BRACE
Law Firm

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DIGEST
of regulation of Russian pharmaceutical industry

Brief news

We bring to your attention the next digest of legal regulation of regulation of Russian pharmaceutical industry for December 2018, prepared by the Law Firm “BRACE”.

Among the main changes is new legal status to clinical recommendations, which are planned to be completely revised in time to December 31, 2021.

Substantial changes have been made to legislation regulating the introduction of medicines for medical use into civilian circulation, most of which will come into force on November 2019.

The Federal Service for Supervision in the Field of Health has additional powers to conduct test purchases in order to verify compliance with the subjects of circulation of medicines engaged in the retail trade of medicines.

The list of vital and essential medicines for 2019 was approved, which was expanded in comparison with the list of 2018.

The Government of the Russian Federation has approved a new program of guarantees for the free provision of medical care to citizens for 2019 and for the planned period 2020 and 2021.

The Rules for placing publicly available information contained in the system for monitoring the movement of medicines for medical use in the Internet information and telecommunications network have been approved.

Decisions of the Government of the Russian Federation have been adopted, which approve the Regulations on the system for monitoring the movement of medicines for medical use and establish the specifics of the implementation of the system for monitoring the movement of medicines.

In connection with the ratification of the Agreement on Common Principles and Rules for the circulation of medicines within the Eurasian Economic Union, the Ministry of Health of the Russian Federation proposes a draft amendment to the Law “On circulation of medicines” in order to improve the regulatory legal regulation in the field of circulation of medicines for medical use. Also, this department, in order to bring into compliance with the standards of the Government of the Russian Federation dated August 28, 2014 N 871 "On approval of the Rules for the formation of lists of medicines for medical use and the minimum range of medicines needed for medical care", is proposed to amendments to the Statute on the Commission of the Ministry of Health of the Russian Federation on the formation of lists of medicines.

1. Laws, by-laws, legal news

1.1. The beginning of a new approach in the application of clinical guidelines, which should be the basis for providing medical care.

Federal Law of December 25, 2018 N 489-FZ "On Amendments to Article 40 of the Federal Law" On Compulsory Health Insurance in the Russian Federation" and Federal Law "On the Basics of the Protection of Citizens" Health in the Russian Federation "Concerning Clinical Recommendations"

The Federal Law of 21 November 2011 N 323-FZ "On the basis of health protection of citizens in the Russian Federation" was amended to establish the definition of the term "*clinical guidelines*", which are documents containing structured information based on scientific evidence on prevention, diagnosis, treatment and rehabilitation, including patient management protocols (treatment protocols), medical intervention options and a description of the sequence of actions of a medical professional taking into account the course of abortion, the presence of complications and comorbidities, other factors affecting the results of medical care.

If it was previously established that medical care is organized and provided in accordance with the procedures for providing medical care, mandatory for all medical organizations on the territory of the Russian Federation, as well as on the basis of standards of medical care (except for medical care provided as part of clinical testing), then Now it is specified that medical care is organized and provided:

• in accordance with the regulation on the organization of the provision of medical care by type of medical care, which is approved by the authorized federal executive body;

• in accordance with the procedures for the provision of medical care, approved by the authorized federal executive body and binding on the territory of the Russian Federation by all medical organizations;

• based on clinical guidelines;

• taking into account the standards of medical care approved by an authorized federal executive body.

Clinical recommendations approved by the Scientific and Practical Council are approved by medical professional non-profit organizations and are subject to revision at least once every three years.

The development and approval of new clinical guidelines should be made no later than December 31, 2021.

Clinical recommendations, approved prior to making the appropriate changes, are applied before their revision, but no later than December 31, 2021.

1.2. Amendments have been made to the legislation on the circulation of medicines in terms of conducting test purchases.

Federal Law dated December 27, 2018 N 511-FZ "On Amendments to Certain Legislative Acts of the Russian Federation"

These changes include the Federal Service for the Supervision of Health in the area of authority to conduct test purchases in order to verify the compliance of medicines circulation entities that carry out retail sales of medicines for medical use, the rules for turnover medicines for medical use, and (or) prohibiting the sale of counterfeit medicines, substandard medicines and counterfeit medicines. The Ministry of Health approved amendments to the Procedure for rendering medical aid to adults in the "anesthesiology and resuscitation" profile.

