BRACE
Law Firm

July 2019

DIGEST
of regulation of the Russian pharmaceutical industry

August 15, 2019

Dear Colleagues!

We are glad to propose to your attention the digest of legal regulation of the Russian pharmaceutical industry for July 2019, prepared by BRACE Law Firm.

- In July 2019, the President of Russia Vladimir Putin gave instructions on the production and circulation of immunobiological drugs. In particular, the Government of the Russian Federation has been instructed to include such drugs in the List of Vital and Essential Drugs.
- Organizations engaged in medical activities will be able to apply income tax rates of 0% for an unlimited time.
- The Federal Antimonopoly Service of Russia has brought together information on the maximum sizes of wholesale premiums and the maximum retail premiums on prices for Vital and Essential medicines established in the constituent entities of the Russian Federation.
- The Ministry of Industry and Trade of Russia has developed standard forms of a contract for charging fees for the provision of marking codes and an agreement on the provision of emission registration devices by providing remote access.
- The Russian Ministry of Healthcare proposed supplementing the requirements for licensing the production of medicines, supplementing the Administrative Regulation on the provision of state services for issuing permits for conducting clinical trials of a medicinal product, as well as tightening administrative liability for violation of the requirements for handling alcohol-containing medicines.
- The Ministry of Finance of Russia developed the draft Procedure for assessing the reliability of accounting for the volume of production, turnover, and use of the pharmaceutical substance of ethyl alcohol (ethanol) for the production of alcohol-containing drugs.

The above, as well as other equally important legal news of regulation of the Russian pharmaceutical industry, are reflected in more detail in this digest.

Sincerely yours,

BRACE Law Firm

1. Laws, by-laws, legal news

1.1. The circle of persons to whom the wholesale drug trade organizations can sell medicines has been expanded, and the term for maintaining the status of a participant in the international medical cluster has been extended.

Federal Law of July 26, 2019 N 240-ФЗ "On Amending Certain Legislative Acts of the Russian Federation"

The specified document amended paragraph 6 of Part 1 of Art. 53 of the Federal Law of April 12, 2010 N 61-ФЗ "On the Circulation of Medicines", in so far as the wholesale drug trade organizations can now sell medicines or transfer them in the manner prescribed by law to medical organizations established and registered in accordance with the law of a foreign state-member of the Organization for Economic Cooperation and Development, to foreign legal entities, individual entrepreneurs who are participants in accordance with the Federal Law of June 29, 2015 N 160-FZ "On the international medical cluster and amendments to the Russian Federation separate legislative acts". Recall that the international medical cluster is a combination of the infrastructure of the territory of the international medical cluster, project participants and the mechanisms of interaction between project participants. A project is a set of measures aimed at achieving the goals of the international medical cluster. An international medical cluster is being created in the territory determined by the supreme executive body of state power of the city of federal significance in Moscow, in order to develop medical activities to provide medical care, improve its quality, and promote the development of medicines.

Now a legal entity, an individual entrepreneur lose the status of a project participant after twenty (instead of the previously established ten) years from the date of conclusion of an agreement with them or from the day of early termination of the agreement, liquidation or reorganization of the project participant, termination of individual entrepreneur. Also, the specified federal law establishes a ban on the provision of medical care to the participants of the territory of the international medical cluster paid for from the budgets of the budget system of the Russian Federation. Previously, medical assistance could be provided to project participants with permits for medical activities issued in Russia.

1.2. Amendments were made to the Administrative Code of the Russian Federation on administrative offenses regarding the imposition on the Federal executive body that exercises control and supervision over the health sector of administrative cases for evading the fulfillment of requirements to ensure conditions for persons with disabilities access to engineering, transport, and social infrastructures

Federal Law of July 18, 2019, N180-ФЗ On Amendments to the Administrative Code of the Russian Federation

Clause 1 of Art. 24.81 of the Administrative Code of the Russian Federation on administrative offenses is supplemented by the provision that the federal executive body, which exercises control and supervision functions in the field of healthcare, its territorial bodies consider cases of administrative offenses provided for in article 9.13 of the Administrative Code of the Russian Federation (evasion of requirements to ensure conditions for disabled people to objects of engineering, transport and social infrastructures) regarding evasion of the requirements to ensure accessibility for disabled persons of objects of organizations engaged in medical and pharmaceutical activities and the services they provide. Recall that such an offense entails the imposition of an administrative fine on officials from 2,000 to 3,000 rubles; for legal entities – from 20,000 to 30,000 rubles. These amendments entered into force on July 29, 2019.

