BRACE
Law Firm

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DIGEST
of the Russian pharmaceutical industry

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Dear Colleagues!

Among the most important changes in the regulation of the Russian pharmaceutical industry in the 1st quarter of 2023, the following can be distinguished:

- The rules of the EAEU for the study of the bioequivalence of medicinal products have been amended. In particular, the research procedures for confirming the therapeutic equivalence of medicinal products in dosage forms that have a local effect in the gastrointestinal tract, topical medicinal products when applied to the skin, as well as the requirements for conducting clinical trials of medicinal products containing a known active substance (substances), in dosage forms that have a local effect.
- A transitional period has been established for integration into the Russian pharmaceutical market of the Donetsk People's Republic, Lugansk People's Republic, Zaporozhzhya region and Kherson region.
- The procedure for the transfer of donor blood to drug manufacturers has been detailed in order to ensure transparency of such transfer at each stage.
- As part of an experiment on remote sale of prescription medicinal products, criteria were developed for including medicinal products on the list that allows such remote sales.
- The Ministry of Health has proposed the introduction of an experimental regimen for prescribing medicinal products in the provision of medical care using telemedicine technologies.
- A draft law has been drafted introducing special penalties for the sale of prescription medicinal products without a prescription, providing for liability up to 200,000 rubles.
- It is proposed to introduce additional criteria for the procurement of medicines from a single supplier in the framework of public procurement.

Sincerely,
BRACE Law Firm

1. Laws, by-laws, legal news

1.1. The EAEU will change the rules for conducting bioequivalence studies of medicinal products.

Decision of the Council of the Eurasian Economic Commission dated February 15, 2023 N 22 "On Amendments to the Rules for Conducting Bioequivalence Studies of Medicinal Products within the Eurasian Economic Union"

The rules are supplemented by the following three new annexes.

Requirements for conducting clinical trials of medicinal products containing a known active substance (substances) in dosage forms that have a local effect. These medicinal products include dermatological creams, ointments, inhaled powders or aerosols, eye drops and ear drops, and nasal medicines.

It is established that if it is not possible to assess the bioavailability of a medicinal product using pharmacokinetic, pharmacodynamic or in vitro endpoints, such a medicinal product is not allowed to be considered as a generic medicinal product. At the same time, the volume of pharmaceutical development of such medicinal products corresponds to the reduced dossier. For such medicinal products, when applying for registration, they should indicate their assignment to the type of hybrid medicinal products. The safety and local tolerability of topical preparations can be substantiated by providing information on the properties of the active substance and the choice of known auxiliary components. In some cases, additional studies of the medicinal product as a whole product (a mixture of the active substance and all excipients) on animals, as well as additional studies involving humans, are required.

Research requirements are being introduced to confirm therapeutic equivalence of medicinal products in dosage forms that have a local effect in the gastrointestinal tract. So, to confirm the equivalence of such medicinal products, it is necessary to use the following data in order of increasing preference for their choice: only data on pharmaceutical quality; pharmaceutical quality data and in vitro model data; pharmaceutical quality data and in vivo pharmacokinetic data; pharmaceutical quality data, and in vitro model data and in vivo pharmacokinetic data.

Another annex establishes requirements for the quality and bioequivalence of topical medicinal products when applied to the skin. According to these requirements, the state and degree of saturation of the active substance in the medicinal product (for example, in dissolved form or in the form of a suspension) are critical quality indicators that must be justified in terms of the effectiveness and safety of the medicinal product, supported by evidence of how the target state of the active substance is achieved during the manufacturing process and is maintained during the storage of the medicinal product.

The rules contain many important additions regarding the requirements for the above medicines. These changes will come into effect on August 28, 2023.

1.2. A transitional period for the circulation of medicines in the new Russian territories has been introduced.

Federal Law N 16-FZ dated February 17, 2023 "On the Peculiarities of Legal Regulation of Relations in the Spheres of Health Protection, Compulsory Medical Insurance, Circulation of Medicines and Circulation of Medical Devices in Connection with the Admission to the Russian Federation of the Donetsk People's Republic, the Luhansk People's Republic, the Zaporozhye Region and Kherson region"

From the date of admission to the Russian Federation of the Donetsk People's Republic and the formation of a new subject within the Russian Federation, there is a transitional period during which issues of their integration are settled.

During this period, in the territories of the Donetsk People's Republic, Lugansk People's Republic, Zaporozhzhya region and Kherson region, the following persons are allowed to apply:

- medicines, information about which is contained in the state register of medicines in accordance with Russian legislation, and (or) medicines, information about which is contained in the unified register of registered medicines of the EAEU in accordance with international treaties and acts constituting the law of the EAEU;
- medicines that are not subject to registration in the territory of Russia in accordance with Russian legislation or international treaties and acts constituting the law of the EAEU;
- unregistered medicines approved for import into Russia in accordance with Russian legislation or international treaties and acts constituting the law of the EAEU;
- medicinal products, including medicines for medical use, produced in the territories of the Donetsk People's Republic, Luhansk People's Republic, Zaporizhia region and Kherson region before January 1, 2025.