1.3. Substantial changes have been made to legislation regulating the introduction of medicines for medical use into civilian circulation, most of which will come into force on November 2019.

Federal Law of 28 November 2018 N 449-FZ "On Amendments to Certain Legislative Acts of the Russian Federation on the entry into civil circulation of medicines for medical use"

On December 3, 2018, a federal law was introduced in the Legislative Assembly of the Russian Federation, introducing significant changes in the procedure for entering into civil circulation of medicines.

From the date of adoption of this law, a mandatory requirement is established for medicine manufacturers or organizations importing medicines to the Russian Federation upon notification of the Federal Service for Supervision of Health and the Ministry of Industry and Trade of the Russian Federation about the planned termination or suspension of the production of medicines or their import into Russian Federation no less than one year. The exceptions are immunobiological medicines intended for conducting clinical trials, examinations for the subsequent state registration of medicines, unregistered medicines intended for rendering medical aid for the life of a particular patient.

Other changes made by the said regulatory act come into force on November 29, 2019. These changes include:

• the introduction into public circulation of medicines for medical use imported into the Russian Federation is carried out in the manner prescribed by the legislation of the Russian Federation on the circulation of medicines;

• to enter into civilian circulation of a medicine produced in the Russian Federation, with the exception of immunobiological medicines, it is necessary to provide the manufacturer to the Federal Service for the Supervision of Healthcare of a document confirming the quality of the medicine, and confirmation of the conformity of the medicine to the requirements of an authorized person of the medicine at its state registration;

• organizations that import a medicines into the Russian Federation must, before entering it into civilian circulation, submit to the Federal Service for Supervision of Health Care a certificate of the manufacturer of the medicine certifying the compliance of the imported drugs with the requirements of the pharmacopoeial article, and in the absence of the pharmacopoeial article regulatory documentation, and confirmation of the representative of the organization that imports the medicine authorized foreign manufacturer medicaments imported medicine compliance requirements set by its state of registration;

• manufacturers of medicines or organizations importing medicines to the Russian Federation are obliged to submit to the Federal Service for Supervision of Health Care every year, no later than February 1, the test report received during the year in civil circulation of the medicine must be submitted to the Federal Service for the Supervision of Health.

1.4. The Government of the Russian Federation approved the list of essential and most important medicines for 2019.

Order of the Government of the Russia of 10 December 2018 N 2738-p "On approval of the list of essential and essential medicines for 2019, as well as lists of medicines for medical use and the minimum range of medicines needed for medical care"

In comparison with the lists approved for 2018, the list of vital and essential medicines was supplemented by the Government of the Russia with new medicine names, and the list of Vital and

Essential medicines was supplemented with such dosage forms as deferasirox (film-coated tablets) and omalizumab.

1.5. The Government of the Russia has approved a new program of guarantees for the free provision of medical care to citizens. The Ministry of Health of Russia is obliged to submit to the Government of the Russia a report on the implementation in 2018 of the Program of state guarantees of free medical care to citizens for 2018 and for the planned period of 2019 and 2020.

Decree of the Government of the Russia of 10 December 2018 N 1506 "On the Program of state guarantees of free medical care to citizens for 2019 and for the planned period of 2020 and 2021"

The program establishes that, at the expense of budget allocations, the budgets of the constituent entities of the Russian Federation are implemented:

• provision of medicines in accordance with the list of population groups and categories of diseases, during outpatient treatment of which medicines and medical products are released according to the prescriptions of physicians in accordance with the legislation of the Russia;

• provision of medicines in accordance with the list of groups of the population, during outpatient treatment of which medicines are dispensed according to the prescriptions of doctors with a 50% discount.

1.6. Approved Regulations on the system of monitoring the movement of medicines for medical use.

Government Decree of 14 December 2018 N 1556 "On approval of the Regulations on the system of monitoring the movement of medicines for medical use"

The provision on the system of monitoring the movement of medicines for medical use determines:

• the procedure for applying the means of identifying a medicine for medical use, the requirements for its structure and information format;

• the order of creation, development, commissioning, operation and decommissioning of the system for monitoring the movement of medicines (hereinafter - the system);

• the procedure for interaction of the system with other state information systems and information systems;

• the procedure for entering into the system by legal entities and individual entrepreneurs information about medicines and its composition;

• the procedure for providing information contained in the system.