1.3. The Government of Russia has approved a list of executive bodies involved in the implementation of the "regulatory guillotine" mechanism.

The list of federal executive bodies that exercise regulatory functions in the areas of state control (supervision), and federal executive bodies that exercise control and supervision functions, participating in the implementation of the "regulatory guillotine" mechanism, types of federal-state control (supervision) implemented by the federal executive bodies, to which the mechanism of the "regulatory guillotine" should be extended, approved by the Government of Russia July 4, 2019

This document clarifies the authority of Federal Service for Health Supervision. In particular, the Federal Service for Supervision of Healthcare implements:

- Federal state supervision in the field of drug circulation.
- Licensing control of pharmaceutical activities.
- Federal state control over the circulation of medical devices.
- Federal state control over the quality and safety of medical activities, including federal state control over the provision of psychiatric care.
- Licensed control of the activities in the circulation of narcotic drugs, psychotropic substances and their precursors, the cultivation of drug-containing plants
- Licensing control of medical activities.
- Licensed control of production and maintenance activities (unless the maintenance is carried out to meet the own needs of a legal entity or individual entrepreneur) of medical equipment.
- Monitoring the use of narcotic drugs and psychotropic substances stored in first-aid kits on international ships and aircraft and international trains.
- Control over the provision of state social assistance to citizens in the form of the provision of social services.
- Monitoring the implementation of measures for the use by medical organizations of the funds of the standardized insurance stock of the territorial fund of compulsory medical insurance.

It was also established that the Federal Service for Veterinary and Phytosanitary Surveillance carries out federal state veterinary supervision and supervision in the field of circulation of medicines in relation to medicines for veterinary use.

Recall that the mechanism of the "regulatory guillotine" refers to the analysis and revision of existing legal acts that put significant pressure on Russian business.

1.4. The Board of the Eurasian Economic Commission approved the form of the customs declaration used in the declaration of goods for personal use.

Decision of the Board of the Eurasian Economic Commission of July 23, 2019 N 124 "On customs declaration of goods for personal use" (together with the "Procedure for filling out a passenger customs declaration and performing customs operations related to changing (supplementing) the information stated in the passenger customs declaration")

The approved customs declaration form includes fields for filling out information on the declared narcotic drugs, psychotropic substances, their prosecutors in the form of medicines (section 3.6 of the customs declaration form).

1.5. In connection with the amendments to the procurement law, amendments were made to the Decree of the Government of the Russian Federation dated February 08, 2017 N 149 "On the federal executive body authorized to establish the procedure for determining the initial (maximum) price of a contract, the price of a contract concluded with a single supplier (

contractor, performer) when procuring medicines for medical use".

Decree of the Government of the Russian Federation of July 27, 2019 N 973 "On Amending Certain Acts of the Government of the Russian Federation and Recognizing Void Individual Decisions of the Government of the Russian Federation".

In connection with the introduction of the concept of "unit price of goods, work, services", the name of the said Decree of the Government of Russia dated February 08, 2017 N 149 will be as follows: "On the federal executive body authorized to establish the procedure for determining the initial (maximum) contract price, contract price, concluded with a single supplier (contractor, performer), the initial unit price of goods, work, services in the procurement of medicines for medical use".

1.6. The use by organizations engaged in medical activities of the income tax rate of 0% is now possible after January 1, 2020.

Federal Law of July 26, 2019 N 210-ФЗ "On Amending Part Two of the Tax Code of the Russian Federation and Certain Legislative Acts of the Russian Federation"

The specified Federal Law eliminated the restriction of the application of the preferential tax rate by amending part 6 of Article 5 of Federal Law dated December 28, 2010 N 395-ФЗ "On Amending Part Two of the Tax Code of the Russian Federation and Certain Legislative Acts of the Russian Federation".

1.7. The President of the Russian Federation gave a list of instructions regarding the regulation of the circulation of immunobiological drugs.

The list of instructions on the production and circulation of immunobiological drugs, approved by the President of the Russian Federation on July 20, 2019 N Pr-1413

In particular, V.V. Putin instructed the Russian Government to ensure the inclusion of immunobiological drugs used for immunoprophylaxis as part of the calendar of vaccinations for epidemiological indications in the list of vital and essential drugs. Also, the Ministry of Healthcare of Russia was instructed to submit proposals by August 15 of this year on the creation of a laboratory complex to conduct an examination of the quality of immunobiological drugs that are introduced into civilian circulation and to evaluate the quality of which it is necessary to use biological agents of pathogenicity groups I and II (danger).

