BRACE
Law Firm

Q 2, 2023

DIGEST
of the Russian pharmaceutical industry

July 28, 2023

Key Excerpts

Among the most important changes in the regulation of the Russian pharmaceutical industry in the 2nd quarter of 2023, are the following:

- Government of Russia approved the Strategy for the Development of the Pharmaceutical Industry of the Russian Federation for the period up to 2030.
- Within the framework of the Eurasian Economic Union, amendments were made to the Rules for Registration and Expertise of Medicinal Products in terms of the procedure for confirming the compliance of the production site with the requirements of good manufacturing practice of the Eurasian Economic Union.
- The list of Vital and Essential Drugs has been updated in terms of dosage forms of a number of medicinal products.
- New rules for the manufacture and dispensing of medicinal products by licensed pharmacies have been adopted.
- Additional criteria have been introduced for sole suppliers in the framework of public procurement of medicinal products.
- Responsibility is introduced for violating the established rules for dispensing drugs subject to subject-quantitative accounting when they are dispensed without a prescription.
- The Ministry of Health proposed to allow the inclusion of medicinal products used in accordance with indicators (characteristics) not specified in the instructions for their use in the standards of medical care for children and clinical recommendations.
- It is proposed to change some formulas for calculating the maximum ex-works prices for Vital and Essential Drugs.

Sincerely,
BRACE Law Firm

1. Laws, by-laws, legal news

1.1. The strategy for the development of the pharmaceutical industry until 2030 was approved.

Decree of the Russian Government N 1495-r dated 07.06.2023 "On Approval of the Strategy for the Development of the Pharmaceutical Industry of the Russian Federation for the period up to 2030"

The strategy indicates that one of the goals of state policy in the field of protecting the health of citizens is the development and implementation of new medical technologies and medicinal products, as well as the creation of competencies to respond to a possible defect.

The development of medical science is inextricably linked with the search for new therapeutic areas for the subsequent development, research and organization of the production of medicinal products.

It is noted that the weaknesses of the Russian pharmaceutical industry are the lack of a methodology for calculating the current need for medicinal products, the critical dependence on the import of raw materials, the relatively small size of domestic drug manufacturers and the relative passivity of the pharmaceutical industry in supporting the implementation of innovative Russian developments.

It is proposed to introduce ensuring drug independence and national security through local production of a full production cycle of strategically important groups of medicinal products in Russia, as well as the creation of stable conditions to ensure the investment attractiveness of the development of the pharmaceutical industry and maintaining the status of the national regulatory system in the field of ensuring and maintaining the quality of production medicinal products.

1.2. The List of Vital and Essential Medicinal Products has been updated.

Decree of the Government of Russia dated 06/09/2023 N 1508-r

New dosage forms for propionylphenylethoxyethylpiperidine (buccal and sublingual tablets), for sapropterin (dispersible and soluble tablets) are introduced in the List of Vital and Essential Medicinal Products, the list of immunosuppressants is supplemented.

1.3. The Rules for the Rules for the Manufacture and Dispensing of Medicinal Products for Medical Use by Pharmacy Organizations have been updated.

Order of the Ministry of Health of Russia dated May 22, 2023 N249n "On approval of the rules for the manufacture and dispensing of drugs for medical use by pharmacy organizations licensed for pharmaceutical activities"

From September 1, 2023, the order of the Ministry of Health of October 26, 2015 N 751n "On approval of the rules for the manufacture and dispensing of medicinal products for medical use by pharmacy organizations, individual entrepreneurs licensed for pharmaceutical activities" becomes invalid. The new order will be valid until the beginning of September 2029 and actually has a new structure. Namely, the order defines such parts as: "Manufacture of medicinal products from pharmaceutical substances" and "Manufacture of medicinal products from finished products". In order N 751n, sections were structured depending on the dosage form. Separate requirements are established for the production of radiopharmaceuticals.

