenses for the production of medicines; a unified register of licenses, including licenses issued by state authorities of the constituent entities of the Russian Federation in accordance with the transferred authority to license certain types of health care activities; unified state information system in the field of healthcare; unified state register of legal entities; unified state register of individual entrepreneurs; state register of accredited branches, representative offices of foreign legal entities; automated information system of Federal Service for Health Supervision; Unified automated information system of customs authorities; information systems of drug circulation entities.

An application for participation in the Experiment on a voluntary basis is executed in the monitoring system in electronic form.

The procedure for entering information by subjects of circulation of medicines into the monitoring system, including a list of information provided, is established. In particular, within the

framework of putting into circulation drugs produced in the Russian Federation, the drug circulation entity that prepares (packs) the drugs in the secondary (consumer) packaging of the drug (and in its absence - the primary packaging of the drug), within 5 working days from the date of completion of the production stage of the packing (packing) of drugs, but until the provision of information on further operations with such drugs provides a monitoring system.

At the same time, when transferring drugs between subjects of circulation of drugs, it is allowed to provide information to the monitoring system both by the subject of circulation of drugs carrying out the transfer of drugs and by the entity taking the drugs.

1.4. The Russian government approved the rules for subsidizing the costs of the Federal State Unitary Enterprise "Moscow Endocrine Plant" for the purchase, import and delivery of psychotropic drugs not registered in the Russian Federation to provide for children.

Decree of the Government of the Russian Federation of October 21, 2019 N 1354 "On approval of the Rules for the provision in 2019 of a subsidy from the federal budget for the reimbursement of expenses of the federal state unitary enterprise "Moscow Endocrine Plant" for the purchase, import and delivery of psychotropic drugs not registered in the Russian Federation to provide for children"

The subsidy is provided in order to reimburse the costs of the recipient of the subsidy for the purchase, import, and delivery of unregistered psychotropic drugs to provide children with medical assistance in the framework of the state program of the Russian Federation "Health Care Development".

The subsidy is granted provided that the recipient of the subsidy on the 1st day of the month preceding the month in which it is planned to conclude between the Ministry of Industry and Trade of the Russian Federation and the recipient of the subsidy an agreement on the provision of subsidies:

- a recipient does not have an unfulfilled obligation to pay taxes, fees, insurance premiums, interest, fines, and interest payable in accordance with the legislation of the Russian Federation on taxes and fees;
- a recipient of the subsidy has no overdue debts on the return to the federal budget of subsidies, budget investments, and other overdue debts to the federal budget;
- a recipient of the subsidy is not in the process of reorganization, liquidation, bankruptcy;
- a recipient of the subsidy does not receive funds from the federal budget on the basis of other regulatory legal acts for purposes that are consistent with the objectives of the subsidy provided.

In order to receive a subsidy, the recipient of the subsidy is not obliged to submit an application for the grant of subsidies to the Ministry of Industry and Trade of the Russian Federation, drawn up in any form and signed by the head of the subsidy recipient, with the calculation of the subsidy for cost recovery. The Ministry of Industry and Trade of the Russian Federation checks the completeness and reliability of the information contained in the documents submitted by the recipient of the subsidy and within 5 calendar days makes a decision on granting the subsidy or on refusing to provide it.

The indicated document instructed the Ministry of Health of Russia to prepare and submit to the Ministry of Industry and Trade of Russia information on the needs of specific legal entities in unregistered medicines before October 25, 2019. The Ministry of Industry and Trade is committed to approving the distribution plan for these drugs by November 1 of this year.

1.5. The Government of Russia approved the principles of modernization of primary health care in the Russian Federation and the rules for the examination of draft regional programs for the modernization of primary health care.

Decree of the Government of the Russian Federation of October 09, 2019 N 1304 "On approval of the principles of modernization of primary health care in the Russian Federation and the Rules for the examination of draft regional programs for modernization of primary health care, monitoring and control of the implementation of regional programs for modernization of primary health care"

This document provides a list of proposed activities, including: on the prevention of complications of cardiovascular diseases in high-risk patients by providing medicines for citizens who have suffered an acute cerebrovascular accident, myocardial infarction and other acute cardiovascular diseases or vascular operations, and which receive medical care on an outpatient basis; equipping vehicles with medical organizations for the transport of biological materials for research, drug delivery to residents of remote areas.

The Russian Ministry of Health has been instructed by November 25 of 2019 to develop and submit to the Government of the Russian Federation in the prescribed manner a draft resolution of the Government of the Russian Federation on the approval of the Rules for the provision of subsidies from the federal budget to the budgets of the constituent entities of the Russian Federation for the prevention of complications of cardiovascular diseases in high-risk patients by providing drugs citizens who suffered an acute violation of cerebral circulation, myocardial infarction and other acute cardiovascular disease or vascular surgery and that receive medical care on an outpatient basis.