1.8. The Federal Antimonopoly Service of Russia of Russia provides information on the size of wholesale and retail premiums on Vital and Essential Drugs in the constituent entities of the Russian Federation in the 2nd quarter of this year.

Information of the Federal Antimonopoly Service of July 1, 2019 "Limit sizes of wholesale allowances and limit sizes of retail allowances to prices for vital and essential medicines established in the constituent entities of the Russian Federation (data for the 2nd quarter of 2019)"

The indicated premiums for Vital and Essential Drugs are approved in each constituent entity of the Russian Federation for drugs of various price categories (up to 50 rubles inclusive, about 50 to 500 rubles inclusive and over 500 rubles). The document contains references to the legal acts of the constituent entities of the Russian Federation, approving the size of retail and wholesale allowances for Vital and Essential Drugs.

2. Drafts of regulatory legal acts

2.1. In order to implement the provisions of the legislation on mandatory labeling of

medicines, the Ministry of Industry and Trade of Russia has developed standard forms of agreements accompanying the implementation of labeling.

Draft Order of the Ministry of Industry and Trade of Russia "On Approving the Standard Form of a Contract for the Collection of Marking Codes"

Draft Order of the Ministry of Industry and Trade of Russia "On the approval of a standard form of an agreement on the provision of emission registration devices by providing remote access"

The specified forms of contracts were approved in order to implement the Regulation on the system for monitoring the movement of drugs for medical use, approved by Decree of the Government of the Russian Federation dated December 14, 2018 N 1556 "On approval of the Regulation on the system for monitoring the movement of drugs for medical use".

In particular, when providing emission devices, a standard contract stipulates that the equipment is the property of the operator. In this case, the operator undertakes to transfer the equipment for free temporary use and possession. Namely, the emission registration device (software-hardware encryption (cryptographic) hardware used to obtain marking codes and exchange information with the Federal State Information System for Monitoring the Movement of Medicinal Products for Medical Use from a Manufacturer to an End User with Use for Medicines) is subject to transfer for medical use of identification tools.

One unit of equipment is in the operator's mode (standby equipment), providing the ability to connect it to be used as the main equipment in case of inoperability or expiration of the service life of the main equipment.

2.2. The Ministry of Finance of Russia proposes to develop a procedure for assessing the reliability of accounting for the volume of production, turnover and (or) use of the pharmaceutical substance of ethyl alcohol (ethanol) for the production of alcohol-containing drugs.

Draft Order of the Ministry of Finance of Russia "On approving the procedure for evaluating the reliability of accounting for the volume of production, turnover and (or) use of the pharmaceutical substance of ethyl alcohol (ethanol) for the production of alcohol-containing drugs and (or) alcohol-containing medical products in the production process of other drugs and (or) medical products, as well as the production, manufacture and (or) turnover (excluding retail) of alcohol-containing drugs and (or) alcohol-containing medical products"

The specified documents have a formula for determining the volume of the pharmaceutical substance of ethyl alcohol (ethanol), obtained according to the primary accounting documents of the organization after the last technological operation associated with the production of the pharmaceutical substance of ethyl alcohol (ethanol), before transferring it to storage or for use. The specified formula includes the amount of products obtained after the end of the last technological operation, the amount of marriage obtained after the end of the last technological operation, the volume of water and (or) alcohol-containing products used to flush the main technological equipment for the production of pharmaceutical substance of ethyl alcohol (ethanol), volume of technological losses.

The purchase volume of the pharmaceutical substance of ethyl alcohol (ethanol) for the production of alcohol-containing drugs and (or) alcohol-containing medical devices, measured by a measuring instrument and recorded in the Journal of accounting for the volume of purchase and use of the pharmaceutical substance of ethyl alcohol (ethanol), as well as the volume of production,

manufacture and (or) turnover (excluding retail sales) of alcohol-containing drugs and (or) alcohol-containing medical devices for the reporting period of time (day), in decalitres.

2.3. The Ministry of Agriculture of Russia proposes to approve the Rules for the manufacture and dispensing of medicines for veterinary use by veterinary pharmacy organizations, individual entrepreneurs licensed for pharmaceutical activities, as well as the requirements form of the veterinary organization.