In addition, the introduction of a quality system in pharmacies is established, and the right of individual entrepreneurs to manufacture medicinal products is excluded.

1.4. A list of criteria for single suppliers in the procurement of medicinal products has

been approved.

Decree of the Government of the Russian Federation of May 16, 2023 N 753 “On Approval of the List of Criteria for Single Suppliers (Contractors, Performers) when Procuring Medicinal Products for Medical Use, and the List of Criteria for Selecting Medicinal Products for Medical Use when Procuring from a Single Supplier (Contractor), performer)"

The following criteria are set for a single supplier:

- the sole supplier must be a legal entity;
- must be a manufacturer of a medicinal product, all stages of production of which, including the synthesis of a molecule of the active substance in the production of pharmaceutical substances, is carried out on the territory of the EAEU Member States;
- the sole supplier should not be under the control of a foreign investor or a group of persons;
- must have experience in the execution of contracts (agreements) for the supply of medicinal products in the framework of public procurement or procurement of goods, works, services by certain types of legal entities within 3 years preceding the date of sending the proposal to determine the sole supplier;
- the sole supplier must have the exclusive right to an invention related to a chemical compound that protects the pharmacologically active substance of a medicinal product for medical use, with a validity period of at least the period for which the sole supplier is determined.

These criteria will be effective from January 1, 2024.

1.5. From March 1, 2024, the rules for the import of medicinal products into Russia are being specified.

Decree of the Government of the Russian Federation of June 17, 2023 N 998 “On Amendments to the Rules for the Importation of Medicinal Products for Medical Use into the Russian Federation”

It is established that in order to obtain an opinion, the applicant fills out an application in the personal account of the federal state information system “Unified Portal of State and Municipal Services (Functions)” (indicating the name of the medicinal product and (or) pharmaceutical substance, dosage form, dose, concentration, packaging, name organization – manufacturer of a medicinal product and (or) pharmaceutical substance, country of manufacture of the medicinal product and (or) pharmaceutical substance and sends it to the Ministry of Health in the form of an electronic document signed with an electronic signature, with a draft conclusion attached, which is filled in the personal account of a single portal.

Recall that the following legal entities can currently import medicinal products into Russia:

- manufacturers of medicinal products – for the purposes of their own production of medicinal products;
- organization of wholesale trade in medicinal products;
- foreign developers of medicinal products for conducting clinical trials of a medicinal product, registration and examination of medicinal products intended for circulation in Russia or the EAEU;
- research organizations, higher educational institutions and drug manufacturers - for the development, research, safety, quality and efficacy of medicines;
- medical organizations to provide medical care according to vital indications of a particular patient.

1.6. Changes have been made to the rules for registration and examination of medicinal products in the EAEU.

Decision of the Council of the Eurasian Economic Commission dated May 22, 2023 N 60 "On Amendments to the Rules for Registration and Expertise of Medicinal Products for Medical Use"

The conceptual apparatus is clarified, and it is also established that if it is necessary for the Commission to provide access to a regulatory document on the quality of a medicinal product using the means of an integrated system, the expert organizations of the Member States send to the Commission an appropriate written request containing information about the laboratories that carry out quality control and experts, who need to be granted such access.

If it is necessary to restrict the previously granted access to the regulatory document, the expert organizations of the EAEU Member States send the relevant written request to the Commission indicating information about the laboratories whose access to the document must be restricted.

If it is impossible to submit a valid document confirming the compliance of the manufacturing site of the medicinal product with the requirements of the good manufacturing practice of the EAEU, the applicant, when submitting an application for registration of the medicinal product before December 31, 2024, instead of this document, shall submit valid documents confirming the compliance of the manufacturing site with the requirements of good manufacturing practice, issued by the manufacturer of the medicinal product by the authorized body of the country - the manufacturer of the medicinal product.

