BRACE
Law Firm

April 2019

DIGEST
of regulation of the Russian pharmaceutical industry

April 14, 2019

Dear Colleagues!

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

The Federal Scientific and Technical Program for the Development of Genetic Technologies for 2019-2027 was approved, the main focus of which is to accelerate the development of genetic technologies, including genetic editing technologies, ensure the development of drugs, immunobiological, biomedical cell products, medical products to improve the health care industry.

A notable change is the introduction of a new type of administrative offense in the form of late entry of data into the system of monitoring the movement of drugs for medical use or entering into it of unreliable data.

From April 7, 2019 new forms of prescription forms for medicines have come into force. However, the Ministry of Health of Russia is allowed to use forms of old samples before the end of the current year.

In April 2019, a significant number of rule-making initiatives came from the Ministry of Health of Russia, proposing to approve such important documents as the procedure for submitting documents and information about drugs for medical use, entered into civil circulation in Russia, the procedure for issuing a test report on the compliance of a drug for medical use, first produced in the Russia and not being an immunobiological medicinal product, the indicator quality of the issuance of authorization to enter into circulation a series of immunobiological or party drug, and others. These documents in case of their entry into force, will allow more detail to regulate a number of issues arising from pharmaceutical companies in the course of their activities.

Sincerely yours,

BRACE Law Firm

1. Laws, by-laws, legal news

1.1. A new type of administrative responsibility has been introduced for the late submission of data to the system for monitoring the movement of drugs or the input of data that are unreliable.

Federal Law of April 15, 2019 N 58-ФЗ "On Amendments to the Code of Administrative Offenses of the Russian Federation"

According to the regulatory legal act, the article 6.34 is stated in the Code on Administrative Offenses of the Russian Federation, which provides for the late introduction of data into the system for monitoring the movement of medicinal products for medical use or invalid data to be imposed on officials in the amount of 5,000 to 10,000 rubles; on legal entities - from 50,000 to 100,000 rubles. At the same time, individual entrepreneurs, subject to such violations, are liable as legal entities. This regulatory legal act establishes that the absence of a means of identification (QR code) on the packaging of a medicinal product imposes a fine on officials in the amount of 5,000 to 10,000 rubles; on legal entities – from 50,000 to 100,000 rubles. Along with the imposition of a fine, both for officials and legal entities, such a sanction as the confiscation of objects of an administrative offense is also applicable. The governmental body authorized to prosecute will be the Federal Health Supervision Service. The Federal Law will come into force on January 1, 2020.

1.2. The launch of the new database "Pharmacovigilance" from April 1, 2019.

Letter of Federal Health Supervision Service dated March 29, 2019 N 01 and-841/19. Information letter dated April 08, 2019 N 01I-945/19 (in addition to the Letter from Federal Health Supervision Service of March 29, 2019 N 01I-841/19)

In the newsletters, it is reported that the updated database will be designed to combine the databases - "Pharmacovigilance" and the Automated System "Monitoring Clinical Studies of Drugs" of the Federal Health Supervision Service. Until September 1 of the current year, a transition period is established in which it is planned to use both the old and the new systems. However, Federal Health Supervision Service recommends not delaying the transition to the use of a new database. Such a procedure for registering / re-registering users of "Pharmacovigilance" resource is described in the "Automated Pharmacovigilance System" section of the Services section of the official Federal Health Surveillance Service website.

1.3. From April 7, 2019 new forms of prescription forms for medicines have come into force. However, the Ministry of Health of Russia is allowed to use forms of old samples before the end of the current year.

Letter of the Ministry of Health of Russia dated April 04, 2019 N 25-4 / I / 2-2885 "On new forms of prescription forms for drugs approved by the Order of the Ministry of Health of the Russian Federation dated January 14, 2019 N 4n"

The Ministry of Health of the Russian Federation reports that the production of new prescription forms requires time-consuming. In this regard, until December 31, 2019 it is possible to allow the use of previously produced prescription forms.

1.4. From April 11, 2019, changes regarding the provision of anti-terrorism protection by medical organizations have taken effect.