The production of the above medicines is allowed without any confirmation by the state bodies of the Russian Federation:

- on the basis of permits issued prior to the date of entry into force of this Federal Law by the state authorities of the Donetsk People's Republic, Lugansk People's Republic, Zaporizhzhya region and Kherson region, as well as Ukraine;
- on the basis of permits issued by the state authorities of the Donetsk People's Republic, Lugansk People's Republic, Zaporizhzhya region and Kherson region, applications for which were submitted before the date of entry into force of the said Federal Law.

Permits are valid until January 1, 2025.

Until January 1, 2025, the regulation of prices for medicines is carried out in accordance with the regulatory legal acts of the Donetsk People's Republic, Lugansk People's Republic, Zaporozhye region and Kherson region.

Until January 1, 2025, the sale of medicinal products that are not Vital and Essential Medicinal products by pharmacies located in the territories of the new constituent entities of the Russian Federation, if such medicinal products are supplied at prices in foreign currency, is carried out in rubles. The purchase price of these medicines, medical devices and other goods is recalculated in rubles at the official exchange rate of the Central Bank of Russia on the date of delivery.

1.3. The list of Vital and Essential Medicinal products and the minimum range of medicines has been updated.

Decree of the Government of the Russian Federation of December 24, 2022 N 4173-r

From February 28, 2023, the list of Vital and Essential Medicinal products is supplemented with such medicinal products as: ramipril (capsules, tablets) - to affect the renin-angiotensin system; tenofovir + elsulfavirin + emtricitabine (coated tablets) - for the treatment of HIV; calcium polystyrene sulfonate (powder for oral suspension) - for the treatment of hyperkalemia and hyperphosphatemia.

Diphtheria and tetanus bacterial vaccines will also appear on the list.

The list of the minimum range of medicines specifies that a single-component sorbed probiotic from bifidobacteria bifidum also belongs to antidiarrheal medicinal products.

1.4. The list of remotely dispensed prescription medicinal products has been

approved, as well as the criteria for their inclusion in this list.

Decree of the Government of the Russian Federation of December 28, 2022 N 2465

Medicines that are not subject to remote dispensing include medicines that are not:

- medicines containing narcotic medicinal products , psychotropic substances and their precursors;
- medicinal products containing potent substances;
- medicines containing toxic substances;
- radiopharmaceutical medicinal products, immunobiological medicinal products, medicinal products for which, in accordance with the instructions for use of the medicinal product, the storage temperature is below 15 degrees Celsius, alcohol-containing medicinal products with a volume fraction of ethyl alcohol over 25%;
- medicinal products manufactured by pharmacies;
- included in the list of medicines subject to subject-quantitative accounting;
- anabolic steroids;
- antipsychotics, anxiolytics, antidepressants, hypnotics or sedatives;
- used to terminate a pregnancy.

Recall that the experiment on the retail sale of prescription medicinal products via the Internet runs from March 1, 2023 to March 1, 2026 in Moscow, the Moscow and Belgorod regions.

1.5. Rules for the transfer of donor blood to drug manufacturers have been approved.

Decree of the Government of the Russian Federation of February 2, 2023 N 153 "On approval of the Rules for the transfer of donated blood and (or) its components to organizations engaged in the production of medicines and (or) medical devices"

According to the document, in order to ensure the safety of donor blood and (or) its components transferred to recipient organizations, organizations-suppliers carry out traceability of data on the donor, donations, donated blood and (or) its components, consumables, donor blood samples, performers work, as well as compliance with the safety requirements of ongoing work on the procurement of donor blood.

Data traceability is achieved through their identification at all stages from a medical examination of a donor to the transfer of donated blood and (or) its components to recipient organizations, including storage and disposal, with consistent entry of relevant information into medical records and a database for the implementation of measures related to ensuring safety of donor blood, development, organization and promotion of donation of blood and its components. Recipient organizations ensure the traceability of donated blood units.

Recipient organizations are provided with donated blood by supplier organizations on the basis of the conclusions:

- a paid agreement (contract) for the performance of work on the procurement and storage of donor blood and (or) its components;
- an agreement (contract) providing for the transfer of donor blood and (or) its components for the purpose of its processing, production and return of medicines and (or) medical devices or their delivery to state (municipal) organizations in accordance with the terms of the agreement (contract).