1.7. New penalties have been introduced for dispensing medicinal products without a prescription.

Federal Law N 175-FZ of April 28, 2023 "On Amendments to the Code of Administrative Offenses of the Russian Federation"

Article 14.4.2 of the Code of Administrative Offenses of the Russian Federation introduces part 1.1, which establishes liability for violation of the established rules for the dispensing of medicinal products subject to subject-quantitative accounting, expressed in the dispensing of these medicinal products without a prescription, if these actions do not contain signs of a criminally punishable act, in the form of an administrative a fine on officials in the amount of 10,000 to 20,000 rubles or disqualification for a period of 6 months to 1 year; for persons engaged in entrepreneurial activities without forming a legal entity – from 50,000 to 100,000 rubles; for legal entities – from 150,000 to 200,000 rubles. Pharmaceutical workers who have committed the above administrative offense bear administrative responsibility as officials.

1.8. Features of drug labeling in new regions of the Russian Federation have been introduced.

Decree of the Government of the Russian Federation of June 14, 2023 N 977 "On the specifics of legal regulation in the field of labeling of medicinal products with identification means in the territories of the Donetsk People's Republic, Luhansk People's Republic, Zaporozhye region and Kherson region" (together with the "Regulation on the specifics of legal regulation in the field of labeling of medicinal means of identification means in the territories of the Donetsk People's Republic, Luhansk People's Republic, Zaporozhye region and Kherson region")

By April 1, 2025, the territorial body of the Donetsk People's Republic and the Lugansk People's Republic must register in the system for monitoring the movement of medicinal products.

Putting into circulation and circulation in the territory of Russia of medicinal products that are not marked with identification means due to their production for export in the territory of new constituent entities of the Russian Federation before October 5, 2022, without marking with identification means is not allowed.

Until April 1, 2025, in the territories of new constituent entities of the Russian Federation, it is allowed to put into circulation, and (or) circulation, (or) withdraw from circulation of medicinal products without applying identification means to them and without entering information about medicinal products into the monitoring system.

When supplying medicinal products labeled with identification means in the territory of new constituent entities of the Russian Federation from other constituent entities of the Russian Federation, the subjects of medicinal products circulation that carry out such delivery shall submit to the monitoring system information on the withdrawal of medicinal products from circulation.

1.9. From July 1, 2023, a new type of medicine is exempt from taxation.

Federal Law N 262-FZ of June 24, 2023 "On Amendments to Article 149 of Part Two of the Tax Code of the Russian Federation"

An innovation is being introduced, according to which the sale (as well as the transfer, execution, provision for own needs) in the territory of Russia of medicinal products imported into the territory of the Russian Federation and not registered in the Russian Federation, by a non-profit organization established in in accordance with the regulatory legal act of the President of the Russian Federation in order to ensure the provision of medical care to children with severe life-threatening and chronic diseases, including rare (orphan) diseases, as well as the free transfer of these drugs to a medical organization and (or) a pharmaceutical organization of the state healthcare system. This provision applies to the sale (transfer) of drugs for the provision of medical care to children with severe life-threatening and chronic diseases, including rare (orphan) diseases, and (or) for the provision of medical care to persons over the age of 18, for 1 year after they reach the specified age if they receive such a form of support within the framework of the activities of this non-profit organization before reaching the age of 18 years. Recall that the specified non-profit organization is the Fund for Support of Children with Severe Life-threatening and Chronic Diseases, including Rare (Orphan) Diseases, "Circle of Kindness".

1.10. Amendments have been made to the procedure for federal state control over the circulation of medicinal products.

Decree of the Government of the Russian Federation of June 10, 2023 N 961 "On Amendments to the Regulations on Federal State Control (Supervision) in the Sphere of Medicinal Products Circulation"

A category of high risk of causing harm (damage) is introduced in the implementation of federal state control (supervision) in the field of drug circulation.

At high-risk control sites, an inspection visit, field or documentary checks will be carried out, as well as preventive visits will be carried out.