Resolution of the Government of the Russian Federation of March 29, 2019 N 357 "On Amendments to the Requirements for the Anti-Terrorism Security of Objects (Territories) of the

Ministry of Health of the Russian Federation and Objects (Territories) Related to the Field of Activity of the Ministry of Health of the Russian Federation

Now for medical organizations occupying parts of buildings (buildings and structures) and having separate entrances, the need to approve anti-terrorism protection requirements has been established. In addition, the fourth category of medical organizations is introduced, in which the predicted number of victims may be less than 50 people and (or) the predicted maximum material damage at a book value of fewer than 30 million rubles. For this category, an abbreviated list of measures aimed at ensuring anti-terrorism protection has been established. For example, the fourth category of medical organizations will not require the organization and provision of access control, the development of measures to identify, prevent and eliminate the causes of unlawful penetration of an object, etc.

1.5. The approved scientific and technical program aimed at the development of genetic technologies.

Decree of April 22, 2019 N 479 "On approval of the Federal Scientific and Technical Program for the Development of Genetic Technologies for 2019-2027"

One of the objectives of the program is to solve the problem of accelerating the development of genetic technologies, including technologies of genetic editing, ensuring the development of medicines, in particular immunobiological, biomedical cell products, medical devices (diagnostic systems), means of indicating and identifying pathogenic biological agents for health care.

The document draws attention to the fact that at present at different stages of preclinical and clinical studies there are drugs based on recombinant monoclonal and single domain antibodies, therapeutic vaccines for the treatment of cancer, gene therapy drugs for the treatment of cancer, cardiac and other diseases, including hereditary as well as biomedical cell products based on genetically modified cell lines and. One of the targets for the implementation of the program will be the development of at least 20 gene therapeutic drugs and biomedical cell products containing genetically modified cell lines that have passed the preclinical stage.

1.6. Changes have been made in terms of reducing the lists of products subject to mandatory certification and products, the confirmation of the conformity of which is carried out in the form of adopting a declaration of conformity.

Resolution of the Government of the Russian Federation of April 24, 2019 N 489 "On Amendments to the Resolution of the Government of the Russian Federation of December 1, 2009 N 982"

From the list of products subject to mandatory certification, approved by this Resolution, the following sections are excluded: "Serum, immuno-and gamma globulins, other blood products and obtained by genetic engineering and other biological substrates used in medicine", "Vaccines, toxoids and toxins used in medicine", "Vaccines and toxoids used in veterinary medicine".

From the list of products, the confirmation of conformity of which is carried out in the form of a declaration of conformity, excludes medicinal products registered in the prescribed manner and entered into the state register consisting of mixed and unmixed products for therapeutic or prophylactic use, packaged in the form of dosage forms in retail packages, as well as vitamins, coenzymes, enzymes, amino acids, organ preparations (endocrine preparations), bacteria phages, allergens, serum, antibodies, and other diagnostic products used in medicine. The specified document comes into force on November 29, 2019.

1.7. The Ministry of Finance of Russia clarified the issue of the possibility of exempting the activity of conducting clinical trials of medicines from VAT.

Letter of the Ministry of Finance of Russia of April 10, 2019 N 03-07-11 / 25268

The Office has answered the question of whether clinical trials of a medicinal product are related to research works and whether such studies are exempt from VAT. Namely, the Ministry of Finance of Russia explains that the services for conducting clinical trials of medicines may be attributed to the implementation of research projects. With regard to clinical trials of medicinal products, the provisions on exemption of these operations from VAT taxation can be applied due to the provisions of subparagraph 16.1 of paragraph 3 of Art. 149 of the Tax Code of the Russian Federation.

2. Drafts of legal acts

2.1. The Ministry of Health of Russia proposes to make changes regarding the procedure for determining the initial maximum contract price using reference prices.