The rules for the examination of draft regional programs for the modernization of primary health care, monitoring and control of the implementation of regional modernization programs for primary health care establish that the consideration of the interdepartmental working group led by the Ministry of Health of Russia, the examination of draft regional programs and expert opinions at them is carried out at meetings of the interdepartmental working group in a period not exceeding 5 working days from the date of receipt from members of a departmental working group of expert opinions on the draft regional program.

1.6. The Ministry of Health has approved a program aimed at improving the provision of emergency medical care and the activities of the All-Russian Disaster Medicine Service.

Decree of the Ministry of Health of the Russian Federation of October 2, 2019 N 827 "On approval of the departmental target program" Improving the provision of emergency, including specialized emergency, medical care and the activities of the All-Russian Service for Disaster Medicine".

Within the framework of this program, measures are envisaged to improve the All-Russian Service for Disaster Medicine, including the creation and replenishment of the reserve of medical resources of the Ministry of Health of the Russian Federation (medicines and medical devices) to eliminate the health consequences of emergencies – annually, until December 31, 2024.

Also noteworthy are events aimed at updating the fleet of ambulances, the creation of stationary emergency departments. The specified program plans to provide citizens of Ukraine and stateless persons permanently residing in the territory of Ukraine, compelled to leave the territory of Ukraine and arrived on the territory of the Russian Federation in an emergency mass order, medical assistance.

1.7. The list of medical goods subject to VAT has been supplemented.

Federal Law of September 29, 2019 N 325-FZ "On Amendments to Parts One and Two of the Tax Code of the Russian Federation"

Section 1 of the List of medical goods codes in accordance with the unified commodity nomenclature of the EAEU foreign economic activity, taxed with a value added tax at a tax rate of 10

percent when they are imported into the Russian Federation, approved by Decree of the Government of the Russian Federation of September 15, 2008 N 688 is supplemented by the position: “artificial radioactive compounds isotopes used for the preparation of medicines (code 2844 40 300 0 *)”. The sections of the list are also supplemented, concerning not only medicines but also medical devices. The specified federal law will enter into force on October 27, 2019.

1.8. The Ministry of Industry and Trade of Russia has approved a standard form of an agreement on the provision of services for the provision of labeling codes to pharmaceutical subjects.

Decree of the Ministry of Finance of Russia of October 14, 2019 N 165н “On Amending the Appendix to Order of the Ministry of Finance of the Russian Federation of June 4, 2018 N 126n “On the conditions for the admission of goods originating from a foreign state or a group of foreign states for the purpose of purchasing goods for ensuring state and municipal needs”.

Recall that, as a general rule, the conditions for the admission of goods originating from a foreign state or a group of foreign states for public procurement, during a tender, request for quotations, request for proposals, consideration and evaluation of applications containing proposals for the supply of goods specified in the Appendix to the order of the Ministry of Finance of Russia dated June 04, 2018 N 126н, and originating exclusively from the EAEU member states, are carried out by commissions of customers for procurement and operators of electronic platforms using m to proposed in these applications as low contract down 15 per cent ratio. The contract is concluded at the price offered in the application by the winner of the tender, request for quotations, request for proposals. The list of goods is given in accordance with the All-Russian Classifier of products by type of economic activity. The list has been amended to exclude their position “Medicines and materials used for medical purposes” (code 21) of codes such as 21.10.9 “Separate basic pharmaceutical products manufacturing services” and 21.20.9 “Services for production of medicines and materials used for medical purposes, separate, performed by the subcontractor”.

1.9. The National Artificial Intelligence Development Strategy for the period until 2030 has been approved.

Decree of the President of the Russian Federation of October 10, 2019 N 490 “On the Development of Artificial Intelligence in the Russian Federation”

Among the applied goals of the Strategy, the forecasting of equipment failures and its preventive maintenance, the optimization of supply planning, production processes and financial decision-making, the use of intelligent logistics management systems, the reduction of human participation in processes associated with increased risk to life and health, the optimization of personnel selection and training, are highlighted: compilation of optimal work schedules, selection of optimal dosages of drugs, automation of surgical interventions, previously identified e gifted children.

It is assumed that the use of artificial intelligence technologies in the social sphere helps to create conditions for improving the standard of living of the population, including by improving the quality of health services (including preventive examinations, diagnostics based on image analysis, predicting the occurrence and development of diseases, and selecting optimal dosages of drugs, reduction of pandemic threats, automation and accuracy of surgical interventions).