The means of identification when applied to the secondary (consumer) packaging of the medicine (in case of its absence - to the primary packaging of the medicine) must comply with the following characteristics:

• a two-dimensional bar code is applied with dotted symbols in accordance with the requirements of the national standard of the Russian Federation (GOST R ISO / IEC 16022-2008 "Automatic identification. Bar coding. Data Matrix symbology specification");

• a two-dimensional bar code is applied with a quality class level of C or higher in accordance with the requirements of the national standard of the Russia (GOST R ISO / IEC 15415-2012 Information Technologies. Automatic identification and data collection technologies. Specification of bar code character tests for assessing print quality. Two-dimensional characters ");

• a two-dimensional bar code is printed using the ECC-200 error correction method in accordance with the requirements of the national standard of the Russian Federation (GOST R ISO / IEC 16022-2008 "Automatic Identification. Bar Coding. Data Matrix Symbols Specification");

• when applying a medicine identification tool, ASCII coding is used based on the national standard of the Russian Federation (GOST R ISO / IEC 16022-2008 "Automatic identification. Bar coding. Data Matrix symbol specification").

1.7. The features of the introduction of a system for monitoring the movement of medicines for medical use have been established.

Government Decree of 14 December 2018 N 1557 "On the peculiarities of the introduction of a system for monitoring the movement of medicines for medical use"

For business entities that belong to the subjects of treatment of medicines intended for the treatment of persons with hemophilia, cystic fibrosis, pituitary nanism, Gaucher disease, lymphoid tumors, hematopoietic and related tissues, multiple sclerosis, organ and / or tissue transplantation , according to the list of medicines, formed and approved by the Government of the Russian Federation, such duties as:

• registration in the system of monitoring the movement of medicines from July 01, 2019 to July 08, 2019, or within 7 calendar days from the date the need arises to carry out activities related to the circulation of medicines, but not earlier than July 01, 2019, if there is a right to carry out such activities;

• sending an application to the operator for monitoring the movement of medicines (hereinafter referred to as the system) for testing information interaction processes - within 21 calendar days from the date of registration in this system and passing the testing of information interaction processes of its own information resource with the system for 2 calendar months from day of readiness of own information resource for interaction;

• from October 01, 2019, add information about medicines and all transactions performed with them to the system.

1.8. The Rules for placing publicly available information contained in the system for monitoring the movement of medicines have been approved.

Decree of the Government of the Russia dated December 14, 2018 N1558 "On approval of the Rules for placing publicly available information contained in the system of monitoring the movement of medicines for medical use in the information and telecommunication network" Internet "(including in the form of open data)"

It is determined that the composition of publicly available information contained in the system of monitoring the movement of medicines for medical use (hereinafter - the system) in the information and telecommunication network "Internet". The system operator ensures the placement of publicly available information on the monitoring system site, as well as the use of classification and systematic search, which are designed to analyze publicly available information, including using the navigation function.

2. Drafts of legal acts

2.1. In connection with the ratification of the Agreement on Common Principles and Rules for the circulation of medicines within the Eurasian Economic Union, the Ministry of Health of the Russian Federation proposed to amend the law "On circulation of medicines" in order to improve the regulatory legal regulation in the field of circulation of medicines.

Draft federal law "On Amendments to Articles 30 and 65 of the Federal Law "On Circulation of Medicines"

December 29, 2018 submitted to the public debate a bill that provides for amendments to Art. 30 of the Federal Law "On circulation of medicines" in terms of establishing a thirty-day period for filing an application for amending the instructions for use by the holder or owner of a registration certificate of a drugs or another legal entity authorized by it from the date of publication of the newly confirmed data on the official website of Federal Service for Health Supervision about side effects, undesirable reactions when using the medicine. In the event that the holder or owner of the registration certificate of the medicine or an authorized by another legal entity fails to submit an application for amending the instructions for use of the medicine concerning new confirmed data on side effects, undesirable reactions when using the medicine, the authorized body shall consider the question of the possibility of suspending the circulation of the medicine. Ministry of Health proposes to change the list of medical works and services subject to licensing.

2.2. It is proposed to make changes in the procedure for the formation of a registration dossier for a medicine product for medical use.