Draft Order of the Ministry of Health of the Russia "On Amendments to the Procedure for Determining the Initial (Maximum) Contract Price, Contract Price, concluded with a single supplier (contractor, performer) when purchasing medicines for medical use, approved by Order of the Ministry of Health of the Russian Federation dated 26 October 2017 № 871n"

The Ministry of Health of Russia proposed to provide that the application of reference prices by customers will be carried out if the relevant information is posted in the Unified Information System. This is due to the gradual transition in 2019 to the calculation and use of reference prices for drugs for medical use.

2.2. The Ministry of Industry and Trade of Russia has launched an initiative to provide subsidies from the federal budget to Russian organizations to reimburse part of the costs of implementing projects to organize the production of competitive drugs.

Draft Resolution of the Government of the Russian Federation "On approval of the rules for granting subsidies from the federal budget to Russian organizations for compensation of a part of the costs for implementing projects to organize the production of competitive drugs"

This document suggests that projects for the development and organization of the production of competitive drugs should be related to interrelated activities limited in time and resources aimed at conducting a complex of preclinical and clinical studies of drugs, as well as the creation of high-tech production, including the production of a pharmaceutical substance and/or its expansion and / or modernization, their registration and output to the market of the Russian Federation and abroad beige

Under the subsidized costs of organizations that conduct these projects, refers to such costs as: remuneration of employees directly involved in the implementation of the project (subsidies in the amount of not more than 70 percent); material costs directly related to the implementation of the project, including the costs of preparing the laboratory and research complex, the purchase of research, testing, testing and auxiliary equipment, (subsidies not exceeding 70 percent); the cost of acquiring laboratory animals for conducting preclinical studies of a medicinal product (in vitro, in vivo) (subsidies of not more than 70 percent); insurance premiums for life and health insurance of patients participating in clinical trials of a medicinal product (subsidies in the amount of not more than 70 percent), etc. The provision of such subsidies is expected to be carried out on a competitive basis.

2.3. The Ministry of Health of Russia is proposing to establish requirements for a

package of medicines and medical products for styling for the provision of emergency medical care to the adult population.

Draft Order of the Ministry of Health of the Russian Federation "On the approval of requirements for completing drugs and medical styling products for the provision of emergency medical care to the adult population"

The specified project establishes a list of essential medicines and medical devices intended for the provision of emergency medical care. Also, such requirements for the packaging of the above-mentioned medicines and medical products are established as the mandatory inclusion of one drug from among the vasodilating nitrate products and one drug from among the non-steroidal anti-inflammatory drugs. The package should be packaged with medicinal products registered on the territory of the Russian Federation in the primary packaging or in the secondary (consumer) packaging without withdrawing the instructions for use of the medicinal product.

2.4. In April 2019, public discussions began on the draft amendments to the Law on the Circulation of Medicinal Products and the Law on the Basics of Citizen Health Protection in terms of toughening the requirements for the production of alcohol-containing drugs in terms of tightening the requirements for the production of alcohol-containing drugs.

The draft law "On Amendments to Certain Legislative Acts of the Russian Federation"

This draft law was submitted for consideration at the initiative of the Ministry of Industry and Trade of Russia. It is proposed to establish a ban on the manufacture of pharmacy organizations, veterinary pharmacy organizations, individual entrepreneurs who have licensed the pharmaceutical activity of alcohol-containing drugs from ethyl alcohol produced from food raw materials, alcohol-containing food products. The bill also provides for the possibility to prohibit the production of pharmaceutical substance ethyl alcohol (ethanol) by the method of separation from chemical raw materials (dilution).

The introduction of such a ban is due to the need to strengthen control over the circulation and use of ethyl alcohol (ethanol) and alcohol made from food raw materials in the production of alcohol-containing drugs and alcohol-containing medical devices.

2.5. The Ministry of Industry and Trade of Russia proposes to make changes to the requirements for inspecting foreign manufacturers of medicines.

Draft Resolution of the Government of the Russian Federation "On Amendments to the Rules for Organizing and Conducting Inspections of Drug Manufacturers for Compliance with the Requirements of Good Manufacturing Practice Rules, and Issuing Conclusions on the Compliance of the Drug Producer with the Required Requirements"

According to the project, in case of detection of inconsistencies during the inspection, the foreign manufacturer shall prepare a plan of corrective and preventive actions and a report on its implementation within 30 calendar days from the date of the inspection report. The authorized institution reviews the submitted plan and report within 30 calendar days and sends the inspection report on the results of the review of the corrective and preventive action plan and the report on its implementation to the authorized body and the foreign drug manufacturer.