1.10. Since October 26, 2019, the Administrative Regulation of the Russian Healthcare Supervision Authority for the provision of public service for the issuance of a certificate for the right to import (export) of narcotic drugs, psychotropic substances and their precursors, if

they are drugs, has been declared invalid.

Order of the Ministry of Health of Russia dated May 15, 2019 N 300n "On the recognition of the order of the Ministry of Health of the Russian Federation dated July 7, 2015 N 421n "On approval of the Administrative Regulations of the Federal Service for Supervision of Health in the provision of public services for the issuance of a certificate of importation (export) of narcotic drugs, psychotropic substances and their precursors, if they are drugs" and paragraph 2 of the changes that are made to some administrative regulations of the Federal Service for Supervision of Health to provide public services in the field of narcotic drugs, psychotropic substances and their precursors, potent substances which are not precursors of narcotic drugs and psychotropic substances, approved by Order of the Russian Federation Ministry of Health from September 1, 2017 N 584n"

By this order, from October 26 of this year, the previous amendments to the Administrative Regulation of the Federal Service for Supervision of Health Care for the provision of the state service for issuing a certificate for the right to import (export) narcotic drugs, psychotropic substances and their precursors, if they are drugs, and the regulation itself.

1.11. The Ministry of Health of Russia has prepared a memo for parents of children in need of drugs containing psychotropic substances, containing recommendations on obtaining drugs that are not registered on the territory of Russia.

The memo is published on the official website of the Ministry of Health of the Russian Federation

The memo consists of two sections: for those parents whose children already have a medical commission and protocol of the council of the federal medical organization on the need to prescribe psychotropic drugs unregistered in the Russian Federation (such as diazepam clobazam, midazolam, phenobarbital); for parents of children who, apparently, need these drugs because the prescribed registered drugs for the treatment of epilepsy were ineffective and/or it is necessary to use a pediatric form of a psychotropic drug (elixir, rectal solution, oromucosal solution), but the conclusions of medical commissions and there are no protocols of federal councils yet.

In particular, if you have a doctor's report and transportation of the drug (for example, when leaving for the country), you must have either a doctor's report or the protocol of the federal council or a receipt for the drug. The drug is given for three months. Therefore, 2.5 months after receiving the drug, you must consult your doctor and inform about the need to receive the medicine for the next three months. In the absence of an appropriate opinion of the medical commission, it is necessary to contact the polyclinic at the place of residence or another medical organization that provides specialized medical care for children in the "neurology" profile or palliative medical care in order to obtain an opinion. If necessary, the attending physician in the district clinic or other medical organization where the child is being observed can refer the child to a specialized medical organization, including a hospital, for additional examination and / or to consider the availability of indications for the use of a psychotropic drug not registered in the Russian Federation drug and dose selection.

1.12. Federal Service for Health Supervision provides a list of the most frequently committed violations when sending mandatory information to be provided to Federal Service for Health Supervision.

Letter of Federal Service for Health Supervision dated October 01, 2019 N 01I-2359/19 "On Information Obligatory Provided to Federal Service for Health Supervision"

The Federal Service for Supervision of Healthcare processed data on the release of drugs into civil circulation for 2019, which were provided by drug circulation entities in electronic form through the Automated Information System of Federal Service for Health Supervision.

As a result of the analysis of the above information, Federal Service for Health Supervision revealed the most frequent violations of the procedure for the submission of information, namely:

- information is not provided on the receipt of drugs in the civil circulation;
- information on medicines received in civil circulation is submitted from violations of the established period;
- information on medicines received in civil circulation does not correspond to the data of the state register of medicines regarding the form of release taking into account the dosage form, dosage, and packaging of the drug;
- information on the data received in civilian circulation of medicines specified in declarations of conformity and certificates of conformity;
- information is not provided on the number and date of adoption of the declaration of conformity / number and date of issue of the certificate of conformity;
- Inaccurate information about the address of the warehouse where the batch of the medicinal product is stored.

2. Drafts of regulatory legal acts

2.1. The Ministry of Health of Russia proposes to amend the accreditation procedure for specialists with medical, pharmaceutical or other education.

Draft order of the Ministry of Health of Russia "On amendments to the terms and stages of accreditation of specialists, as well as categories of people with medical, pharmaceutical or other education and subject to accreditation of specialists, approved by order of the Ministry of Health of the Russian Federation dated December 22, 2017 N 1043n"

The project proposes to establish that from January 1, 2020, the following categories of persons will have to undergo the procedure for confirming their level of professionalism:

- doctors who have completed higher education in basic educational programs in accordance with the federal state educational standards in the field of education "Health and Medical Sciences" (undergraduate level, residency level) after January 1, 2020;
- medical specialists who completed additional professional education in vocational retraining programs developed on the basis of established qualification requirements, professional standards and the requirements of the relevant federal state educational standards of secondary professional and (or) higher education for the results of the development of educational programs after January 1, 2020.