Recipient organizations audit the conditions for the procurement and storage of donated blood from supplier organizations at intervals established on the basis of risk analysis, but not more than once a year.

Supplier organizations, within 3 working days from the date of detection, inform recipient organizations in writing (including by facsimile, electronic communication) about the detection of markers of bloodborne infections in donated blood and (or) its components for a period of 12 months from the date of transfer of such donor blood and (or) its components.

If the recipient organization detects pathogens of blood infections in donor blood and (or) its components, the recipient organization informs the supplier organizations in writing (including by facsimile, electronic communication) within 3 working days from the date of detection.

Units of donated blood and (or) its components, in which pathogens of blood infections are detected, are withdrawn from circulation and disposed of.

A series (batch) of a medicinal product and (or) a series (batch) of a medical device containing units of donated blood and (or) its components, in which pathogens of blood infections are detected, are subject to withdrawal from circulation.

1.6. Amendments have been made to the regulation of the medicinal product monitoring system.

Decree of the Government of the Russian Federation of March 24, 2023 N 468 "On Amending Decree of the Government of the Russian Federation of December 14, 2018 N 1556 and Recognizing Certain Provisions of Certain Acts of the Government of the Russian Federation as Invalid"

From September 1, 2023, the period during which the system operator is obliged to provide devices for registering the emission of codes and registrars for withdrawing medicines from circulation is reduced. This period has been reduced from 45 to 30 calendar days.

Also, instructions for the use of medicines are being introduced into the drug labeling system, which must be submitted by pharmaceutical manufacturers by June 30, 2024.

1.7. The rules for issuing permits for online trade of medicines have been changed.

Decree of the Government of the Russian Federation of February 18, 2023 N 272 "On Amendments to the Rules for Issuing Permits for the Remote Retail Trade of Medicinal Products for Medical Use, Such Trade and Delivery of These Medicinal Products to Citizens"

The amendments supplement the list of documents that are submitted along with the application for obtaining a permit. Namely, it's necessary to provide:

- copies of documents (information) confirming the availability of equipped premises (places) for storing formed orders in accordance with the rules of good practice for the storage and transportation of medicines;
- copies of documents (information) confirming the presence of its own courier service, which has equipment that ensures the maintenance of the required temperature regime for the delivery of thermolabile medicinal products, or an agreement with other persons delivering using such equipment;
- copies of documents (information) confirming the availability of an electronic payment system and (or) mobile payment terminals intended for making electronic payments, including with the help of bank cards, directly at the place of service provision.

It is also established that an application for making changes to the register of permits, the information attached to it and a copy of the agreement (if concluded), signed and certified by an enhanced qualified electronic signature or an enhanced unqualified electronic signature of an individual, shall be submitted in the manner prescribed by the administrative regulation, with the use of using a single portal.

1.8. The issues of the activities of the Fund for Support of Children with Severe Life-threatening and Chronic Diseases, including rare (orphan) diseases "Circle of Good" have been clarified.

Decree of the Government of the Russian Federation of February 15, 2023 N 229 "On Amendments to Certain Acts of the Government of the Russian Federation on the Activities of the Fund for Support of Children with Severe Life-threatening and Chronic Diseases, Including Rare (Orphan) Diseases, "Circle of Kindness"

The amendments clarify that the source of financing for the organization of providing medicines to children under the age of 18 with hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, malignant neoplasms of the lymphoid, hematopoietic and related tissues, multiple sclerosis, hemolytic uremic syndrome, juvenile arthritis with systemic onset, mucopolysaccharidosis types I, II and VI, unspecified aplastic anemia, hereditary deficiency of factors II (fibrinogen), VII (labile), X (Stuart-Prauer), children under 18 years of age after organ and (or) tissue transplantation from 2023 years are the budgetary allocations provided in the federal budget to the Ministry of Health of the Russian Federation for the Fund for Support of Children with Severe Life-threatening and Chronic Diseases, including Rare (Orphan) Diseases, "Circle of Kindness" (hereinafter referred to as the Fund).

The volume of supplies of medicines for children under the age of 18 is approved by the commission of the Ministry of Health of the Russian Federation, and within 3 working days from the date of receipt of information about the need for medicines, information about the indicated volumes of supplies is sent to the Fund and the state customer.

2. Drafts

2.1. An experimental program for the introduction of telemedicine technologies has been proposed.

Draft Decree of the Government of the Russian Federation "On the establishment of an experimental legal regime in the field of digital innovations and the approval of the program of the experimental legal regime in the field of digital innovations in the direction of medical activity using telemedicine technologies"

It is proposed to establish an experimental legal regime, which is aimed at expanding the possibilities for consulting a patient (including with the participation of his legal representative) in the provision of medical care in a planned form within one case of treatment for a disease (condition) started at a face-to-face appointment by one doctor and continued at the patient's choice by another healthcare professional for the same disease (condition) using telemedicine technologies, with the possibility of prescribing treatment, including the formation of prescriptions for medicinal products.