1.11. The simplified drug registration procedure is extended until the end of 2024.

Decree of the Government of the Russian Federation N 824 of May 27, 2023 "On Amendments to Decree of the Government of the Russian Federation of April 5, 2022 N 593"

Until December 31, 2024, a simplified procedure for the state registration of certain drugs is being extended, which allows you to quickly bring medicinal products to the market, avoid their

shortage and interruptions in supplies to pharmacies, clinics and hospitals. Also, until the specified date, the circulation of defective drugs in foreign packages is allowed. In addition, each package must have instructions for use translated into Russian and a self-adhesive label containing information about the medicine in Russian.

1.12. A new indicator of the risk of violation of mandatory requirements in the implementation of federal state control (supervision) in the field of drug circulation has been introduced.

Order of the Ministry of Health of Russia N 148n dated April 7, 2023 "On Amendments to the List of Risk Indicators of Violation of Mandatory Requirements in the Implementation of Federal State Control (Supervision) in the Sphere of Circulation of Medicinal Products for Medical Use, approved by Order of the Ministry of Health of the Russian Federation dated December 7, 2021 N 1130n "On approval of the list of indicators of the risk of violation of mandatory requirements in the implementation of federal state control (supervision) in the field of circulation of medicinal products for medical use"

A new indicator is now a two-fold or more excess of the average dispensing of medicines subject to subject-quantitative accounting by a controlled person in comparison with the subjects of circulation of medicinal products that carry out retail trade in medicinal products located in the same region for a quarter compared to the previous quarter, according to the system for monitoring the movement of medicinal products.

2. Drafts

2.1. It is proposed to approve the requirements for off-label medicinal products.

Draft Decree of the Government of the Russian Federation "On approval of requirements for a medicinal product registered in the Russian Federation, used in accordance with the indicators (characteristics) of the medicinal product, not specified in the instructions for its use, the inclusion of which is allowed in the standards of medical care for children and clinical recommendations"

The project proposes that the inclusion of a drug registered in Russia, used in accordance with indicators (characteristics) not specified in the instructions for its use, in the standards of medical care for children and clinical recommendations is allowed provided that the following requirements are met:

- the effectiveness and safety of the use of a medicinal product registered in the Russian Federation in accordance with the indicators (characteristics) of the medicinal product that are not specified in the instructions for its use are confirmed by those published in scientific publications posted in the database of the Russian Science Citation Index, and (or) in Scopus or Web of Science databases, scientific research data and (or) clinical case descriptions, in relation to each deviation from the instructions for its use, in terms of indications for use, and (or) dosing regimen and method of administration, and (or) interaction with other drugs and other types of interaction;
- an indication of the efficacy and safety of the use of the medicinal product is confirmed by its inclusion in the recommendations adopted by international professional organizations.

The explanatory note to the draft explains that based on a systematic understanding of the provisions of Article 37 of Federal Law N 323-FZ, the standards of medical care, among other things, should include average indicators of the frequency of provision and frequency of use of drugs registered in Russia (indicating average doses) in accordance with the instructions for use of the medicinal product and the pharmacotherapeutic group according to the anatomical-therapeutic-chemical classification recommended by the World Health Organization.

Instructions for use of a medicinal product, in addition to the dosing regimen of medicinal products, also include indications for use, method of administration, patient age, contraindications and other parameters.

At the same time, if in relation to the standards of medical care it is legally established that they should include average indicators of the frequency of provision and frequency of use of the medicinal product in accordance with the instructions for use, then with regard to clinical recommendations, Federal Law N 323-FZ does not establish such a requirement, in Therefore, there are no legislative obstacles for inclusion in the latest medicinal products for medical use outside the instructions for their medical use (off-label).

It is noted that it is impossible to organize the treatment process of patients without the use of off-label drugs, which is especially important when providing medical care to children with serious illnesses, where the proportion of use of such drugs reaches 60-70%.

2.2. The Ministry of Health proposed to change the Rules for the formation of lists of medicinal products and their minimum range.