2.2. The Ministry of Industry and Trade of Russia proposed concretizing the terminology of the Regulation on the system for monitoring the movement of drugs for medical use, approved by Decree of the Government of the Russian Federation of December 14, 2018 N 1556.

Draft Decree of the Government of the Russian Federation "On Amending Certain Decisions of the Government of the Russian Federation in the Field of Labeling of Goods and Pharmaceutical Products Subject to Mandatory Labeling with Identification Tools"

The Office proposes to expand the interpretation of the term "emission registration device", setting out paragraph twenty-fifth of paragraph 2 of the Regulation on the system for monitoring the

movement of drugs for medical use, approved by Decree of the Government of the Russian Federation of December 14, 2018 N 1556 as follows: “emission registration device” – technical means of information exchange designed to obtain marking codes and transfer to the monitoring system information on marking goods with means of identification a state acting as a technical means of verifying a verification code, for which the Federal Security Service of the Russian Federation issued a document on its compliance with the established requirements for encryption (cryptographic) means of information protection, applicable to encryption (cryptographic) means intended for verifying marking codes, or which includes a technical means of checking verification codes, for which the Federal Security Service of the Russian Federation and issued a document on its compliance with the requirements for encryption (cryptographic) means of protection of information in force in respect of encryption (cryptographic) means, designed to test the marking codes.

2.3. The Ministry of Health is proposing to amend the procedure for determining the level of professional training of experts in the examination of medicines for medical use.

Draft order of the Ministry of Health of Russia “On Amending the Procedure for Determining the Level of Professional Training of Experts of the Federal State Budget Institution for the Examination of Medicines for Medical Use and their Certification for the Right to Examine Medicines for Medical Use approved by order of the Ministry of Health and Social Development of the Russian Federation of 26 August 2010, N 755n

To pass the certification, experts no longer need to submit a specialist certificate to the Commission, while now such a certificate is required for specialists with a medical and pharmaceutical education. Moreover, the meetings of the Certification Commission of Experts are held upon receipt of expert documents, while the project proposes to hold at least once a year, while now the frequency is set at least once every three months.

2.4. The Ministry of Health of Russia proposes that the List of medicines prescribed by the attending physician to the taxpayer and purchased at his own expense, the amount of which is taken into account when determining the amount of social tax deduction, be invalidated.

Draft Decree of the Government of the Russian Federation “On invalidating the List of medicines prescribed by the attending physician to the taxpayer and acquired by him at his own expense, the value of which is taken into account when determining the amount of social tax deduction approved by the Government of the Russian Federation dated March 19, 2001 N 201 “On approval of lists of medical services and expensive types of treatment in medical institutions of the Russian Federation, medicines, amounts payment of which for its own account of the taxpayer are taken into account when determining the amount of Social Tax Deduction”

This draft was adopted taking into account paragraph 2 of Article 1 of Federal Law N 147-FZ dated June 17, 2019 “On Amending Part Two of the Tax Code of the Russian Federation”, which, from paragraph 1 of subparagraph 3 of paragraph 1 of Article 219 of the words of the Tax Code of the Russian Federation containing the list of social tax deductions to which a taxpayer is entitled, the words “in accordance with the list of medicines approved by the Government of the Russian Federation” are excluded for the tax deduction in the amount paid by the taxpayer in the amount of the cost of medicines for medical use prescribed by the attending physician and acquired by the taxpayer at his own expense.

2.5. The Ministry of Health is proposing the creation of the Metrological Service at

this ministry.

Draft order of the Ministry of Health of Russia "On the Metrological Service of the Ministry of Health of the Russian Federation in the field of circulation of medicines for medical use"

According to the explanatory note to this document, the draft Order was developed in order to implement Article 22 of Federal Law dated 26.06.2008 N 102-FZ "On Ensuring the Uniformity of Measurements", according to which the federal executive bodies and state corporations create metrological services in the prescribed manner with a view to organizing activities to ensure the uniformity of measurements within its competence.

This project creates a metrological service that will ensure the uniformity of measurements in the Russian Federation when establishing and observing the requirements for pharmacopoeial standard samples, as well as create pharmacopoeial standard samples to monitor the quality of the studied drugs for medical use. The organization of activities on metrological support in the field of drug circulation is proposed to be entrusted to the "Scientific Center for Expertise of Medical Devices" of the Russian Ministry of Health.