Draft Order of the Ministry of Health of the Russian Federation in the order of formation of the registration dossier for a medicine for medical use and the requirements for documents in its composition, approved by order of the Ministry of Health of Russia of July 12, 2017 N 409n

In the application for state registration of a medicines for medical use, in addition to specifying the name and addresses of the applicant and the manufacturer of the medicines, such data as the taxpayer identification number, the country of registration, the name of the registering authority, the registration number, the taxpayer code in the country of registration (incorporation) or its analogue and the address of the place of production of the medicine (If there are several participants in the production process, it is necessary to indicate each participant in accordance with stage of production).

2.3. The Ministry of Health of the Russia made amendments to the Regulation on the Commission of the Ministry of Health of the Russia on the formation of medicine lists to bring it in line with the regulations of the Government of the Russia dated August 28, 2014 N 871 "On approval of the Rules for the formation of medicine lists for medical use and the minimum range of medicines needed to provide medical care".

Draft order of the Ministry of Health of the Russia "On Amendments to the Regulation on the Commission of the Ministry of Health of the Russia on the formation of lists of medicines for medical use and the minimum range of medicines needed for medical care, approved by order of the Ministry of Health of the Russia dated September 9, 2014 N 498n"

A supplement is proposed that information about decisions taken at a meeting of a commission is posted on the official website on the Internet within 5 working days after the meeting of the commission.

The project establishes that the meetings of the commission are held until the 10-th of the second month of the quarter following the quarter in which the proposal is submitted. At the same time at one meeting of the commission is considered no more than 15 drugs. The meeting of the Commission is considered valid if it is attended by at least half of the members of the Commission, whereas a quorum of two thirds of the commission's membership was previously established.

Decisions on proposals are made with the support of at least half of the votes of the Commission members present at the meeting in accordance with the lists of members of the commission containing the results of a comprehensive assessment, taking into account the scientifically based recommendation of the chief expert. Previously, it was necessary to take two thirds of the votes present at the meeting.

When voting, each member of the Commission has the right to one vote.

In exceptional cases, a member of the Commission is allowed to transmit his vote by proxy to his representative due to the absence at a meeting for a good reason".

2.4. Submitted for public discussion draft of the application form for the delivery of medicines intended for people with hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, malignant neoplasms of lymphoid, haematopoietic and related tissue, multiple sclerosis, hemolytic-uremic syndrome, juvenile arthritis with systemic onset, mucopolysaccharidosis of I, II and VI types, persons after transplantation of organs and (or) tissues.

Draft order of the Ministry of Health of the Russian Federation "On approval of the application form for the supply of medicines intended to provide persons with hemophilia, cystic fibrosis, hypophysial nanism, Gaucher disease, lymphoid, hematopoietic and related tissues, multiple sclerosis, hemolytic-uremic syndrome, youth arthritis, and patients with arthritis, mucopolysaccharidosis type I, II and VI, persons after organ and (or) tissue transplantation"

Preparation of the draft application form was carried out in order to implement the norms of the Government of the Russian Federation dated November 26, 2018 N 1416 "On the order of organizing the supply of medicines to people with hemophilia, cystic fibrosis, pituitary nanism, Gaucher disease, malignant neoplasms of lymphoid, hematopoietic and related tissue, scattered sclerosis, hemolytic-uremic syndrome, juvenile arthritis with systemic onset, mucopolysaccharidosis type I, II and VI, after organ transplantation and / or tis sues, and also about recognizing as invalid some acts of the Government of the Russian Federation". The specified draft application form contains the need to indicate a specific disease and for the period of delivery.

2.5. The regulatory impact on the proposal of the Ministry of Health of the Russia is being amended in the Federal Law "On circulation of medicines" in order to solve the problem of excluding the provisions of the legislation of the Russian Federation regulated by the Council of the Eurasian Economic Commission.

Notification of consideration of the issue of starting the development of amendments to the Federal Law "On circulation of medicines"

According to the notification posted on the federal portal of draft regulatory legal acts, the question of the need to start developing amendments to the Federal Law "On the circulation of medicines" was submitted for consideration. This initiative is due to the fact that research on a replicated medicine or making changes and additions to the registration dossier of a medicine, including in terms of substantiation of the composition and research of auxiliary substances of the medicine, is carried out as part of the procedure for the examination of the medicine. In addition, the provisions of Council Decisions N 78 and N 85 of the Eurasian Economic Commission contain the necessary procedures for the applicant to conduct relevant studies to prove the absence of the influence of various excipients or assistive devices on the safety and (or) effectiveness of the medicine for medical use, in case it is not may provide such evidence and (or) does not have access

to relevant data. Therefore, it is proposed to exclude some provisions that duplicate and contradict these documents.