Draft Order of the Ministry of Agriculture of Russia "On approval of the Rules for the manufacture and dispensing of medicines for veterinary use by veterinary pharmacy organizations, individual entrepreneurs licensed for pharmaceutical activities, as well as the requirements form for a veterinary organization"

The specified draft procedure establishes a shelf life of documentation of a veterinary pharmacy of at least three years.

The head of the veterinary pharmacy should develop and approve specifications for each type of pharmaceutical substances, herbal raw materials, excipients, registered pharmaceutical preparations of packaging materials, intra-pharmaceutical blanks and for each dosage form of manufactured medicines.

It is established that the veterinary pharmacy is obligatory to ensure: production and dispensing of medicines of good quality; storage of medicines in accordance with the Rules for the storage of medicines for veterinary use, approved by order of the Ministry of Agriculture of Russia dated April 15, 2015 N 145; proper storage of raw materials and packaging materials in accordance with the requirements established by the manufacturer, and, where applicable, with the requirements of pharmacopoeial articles; the implementation of measures to prevent the entry into circulation of substandard drugs; training activities for employees whose activities are related to the dispensing, storage and manufacture of medicines, etc.

2.4. The Ministry of Healthcare of Russia proposes to amend the Administrative Regulation for the provision of public services for the issuance of permission to conduct clinical trials of a medicinal product.

The draft order of the Ministry of Healthcare of the Russian Federation "On Amendments to the Administrative Regulations of the Ministry of Healthcare of the Russian Federation on the provision of public services for the issuance of permits for clinical trials of a medicinal product for medical use, approved by Order N 20n of the Ministry of Healthcare of the Russian Federation on January 19, 2018, and the Administrative Regulations Ministry of Healthcare of the Russian Federation for the provision of public services for the accreditation of medicines organizations for the right to conduct clinical trials of drugs for medical use, approved by order of the Ministry of Healthcare of the Russian Federation of February 13, 2018 N 67n

The draft order specifies the requirements for the procedure for providing and informing on the provision of public services for issuing permits to conduct clinical trials of a medicinal product for medical use and the state accreditation services for medical organizations for the right to conduct clinical trials of medicinal products for medical use and the procedure for performing administrative procedures (actions) , and also clarifies the pre-trial (extra-judicial) procedure for appealing actions (inaction) of the Russian Ministry of Healthcare and officials. It is established that the receipt of public services in the multifunctional center for the provision of state and municipal services is not provided. The provision of public services on an extraterritorial basis is not carried out.

2.5. The Ministry of Health of Russia proposes to approve the Administrative Regulation on the provision of public services for the issuance of opinions (permits) for the import into the territory of the Russian Federation and export of biological materials obtained from a clinical trial of a medicinal product for medical use outside the territory of the Russian Federation, instead of previously approved.

Draft Order of the Ministry of Health of Russia Ministry of Health "On Approving the Administrative Regulation of the Ministry of Health of the Russian Federation on the provision of public services for the issuance of opinions (permits) for the import into the territory of the Russian Federation and export of the biological materials obtained during the clinical trial of a medicinal product for medical use application and recognition invalidated the order of the Ministry of Health of the Russian Federation on August 2, 2012 number 61n".

The draft new administrative regulation proposes to resolve issues of the procedure for the correction of typos. In the event that typos and (or) errors are identified, the responsible executor corrects such typos and (or) errors within a period not exceeding 5 working days from the date of receipt of the corresponding application by the Ministry of Health of Russia.

In order to obtain permission, the applicant must submit such documents as:

- application for the import (export) of biological materials;
- the rationale for calculating the number of units of each type of imported (exported) biological material based on the protocol of the clinical trial and the number of patients participating in the clinical trial;
- a copy of the issued permission to conduct a clinical study, in which it is assumed to obtain biological material, in the case of such a study in the territory of the Russian Federation;
- copies of company formation documents.

The term for the provision of public services and the issuance (direction) of documents arising from the provision of public services is 10 working days from the date of registration of receipt of these documents.

2.6. The Ministry of Health of Russia proposes to amend the Regulation on licensing the production of medicines.

Draft Order of the Ministry of Health of Russia "On Amending the Regulation on the Licensing of the Production of Medicines, approved by Decree of the Government of the Russian Federation of July 6, 2012 N 686

According to the draft licensing requirements are supplemented by the following:

- availability of a valid licensee registration record in the system for monitoring the movement of drugs for medical use;
- compliance by the licensee with requirements to ensure the entry of information on pharmaceuticals for medical use into the system for monitoring the movement of pharmaceuticals for medical use;
- compliance with the requirements for applying to the primary packaging (and secondary (consumer) packaging of drugs for medical use of identification tools.