2.6. It is proposed to amend the Federal Law "On the Basics of Protecting the Health of Citizens in the Russian Federation" regarding the establishment of the maximum level of allowable expenses for a citizen to pay for vital and essential medicines

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

The bill establishes that subsidies for the payment of vital and essential medicines are provided to a citizen if his expenses for the payment of medicines included in the list of Vital and Essential Drugs exceed 10 percent of his total income from labor, business, and other activities.

For citizens whose income does not exceed the cost of living, the maximum allowable share of expenses is reduced following a correction factor equal to the ratio of the citizen's income to the cost of living, which ensures a fair, proportionate decrease in the maximum share of expenses for the least well-off citizens.

Subsidies are transferred to the transfer until the deadlines set for the intake of vital and essential medicines by medical prescription. If a citizen has acquired vital and essential medicines at his own expense, the subsidy is paid to compensate for the costs incurred in the amount established by the bill.

2.7. A group of deputies took the initiative to allow the import into Russia of unregistered drugs containing narcotic and psychotropic substances in the presence of medical indications of a particular patient

United Russia proposed to allow the import of psychotropic drugs with the permission of the medical commission. Interfax Information Group of October 01, 2019

As part of the initiative, a proposal is being prepared to amend the legislation on the circulation of medicines, in terms of granting a free permit for the import of unregistered drugs containing narcotic and psychotropic substances if registered drugs are not suitable for use by the patient due to individual intolerance. For such an import, an appropriate decision by the medical board regarding the patient's contraindications will be required. It is important to note that the draft law under consideration, which proposed introducing the norm that the import of a specific consignment of registered and (or) unregistered medicines intended to provide medical care according to the vital indications of a particular patient, to the Russian Federation is carried out in accordance with the

legislation of the Russian Federation Federation on customs, but not subject to collection of customs duties, taxes and other funds was rejected at the seizure of the State Duma 2 October 4, 2019.

2.8. The Russian Ministry of Health proposes to return to considering the issue of changing the procedure for providing medical care to the population according to the profile of "cosmetology".

Draft Order of the Ministry of Health of the Russian Federation "On Amending the Procedure for the Provision of Medical Assistance to the Population on the Profile of "Cosmetology", approved by Order N 381n of the Ministry of Health and Social Development of the Russian Federation of April 18, 2012

At the International Forum of Dermatovenerologists and Beauticians announced the question of the return of the Ministry of Health to the issue of amending the rules for the provision of services in the field of cosmetology. In April of this year, a draft amendment was prepared in the Procedure for the provision of medical care to the population according to the profile of cosmetology, according to which medical care according to the profile of cosmetology includes a set of preventive, therapeutic, diagnostic and rehabilitation measures aimed at maintaining or restoring the structural integrity and functional activity of integumentary tissues of the human body (skin and its appendages, subcutaneous fat and superficial muscles). A specialist is appointed to the post of cosmetologist who meets the Qualification requirements for specialists with higher and postgraduate medical and pharmaceutical education in the field of healthcare, approved by order of the Ministry of Health of Russia N 707n dated 08.10.2015 "On approval of Qualification requirements for medical and pharmaceutical workers with higher education in the direction training "Health and Medical Sciences".

2.9. The bill aimed at improving the procedure for determining the interchangeability of drugs for medical use is considered in the first reading of the meeting of the State Duma.

The draft Federal Law "On Amendments to the Federal Law "On Circulation of Medicines" and the Federal Law "On Amendments to the Federal Law "On Circulation of Medicines" in terms of improving the procedure for determining the interchangeability of drugs for medical use.

The bill proposes amendments to the Federal Law in terms of establishing the specifics of determining the interchangeability of certain groups of medicines, as well as an exception for homeopathic and herbal medicines, as well as the formation and regular updating of the list of interchangeable medicines and its placement on the Internet.

The draft law provides for the establishment of the possibility of additional submission of the necessary materials by the applicant in the event of insufficient material to identify the interchangeability of the medicinal product identified by the commission of experts of the expert institution.

The draft law provides for a period of 40 working days for the holder or owner of the registration certificate of the medicinal product to submit an application for amending the instructions for the use of the medicinal product for medical use from the date of publication on the official website of Federal Service for Health Supervision of information about new confirmed data on side effects and undesirable reactions during its use, including for interchangeable drugs. It also establishes the possibility of considering the suspension in accordance with the procedure established by the authorized federal executive body for the use of a medicinal product in case of failure to submit the specified application within 40 business days by the holder or owner of the registration certificate of the medicinal product, as well as the failure to submit the necessary documents for the expert institution to determine the interchangeability of the medicinal product drug for medical use.