2.6. Ready to be approved the draft standard terms of contracts for the supply of medicines for veterinary use.

Draft order of the Ministry of Agriculture of the Russian Federation "On approval of standard terms of contracts for the supply of medicines for veterinary use"

The final version of the text of the draft standard terms and conditions of contracts for the supply of medicines for veterinary use has been formed. The project proposes to approve the standard terms of contracts for the supply of medicines for veterinary use in accordance with Annex 1 to the draft order, taking into account the indicators determined by the information map of standard conditions for contracts for the supply of medicines for veterinary use contained in Annex 2 to this draft order. As part of the finalization of the draft text, technical amendments were made.

2.7. It is proposed to approve the procedure for providing medical care to children with parasitic diseases.

Draft order of the Ministry of Health "On approval of the provision of medical care for children with parasitic diseases"

The project established that, if there are medical indications, the treatment of children with parasitic diseases is carried out with the involvement of specialist doctors in specialties stipulated by the nomenclature of specialties of specialists with higher and postgraduate medical and pharmaceutical education in the field of healthcare.

3. Judicial and other law enforcement practice

3.1. The Supreme Court of the Russia recognized as legitimate the position of the state customer regarding the recognition of the participant of the electronic auction for the supply of medicines evaded from the conclusion of the contract and did not accept the arguments of the supervisory authority on the legality of the participant's presentation.

Determination of the Supreme Court of the Russian Federation of December 20, 2018 N 303-KG18-20816 in case N A73-686 / 2018

According to the supervisory authority, the procurement legislation does not provide for a closed list of documents confirming the rationale for the proposed contract price, as well as the form of such documents.

However, the court found that according to part 9 of art. 37 of the Law on the contract system, if the subject of the contract for which a tender or auction is being held is the supply of goods necessary for a normal livelihood, including medicines, the procurement participant who has offered a contract price that is twenty-five or more percent lower (maximum) contract price, must provide the customer with a justification of the proposed contract price, which may include a letter of guarantee from the manufacturer stating the price and quantity of the supplied goods, documents confirming the availability of goods from the procurement participant, other documents and calculations confirming the possibility of the procurement participant to deliver goods at the proposed price. In this regard, the Supreme Court supported the conclusions of the courts of lower instances that the submission of an electronic auction by the participant of an exclusively letter of guarantee emanating from the procurement participant itself is not in compliance with the requirements of paragraph 9 of art. 37 of the Law on the contract system.

3.2. The Supreme Court overturned the decision of the Arkhangelsk Regional Court, which declared Article 26.1 invalid from the day the court decision came into force. Law of the Arkhangelsk Region dated March 18, 2013 N 629-38-OZ "On the implementation of state powers of the Arkhangelsk Region in the field of public health".

Determination of the Supreme Court of the Russian Federation of December 12, 2018 in the case of N 1-APG18-17

The contested provision of the Law of the Arkhangelsk region dated March 18, 2013 N 629-38-OZ "On the implementation of state powers of the Arkhangelsk region in the field of public health protection" established the procedure for interaction between the Ministry of Health of the Arkhangelsk region, the state unitary enterprise of the Arkhangelsk region "Pharmacy" and the state medical organizations of Arkhangelsk the areas involved in the implementation of the program of state guarantees of free medical care to citizens in the implementation of The State Unitary Enterprise of the Arkhangelsk Region "Pharmacy" as the sole supplier (executor) at the expense of all sources of funding the authority to provide services such as the purchase, acceptance, storage, accounting, delivery and delivery of pharmaceuticals, specialized medical nutrition products, medical products, funds for disinfection for state medical organizations of the Arkhangelsk region participating in the implementation of the program of state guarantees of free provision to citizens of social services; manufacturing, storage, accounting, delivery and tempering of extemporal dosage forms for medical organizations.

The Supreme Court of the Russian Federation did not accept the conclusions of the lower court that, based on the literal meaning of clause 6 of part 1 of article 93 of the Law on the Contract System, a constituent entity of the Russian Federation has the right to secure the authority of the enterprise under its jurisdiction, but not to define it as the sole supplier.

Currently, the court has published only the operative part of the adopted Definition. When publishing this judicial act in full, we believe it is possible to carry out an additional analysis on the formation of this judicial practice.