Also, when carrying out work on the production of medical gases for obtaining a license, it is necessary to provide copies of documents confirming that the applicant has a license on the right of ownership or on any other legal basis for cylinders and (or) monoblocks (bundles of cylinders).

2.7. The Ministry of Industry and Trade of Russia proposes to amend the Rules for

the organization and inspection of pharmaceutical manufacturers for compliance with the requirements of the rules of the good manufacturing practice.

Draft Decree of the Government of the Russian Federation "On Amending the Rules for the Organization and Inspection of Pharmaceutical Manufacturers for Compliance with the Rules of Good Manufacturing Practice, as well as Issuing Conclusions on the Compliance of a Pharmaceutical Drug Manufacturer with the Specified Requirements, approved by Decree of the Government of the Russian Federation dated December 3, 2015 N 1314 "On determining the conformity of drug manufacturers to the requirements of the rules of good manufacturing practice"

The draft proposes to amend the inspection rules. If, during the inspection, inconsistencies with the requirements of the rules of good manufacturing practice have not been identified, the inspection report is drawn up in 3 copies on the letterhead of the authorized institution, which is signed by all members of the inspector commission no later than 25 business days from the date of inspection. Within 3 working days from the date of signing the inspection report, one copy is sent to the foreign manufacturer or its authorized representative, the second copy is sent to the authorized body, and the third copy is to be stored in the authorized institution.

In particular, it is established that a foreign manufacturer, no later than 25 working days from the day the inspection report was sent, shall provide an answer to the authorized institution with an appendix of a corrective and preventive action plan and a report on its implementation. The commission of inspectors evaluates the information contained therein and prepares an inspection report based on the results of consideration of the corrective and preventive action plan and a report on its implementation.

2.8. The Ministry of Health of Russia has taken the initiative to tighten liability for violation of the requirements for the turnover of the pharmaceutical substance of ethyl alcohol (ethanol) and alcohol-containing drugs

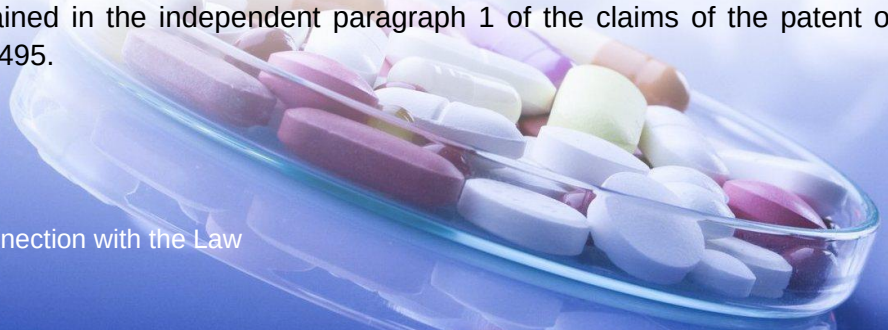
Currently, the regulatory impact assessment stage of the bill on amendments to the Administrative Code of Russia and increasing administrative fines for persons violating the requirements of the legislation on the circulation of medicines, including the requirement for the circulation of the pharmaceutical substance of ethyl alcohol (ethanol) and alcohol-containing drugs, is undergoing This bill is planned to be developed this year.

3. Judicial and law enforcement practice

3.1. The Supreme Court upheld the arguments of the court of appeal on the obligation of Jodas Expoim LLC to submit to the Ministry of Health a statement on the deletion from the State Register of maximum selling prices of manufacturers of drugs included in the list of vital and essential medicines, information on state registration of the maximum selling price of producers for drug "Gefitinib"

The determination of the Supreme Court of the Russian Federation of July 31, 2019 N 305-ES19-8449 in the case N A40-106405 / 2018.

The court, on the basis of a statement by AstraZeneca U.K. Limited (Great Britain), established that the Ministry of Health, upon application of the company, registered a medicinal product N LP-003076 under the trade name Gefitinib, which contains the chemical compound gefitinib, also contained in the independent paragraph 1 of the claims of the patent of the Russian Federation N 2153495.



Thus, the court concluded that Jodas Expoim LLC had taken preparatory steps to use each feature of the independent claim 1 of the claimant's patent formula, since without state registration of the drug and state registration of maximum selling prices for the drug included in the list of vital and essential drugs, the introduction into the civil circulation of a drug is not allowed.

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

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 industry 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 and a number of other areas.