2.10. The government is advised to implement the phased introduction of drug labeling, starting with medicines from the "seven nosologies"

The government is encouraged to consider phasing in drug labeling. According to the official website of the Association of pharmacy institutions "Union Pharma"

At a meeting of the State Duma Committee on Health Protection on October 15, 2019, the Government of the Russian Federation was recommended to consider introducing a phased labeling of drugs by starting the labeling of drugs named in the List of Medicines designed to provide people with hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, malignant neoplasms of lymphoid, hematopoietic and related tissues, multiple sclerosis, hemolytic uremic syndrome, juvenile arthritis with systemic m onset, mucopolysaccharidosis of types I, II and VI, individuals after transplantation of organs and (or) tissues.

The reason for this proposal was that, despite the postponement of the introduction of drug labeling, participants in the drug circulation system are not ready for the introduction of mandatory labeling since 2020.

2.11. The Ministry of Health proposes to introduce the obligation of licensees, when carrying out pharmaceutical activities, to enter information on drugs for medical use into the system for monitoring the movement of drugs for medical use.

Draft Decree of the Government of the Russian Federation "On Amendments to Clause 5 of the Regulation on the Licensing of Pharmaceutical Activities"

According to cl. 7 of art. 67 of the Federal Law "On the Circulation of Medicines" dated April 12, 2010 N 61-FZ, legal entities and individual entrepreneurs engaged in the production, storage, importation into the Russian Federation of the dispensation, sale, transfer, use and destruction of medicines for medical use shall ensure that with the Regulation on the system for monitoring the movement of drugs for medical use, approved by the Decree of the Government of the Russian Federation of December 14, 2018 N 1556, taking into account the type of uschestvlyaemoy their activities, including the information about the drug for medical use in drug traffic monitoring system for medical use.

The explanatory note to the draft said legal act states that paragraph 5 of the Regulation on the licensing of pharmaceutical activities, which establishes a list of licensing requirements that a licensee must comply with in carrying out pharmaceutical activities, is supplemented by the norms that licensees engaged in wholesale and retail sale of medicines for medical use, including pharmacy organizations, individual entrepreneurs licensed to exercise pharmaceutical activities, medical organizations are obliged to ensure that information on drugs for medical use is included in the system for monitoring the movement of drugs for medical use.

2.12. The Ministry of Health of Russia proposes to amend the Rules for maintaining and storing special registers of operations related to the circulation of narcotic drugs and psychotropic substances

Draft Decree of the Government of the Russian Federation "On Amending the Rules for Maintaining and Storage of Special Logs for Recording Operations Associated with the Turnover of Narcotic Drugs and Psychotropic Substances"

By the indicated draft legal act, the Rules for maintaining and storing special transaction logs related to the circulation of narcotic drugs and psychotropic substances are supplemented by the provision that, in case of unintentional damage to a narcotic drug or psychotropic substance, which

led to its destruction, which occurred during medical or pharmaceutical activity, no later than one business day following the day of the occurrence of this fact, an act is drawn up, the form of which also establishes I draft regulation as an annex number 3 of the Regulations.

Since the maintenance of registration journals is permitted by the Rules both on paper and in the form of electronic documents, this act can also be executed on paper or in the form of an electronic document with subsequent attachment in the latter case to the registration journals.

It is also proposed to introduce an act form fixing an unintentional spoilage of a psychotropic substance.

2.13. Prime Minister Dmitry Medvedev instructed to amend the procedure for determining the initial (maximum) price of the contract for public procurement of medicines.

The results of the 33rd meeting of the Foreign Investment Advisory Council in Russia on October 21, 2019 are published on the official website of the Government of the Russian Federation

The Ministry of Health of Russia is entrusted with ensuring amendments to the Procedure for determining the initial (maximum) price of a contract, the price of a contract concluded with a single supplier (contractor, contractor) when purchasing medicines for medical use, approved by order of the Ministry of Health of Russia dated October 26, 2017 N 871n, aimed at solving the problem of failed auctions in the implementation of such purchases.

2.14. The Ministry of Health of Russia submitted for consideration the revised Draft Rules for the mandatory re-registration in 2019-2020 of all previously registered by various methods, maximum selling prices for drugs included in the list of vital drugs, as well as the rules according to which the owners of registration certificates for drugs included in List of Vital and Essential Drugs Must Reduce Previously Registered Prices for Medicinal Products Included in the List of Vital and Essential Drugs

Draft Resolution of the Government of the Russian Federation "On Amending the Decree of the Government of the Russian Federation of October 29, 2010 N 865 "On State Regulation of the Prices of Medicinal Products Included in the List of Vital and Essential Medicines", in the Decree of the Government of the Russian Federation of September 15, 2015 N 979 "On Introducing of amendments to the Decree of the Government of the Russian Federation of October 29, 2010 N 865 and on the approval of the methodology for calculating the maximum selling prices for pharmaceutical products established by manufacturers The drugs included in the list of vital and essential medicines during their state registration and re-registration"

The draft resolution establishes the rules for mandatory re-registration in 2019-2020 of all previously registered by various methods, maximum selling prices for drugs included in the list of Vital and Essential Drugs, as well as the rules according to which the owners of registration certificates of medicines included in the list of Vital and Essential Drugs are obliged to reduce previously registered prices for drugs included in the list of essential drugs.