Draft Decree of the Government of the Russian Federation "On Amendments to the Rules for the Formation of Lists of Medicinal Products for Medical Use and the Minimum Range of Medicinal Products Necessary for the Provision of Medical Assistance"

The project provides for the presentation of the position of state authorities of the constituent entities of the Russian Federation in the field of health care regarding the advisability of including drugs in the lists, taking into account the change in the burden on the budgets of the regions in the event that drugs are included in the relevant lists, taking into account the number of patients in the constituent entity of the Russian Federation who need therapy with these drugs, and the position of the main freelance specialists of the constituent entities of the Russian Federation.

It is proposed to change the approach for assessing the methodological quality of clinical and economic studies of drugs and studies using budget impact analysis with the possibility of refining such studies at a low and medium level of methodological quality in accordance with the comments indicated in the expert opinion.

The possibility of remote voting by members of the Commission of the Ministry of Health on the formation of lists of drugs for medical use and the minimum range of drugs necessary for the provision of medical care, the regulation of which was approved by order of the Ministry of Health of Russia dated 09.09.2014 N 498n, is also excluded.

2.3. It is proposed to introduce a procedure for purchasing medicines for war veterans.

Draft Decree of the Government of the Russian Federation "On the procedure for the acquisition of medicinal products and medical devices, including those not registered in the Russian Federation, technical means of rehabilitation that are not included in the federal list of rehabilitation measures, technical means of rehabilitation and services provided to the disabled, including highly functional prostheses and prosthetic devices - orthopedic products for combat veterans who took part (contributed to the fulfillment of tasks) in a special military operation in the territories of the Donetsk People's Republic, the Luhansk People's Republic and Ukraine from February 24, 2022, in the territories of the Zaporozhye region and Kherson region from September 30, 2022 ., dismissed from military service (service, work), as well as persons who, in accordance with the decisions of public authorities of the Donetsk People's Republic, the Lugansk People's Republic, took part in hostilities as part of the Armed Forces of the Donetsk People's Republic, the People's Militia of the Luhansk

People's Republic, military formations and bodies of the Donetsk People's Republic and the Lugansk People's Republic, starting from May 11, 2014"

As part of the implementation of one of the main goals of the activities of the State Fund for Supporting Participants in the Special Military Operation "Defenders of the Fatherland" and the implementation of additional financial mechanisms for providing medicines, it is proposed to introduce rules for the purchase of medicinal products for combat veterans who took part (assisted in the fulfillment of tasks) in a special military operation on territories of the Donetsk People's Republic, Lugansk People's Republic and Ukraine.

The project provides that the purchase of medicinal products, medical devices, technical means of rehabilitation is carried out by the specified Fund at the expense of grants in the form of subsidies provided from the federal budget to the Fund, as well as voluntary property contributions and donations from individuals and legal entities and other sources in accordance with the legislation of the Russian Federation.

The Foundation purchases medicinal products, medical devices and technical means of rehabilitation in accordance with the procedure established by the legislation of the Russian Federation, based on the decision of the Foundation's expert council.

2.4. The Federal Service for Surveillance in Health Care proposes to supplement the Rules for providing information about medicines entering the civil circulation.

The draft order of The Federal Service for Surveillance in Health Care "On Amendments to Clause 9 of the Procedure for Providing Information on Medicinal Products for Medical Use Entering into Civil Circulation, approved by Order of the Federal Service for Surveillance in Healthcare of September 28, 2022 N 9193" was developed in accordance with part 2 of the article 9.1 of the Federal Law of April 12, 2010 N 61-FZ "On the Circulation of Medicinal products".

The draft provides for an amendment to paragraph 9 of the Procedure for providing information on medicinal products for medical use entering the civil circulation, approved by order of the Federal Service for Surveillance in Healthcare dated September 28, 2022 N 9193. Namely, supplementing the wording of paragraph 4 clause 9, which contains a list of information that is posted on the official website of Federal Service for Surveillance in Health Care on the Internet information and telecommunication network, information on the form of release (indicating the dosage form, dosage, packaging) (for medicinal products) / form of release (indicating the physical state, dosage (if any), packaging) (for pharmaceutical substances).