It also provides for a change in the period for issuing a conclusion on the compliance of the drug manufacturer with the requirements of the rules of good manufacturing practice up to 30 calendar days from the date of signing the inspection report.

This document was developed in order to bring the Russian regulatory legal acts in compliance with the requirements of the decision of the Council of the Eurasian Economic Commission and N 83 dated November 3, 2016 “On Approving the Rules for Conducting Pharmaceutical Inspections”.

2.6. The Ministry of Health of Russia is proposing to introduce a method for determining the amount of fees for the provision of services for testing immunobiological drugs with the establishment of the limits for such fees.

Draft Order of the Ministry of Health of the Russian Federation “On Approval of the Methodology for Determining the Amount of Payment for Rendering Testing Services and Issuing a Conclusion on the Compliance of a Series (Party) of an Immunobiological Drug Product to the Requirements Established during its State Registration Federation series (batch) of an immunobiological medicinal product and the maximum amount of payment for the provision of this service”

The method of calculation includes indicators such as the cost of performing a summary protocol analysis, quality examination, the purchase of consumables, labor costs, etc. Special formulas are established for detailed calculations. In this case, the marginal fee for the provision of such services is 467 629.50 rubles (excluding VAT).

2.7. The Ministry of Health of Russia proposes to approve a special procedure for the termination of civil circulation of drugs, documents, and information about which are not submitted to the authorized body in accordance with the requirements of current legislation.

The draft Decree of the Government of the Russian Federation “On approving the procedure for making a decision on the cessation of civil circulation of a series or a batch of a medicinal product for medical use, documents and information about which are not submitted to the federal executive body exercising control and supervision functions in the health sector, or a series or batch of immunobiological medicinal product that does not have permission to enter into civilian circulation of the federal executive body, -governing function in the health control and supervision”

It is proposed to establish the following rule: when a medicinal product for medical use is detected in civilian circulation, the documents and information about which provided for by the legislation of the Russian Federation are not submitted to the Federal Health Supervision Service, or the immunobiological medicinal product that does not have permission to enter into civilian circulation, Federal Service for Federal Health Supervision Service decides termination of the civil circulation of such drugs before the submission of the necessary documents and information or the receipt of for permission. The decision on the termination of civilian circulation is subject to mandatory publication on the official website of Federal Health Supervision Service with the observance of the restrictions established by the legislation on commercial and other secrets protected by law.

2.8. The Ministry of Health of Russia has proposed to approve the procedure for issuing permits for putting immunobiological drugs into civil circulation.

The draft Decree of the Government of the Russian Federation “On approving the procedure for issuing permits for putting into circulation a series or a batch of an immunobiological medicinal product and a procedure for issuing by the federal state budget institutions a statement on the compliance of a batch or batch of an immunobiological medicinal drug with the requirements established during its state registration and his issuance”

The draft procedure for introducing immunobiological medicinal products into civilian circulation includes monitoring each series by analyzing the manufacturer’s summary protocols, controlling the

quality of samples in the amount established on the basis of data obtained by authorized bodies in the course of analyzing incoming documents and information and examining immunobiological samples.

It is established that to obtain an opinion on the compliance of a series or a batch of an immunobiological medicinal product with the requirements established during its state registration, the following should be submitted to the Russian Ministry of Health or Federal Health Supervision Service: a summary protocol of the manufacturer that includes information on the stages of production and quality control of the immunobiological medicinal product; a manufacturer's document certifying the compliance of the quality of the medicinal product with the requirements of regulatory documentation confirmation of the authorized person of the manufacturer of the medicinal products on the compliance of the medicinal product with the requirements of the registration dossier; certified copy of the regulatory documentation for the drug. In addition, the applicant submits the requested samples of drugs, standard samples, and materials. Test samples of the drug are carried out in a period of not more than 60 working days from the date of receipt.