In addition, the draft resolution is being brought into line with Law N 134-FZ of the norms of decrees of the Government of the Russian Federation of October 29, 2010 N 865 "On state regulation of prices for medicines included in the list of vital and essential medicines", dated September 15, 2015 N 979 "On Amending the Decree of the Government of the Russian Federation of October 29, 2010 N 865 and on approving the methodology for calculating the maximum selling prices established by manufacturers of pharmaceutical products and drugs included in the list of vital and essential drugs during their state registration and re-registration".

Besides, it is important to note that this draft has finalized the section of the Price Re-registration Rules approved by Decree of the Government of the Russian Federation of October 29, 2010 N 865, which regulates the rules for re-registration of maximum selling prices for vital and essential drugs. According to the Rules, the mandatory re-registration of registered maximum selling prices for medicines in 2019-2020 is carried out with the last registered (re-registered) maximum selling prices for immunobiological pharmaceuticals, pharmaceutical preparations containing narcotic drugs and psychotropic substances being preserved in relation to domestic manufacturers, as well as medicines in the price segment up to 100 rubles, not exceeding the maximum selling prices, determined s subject to the provisions of Part 4 of Article 61 of the Federal Law of April 12, 2010 N 61-FZ "On Circulation of Medicines". At the same time, the limits are registered before the entry into force of the Federal Law of June 6, 2019 N 134-FZ "On Amendments to the Federal Law "On Circulation of Medicines" regarding the state regulation of prices for medicines included in the list of vital and essential medicines" selling prices for reference medicines are subject to mandatory re-registration in 2019-2020 on the basis of applications from holders or holders of registration certificates. Thus, the submission of an application for re-registration of maximum selling prices is mandatory.

At the same time, prices are maintained provided that they do not exceed prices determined to take into account part 4 of Art. 61 of the Federal Law of April 12, 2010 N 61-FZ "On the Circulation of Medicines". Under Part 4 of Art. 61 of the specified part of Article 61 of the Federal Law, the holder or owner of the registration certificate of a medicinal product (an authorized person) is required to submit to the authorized federal executive body an application for re-registration of the registered maximum selling price of the manufacturer for the medicinal product included in VED, downward, including in the case of a decrease in the price in foreign currency for a drug in the country of manufacture and (or) in countries in which the drug At registered and (or) which is supplied by the manufacturer.

Thus, in our opinion, the indicated draft does not fully resolve the question of for what period a decrease in prices in foreign currency for drugs manufactured in other states is recorded, how the price data are compared.

2.15. Deputies of the State Duma returned to the consideration of the bill, which was planned to provide the right to retail over-the-counter medicines for medical and veterinary use remotely by pharmacy organizations and veterinary pharmacy organizations.

Draft Federal Law "On Amending Certain Legislative Acts of the Russian Federation in the Part of the Retail Trade in Medicinal Products by Remote Method"

When discussing the bill, proposals were made regarding the admission of wholesale companies to the market for selling drugs via the Internet.

Recall that this bill proposed to prohibit the retail sale of prescription drugs remotely, as well as to allow the inclusion of narcotic and psychotropic drugs in the list of drugs established by the executive authorities of the constituent entities of the Russian Federation, the sale of which can be carried out by medical organizations licensed for pharmaceutical activities, and their separate divisions.

2.16. The Ministry of Health has determined the time frame for which it plans to switch to a system of full or partial reimbursement of the cost of drugs on an outpatient

Information is given according to the state news agency TASS

It is supposed to move away from preferential security "for very limited categories of citizens to total security" within two to three years.

3. Judicial and law enforcement practice

3.1. The court confirmed the validity of the argument that, when purchasing disinfection work, the requirement of a license is legitimate.

The decision of the Seventeenth Arbitration Court of Appeal on October 2, 219 in case N A71-3698/2019

The supervisory authority recognized that the complaint of the procurement participant against the actions of the customer was justified. The customer (State Unitary Enterprise of the Udmurt Republic “Pharmacies of Udmurtia”) was ordered to exclude from the auction documentation the requirement for bidders to have a license to carry out medical activities by type of work (service): disinfection as a single requirement.