The main goal of the project is to approve an exhaustive list of information that is posted on the official website of Federal Service for Surveillance in Health Care and is necessary for the subjects of medicinal products circulation to identify medicinal products and pharmaceutical substances that enter the civil circulation.

2.5. It is proposed to supplement the procedure for regulating the maximum ex-works prices for vital and essential drugs.

Draft Decree of the Government of the Russian Federation "On Amendments to the Features of State Regulation of Manufacturers' Maximum Selling Prices for Medicinal Products Included in the List of Vital and Essential Medicines"

It is proposed to change the formula for calculating the deviation index for the entry of a medicinal product into civil circulation and the index for meeting the need for a medicinal product in order to promptly identify defects depending on the needs of the healthcare system.

According to the explanatory note to the project, this will help avoid interruption of therapy in patients, provide citizens of the Russian Federation with effective and safe medicinal products, and reduce the growth of social tension.

The draft resolution additionally proposes to implement:

- conducting an examination in terms of determining the interchangeability of drugs, establishing the equivalence of dosage forms;
- notification of the applicant about the redirection of documents to the Federal Antimonopoly Service by means of a message in the personal account;
- provision of public services (functions) in electronic form;
- conducting an economic analysis using sources of information containing prices for medicinal products in foreign countries, specified in Appendix N 2 to the methodology for calculating maximum ex-works prices;
- grounds for canceling the decision to agree on the re-registration of the maximum selling price;
- application of re-registered maximum ex-works prices for all medicinal products introduced into civil circulation after the issuance of such orders, including in the event of a decrease in the maximum ex-works price.

3. Law Enforcement

3.1. The Federal Antimonopoly Service of Russia has identified a person guilty of maintaining prices for blood pressure monitors.

On June 21, 2023, the Federal Antimonopoly Service of Russia announced on its official website that Microlife AG, a Swiss manufacturer of blood pressure monitors, was found guilty of setting and maintaining prices for blood pressure monitors on the Russian market. The case has been pending since February 2023 on the fact that the said company sent price lists to customers indicating the minimum price level for subsequent retail sale to consumers.

As a result of the consideration of the case, the service concluded that Microlife set the recommended retail price for blood pressure monitors on the Yandex.Market, Ozon and Apteka.ru sites, controlled prices and influenced them.

Microlife was found guilty by the Federal Antimonopoly Service of Russia in coordinating economic activities (Part 5, Article 11 of the Law “On Protection of Competition”). It is possible to impose a fine from 1,000,000 to 5,000,000 rubles.

3.2. The pharmacy received a fine for dispensing substandard medicinal products.

Decision of the Arbitration Court of the Volgograd Region dated April 12, 2023 in case N A12-4552/2023

The court sided with Federal Service for Surveillance in Health Care, which revealed the fact of the sale of goods during the analysis of information from the drug movement monitoring system (MDLP). Namely, in July 2022, a letter was published on the website of the Federal Service about the identification of a low-quality drug “Nurofen Forte” of the MM331 series and about its withdrawal from circulation. However, in November this medicine was sold in a pharmacy. At the same time, during the inspection visit of employees of the territorial body of Federal Service for Surveillance in Health Care to the pharmacy, these packages were not found either on the premises or in the quarantine zone, which is assessed by the court as additional evidence that the drugs were sold to customers.

If you have any questions regarding this digest, please contact us at the following contacts:

- info@brace-lf.com
- +7(499)755-56-50

About Us

Our key practice is the legal support of pharmaceutical industry.

At the same time, our area of expertise also includes such areas of international trade, litigation, real estate, procurement, antitrust law and a number of other practices.

We provide high quality, efficient and timely solutions. In each case, the BRACE team strives to achieve the best result with the least cost.