2.9. The Ministry of Health of Russia proposed to approve the procedure for issuing a test report on the compliance of a medicinal product for medical use, first produced in the Russian Federation and not an immunobiological medicinal product, quality indicators.

Draft Resolution of the Government of the Russian Federation "On Approval of the Procedure for Issuing by the Federal State Budgetary Institutions Subordinate to the Federal Executive Authority Performing the Functions for Developing and Implementing State Policy and Legal Regulation in the Field of Health Care and the Federal Executive Authority Implementing the Control and Supervision Functions in the field of health, test protocol on the compliance of the first three series or batches of medicinal th product for medical use, for the first time produced in Russia or imported for the first time in the Russian Federation (except for immunobiological drug), the quality indicators provided by normative documents, and fees for its issuance"

According to the project, the applicant provides the federal institution with the requested samples of medicinal products, standard samples and materials, a manufacturer's document certifying that the quality of the tested batch or batch of the medicinal product meets the established requirements, and a certified copy of the regulatory documentation for the medicinal product. The project also provides a method for calculating fees for the provision of this service.

In particular, it is established that the amount of fees for testing and issuing a test report is determined taking into account the work required, in accordance with regulatory documentation, and economically sound material and labor costs.

2.10. The Ministry of Health of Russia proposes to approve the procedure for the submission of documents and information about drugs introduced into civilian circulation on the territory of Russia.

Draft Resolution of the Government of the Russian Federation "On Approval of the Procedure for Submitting Documents and Information about Medicinal Preparations for Medical Use entered into civil circulation on the territory of the Russian Federation"

This project details the provisions of the Federal Law of 28.11.2018 N 449-ФЗ "On Amendments to Certain Legislative Acts of the Russian Federation on the issue of putting into circulation of medicinal products for medical use".

The main requirements for the documents provided include the need to provide in the Automated Information System of the Federal Health Supervision Service: information about the medicinal product (trade name, International Non-proprietary name, release form, name of the

manufacturer, name of the pharmaceutical substance, number and volume planned for the introduction the circulation of the drug series, the name of the organization that produces the drug, the address of the warehouse the storage number of the registration certificate); manufacturer's document confirming compliance with the requirements of regulatory documentation; confirmation of the authorized person of the manufacturer of the compliance of the medicinal product with the requirements established during its state registration; test protocol samples of the drug.

2.11. The State Duma of Russia is discussing the possibility of increasing the limit of the amount of drugs procured by the decision of the medical commission outside competitive procedures.

It is proposed to raise the threshold for the marginal cost of a single procurement from a single supplier of drugs, from 200,000 rubles to 1,000,000 rubles. Such an initiative is explained by the fact that in the amount of 200,000 rubles it is far from always possible to procure all the medicines needed to provide quality medical care. It is possible that the relevant draft law will soon be developed and it will be possible to get acquainted with its text in more detail.

3. Judicial and other law enforcement practice

3.1. A criminal case has been opened on a cartel agreement between pharmaceutical companies from Novosibirsk.

As reported by the Federal Anti-Monopoly Service of Russia, earlier in relation to LLC “Company “FITO” and LLC “Terra” on March 7, 2018 a decision was made in case N 33 in the framework of which a violation was discovered in the form of an agreement on the participation of LLC “Company “FITO”, LLC “Terra” in the auction held by the Federal State Institution “National Medical Research Center named after Academician E.N. Meshalkin”, while such an agreement led to a restriction of competition and (or) the creation of preferential conditions for these companies. Based on the above verification materials, on the basis of which the decision of the Federal Antimonopoly Service of Russia was issued, a criminal case was initiated under art. 178 of the Criminal Code (restriction of competition). Currently, it is about the participation of these organizations in 437 auctions, in which they were recognized as winners, with the extraction of the total income of 576 million rubles.

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About us

BRACE Law Firm renders legal services to manufacturers and distributors of medicines, medical products, dietary supplements and other health 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.