However, in court, this order of the Federal Antimonopoly Service was appealed. The state-owned unitary enterprise of the Udmurt Republic “Pharmacies of Udmurtia” explained that it carries out medical activities in a pharmacy that is on the list of auction objects for the provision of disinfestation and disinfection services, which is confirmed by the corresponding license. At the same time, the applicant notes that the procurement participant did not need a license to carry out activities at a specific pharmacy location address, but generally indicated the need for a license to carry out medical activities by type of work (services) “disinfection” to confirm the possibility of a quality organization and safe deratization and pest control in pharmacies.

Canceling the decision of the control body, the court concluded that the implementation of sanitary and epidemiological (preventive) measures is an integral part of the complex of measures that protect the health of citizens, and includes organizational, administrative, engineering, medical, sanitary, veterinary and other measures aimed at including the prevention of the occurrence and spread of infectious diseases and mass noncommunicable diseases (poisoning). Following paragraph 46 of part 1 of article 12 of the Federal law dated 04 May 2011 N 99-FZ, medical activities are subject to licensing.

3.2. The court confirmed the compulsory license for Sunitinib-native.

The judgment of the Court of Intellectual Property Rights dated October 29, 2019, N C01-906/2019 in case N A40-166505 / 2017

As established by the court, in accordance with paragraph 2 of Article 1362 of the Civil Code of the Russian Federation, if the patent holder cannot use the invention to which he has the exclusive right, without violating the rights of the holder of another patent (first patent) to an invention or utility model that has refused to conclude a license agreement on conditions consistent with established practice, the holder of the patent (second patent) has the right to apply to the court with the claim against the holder of the first patent for granting compulsory simple (non-exclusive) whether censorship for the use in the territory of the Russian Federation of an invention or utility model of the first patent holder. The claim must indicate the conditions proposed by the holder of the second patent for granting him such a license, including the amount of use of the invention or utility model, size, procedure, and terms of payments. If this patent holder, having the exclusive right to such a dependent invention, proves that it represents an important technical achievement and has significant economic advantages over the invention or utility model of the holder of the first patent, the court decides to grant him a compulsory simple (non-exclusive) license.

In such circumstances, the courts of the first instance and appeal had sufficient grounds to agree with the opinion of the forensic experts mentioned.

Claiming that society has failed to conduct full-fledged clinical trials confirming the therapeutic benefits of the dependent invention, the plaintiffs at the same time did not provide evidence refuting the results of the experiment and Sunitinib polymorphism.

3.3. In a high-profile case on the purchase of anabolic steroids, the court concluded that there was the fault of the athlete who illegally purchased this product.

The court sentenced the Volgograd athlete, who made the purchase of anabolic steroids on the website of the Belarusian company. The defendant is sentenced to three years in prison. The court did not accept the accused's arguments that he was not aware that the prohibited product contains prohibited potent substances. Presumably, the number of such criminal cases may tend to increase due to the growing interest of the population in sports training using "sports nutrition", as well as the lack of control over sellers of this type of product.

3.4. A pharmaceutical company was fined 500,000 rubles for handling unregistered drugs.

The decision of the Arbitration Court of the Rostov Region on October 14, 2019 in the case N A53-33096/2019

It follows from the case materials that the Territorial Authority of Federal Service for Health Supervision in the Rostov Region received information on the fact of the sale of the unregistered Vitrum Junior drug Polyvitamins + Mineral salts, dosage form: "chewing tablets," form release: "30 tablets each", manufacturer Unifarm Inc., USA, in the amount of 1 (one) package in a pharmacy located in Rostov-on-Don, indicating the presence of an administrative offense tions under Part 2 of the Administrative Code st.6.33.

The court did not accept the arguments of the pharmacy institution that the information letter on the fact of withdrawal of the registration certificate of the medicinal products was not published on the website www.roszdravnadror.ru, on the website 61reg.roszdravnadror.ru, and also on the fact that they supplied medicines to the company suppliers of drugs also did not inform the public about the fact of withdrawal of the registration certificate of the drug, since the decision to cancel the state registration of the drug and its deletion from the state register and medicines dated June 25, 2019 N20-3 / 1082 was included by the Ministry of Health of the Russian Federation in the State Register of Medicines on June 25, 2019 (https://grls.rosminzdrav.ru), which is in the public domain.

3.5. The court ruled on the distinction between the concepts of "information sign" and "advertising" taking into account the content of the information in it.

The decision of the Arbitration Court of the Krasnodar Territory of October 24, 2019 in case N A32-37090/2018

The court concluded that the inscription "Cheap pharmacy. We'll sell it cheaper if you call the competitor's price" it contains advertising information and deals with the offer to sell pharmaceutical products at a lower price, and therefore is considered by the court as advertising, in accordance with paragraph 1 of Article 3 of Federal Law of March 13, 2006 38-FZ "About advertising" advertising.

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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.