Thus, according to the draft, it is proposed that when conducting consultations using telemedicine technologies, a doctor can correct the treatment prescribed at a face-to-face appointment, prescribe treatment (if it is not available), including the formation of prescriptions for medicines in the form of an electronic document, subject to the determination by the attending physician diagnosis and treatment (if any) for the same disease at an in-person appointment (examination, consultation).

2.2. Draft law on fines for the sale of prescription medicinal products without a prescription has been approved.

Draft federal law "On Amendments to the Code of the Russian Federation on Administrative Offenses"

It is proposed to establish administrative liability for violation of the established rules for dispensing medicinal products subject to subject-quantitative accounting, expressed in over-the-counter dispensing of these medicinal products , if these actions do not contain signs of a criminally punishable act, providing for an increased amount of fines for pharmaceutical workers and officials from 10,000 to 20,000 rubles for persons engaged in entrepreneurial activities without forming a legal entity – from 50,000 to 100,000, as well as legal entities – 150,000 to 200,000 rubles.

Also, in the explanatory note to the draft, it is noted that when determining the types of sanctions, it is necessary to be guided by the principle of proportionality of punishment to the committed offense, excluding factors of excessive burden on small and medium-sized businesses. To this end, the draft federal law does not envisage the establishment of such a type of sanction as an administrative suspension of activities, since this may adversely affect the activities of pharmacies.

2.3. It is proposed to introduce criteria for the purchase of medicines from a single supplier and criteria for the selection of medicines.

On approval of the list of criteria for single suppliers in the procurement of medicinal products for medical use, and the list of criteria for the selection of medicinal products for medical use

The criteria for purchasing from a single supplier are proposed to include the following:

- the intended sole supplier is a legal entity;
- the only supplier is 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, are carried out on the territory of the EAEU Member States;
- the sole supplier is not under the control of a foreign investor or a group of persons;
- the sole supplier has experience in the execution of contracts (agreements) for the supply of medicines under 44-FZ or 223-FZ for 3 years prior to the date of sending the application for determining the sole supplier to the Government of the Russian Federation, taking into account succession;
- the sole supplier has 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.

As criteria for the selection of medicinal products , medicinal products are proposed, all stages of production of which, including the synthesis of a molecule of the active substance in the production of pharmaceutical substances, are carried out on the territory of the EAEU member states and the pharmacologically active substance of the drug as a chemical compound is protected by a patent in Russia, which is held by the alleged sole supplier in public procurement, with a validity period of at least the period for which the sole supplier is determined.

2.4. The Ministry of Health has proposed introducing rules for the manufacture of medicines by pharmacies licensed for pharmaceutical activities.

Draft order of the Ministry of Health of the Russian Federation "On approval of the rules for the manufacture and dispensing of medicinal products for medical use by pharmacy organizations licensed for pharmaceutical activities"

The document was developed to replace the order of the Ministry of Health of Russia dated 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".

The draft order excludes individual entrepreneurs who have a license for pharmaceutical activities from among the persons who manufacture medicines according to prescriptions for medicines, according to the requirements of medical organizations; pharmacy organizations are given the opportunity to use registered medicinal products in the manufacture of medicines; establishes the procedure for the manufacture of radiopharmaceuticals.

2.5. It is proposed to expand the powers of the interdepartmental commission to determine the defectiveness of medicines.

Draft order "On Amending Clause 3 of the Regulations on the Interdepartmental Commission for Determining Defects or the Risk of Defects in Medicinal Products in Connection with the Introduction of Economic Restrictive Measures against the Russian Federation, approved by Order of the Ministry of Health of the Russian Federation dated May 19, 2022 N 339n"

The draft order amends the order of the Ministry of Health of Russia dated May 19, 2022 N 339n, which determines the procedure for the activities of the interdepartmental commission to determine the defect or the risk of a defect in medicinal products for medical use, and also approves the forms of the conclusion of the interdepartmental commission on the possibility (impossibility) of issuing a permit for temporary circulation of a series (batch) of an unregistered medicinal product and on the possibility of circulation in the Russian Federation of a series (batch) of a medicinal product in a package intended for circulation in foreign countries.

It is assumed that the adoption of the draft order will help to avoid the shortage and lack of medicines, including those included in the list of vital and essential medicinal products, on the Russian market in connection with the introduction of sanctions against Russia.

The draft order will allow the interdepartmental commission to make decisions in 2023 on the possibility of circulation in the Russian Federation of a series (batch) of a medicinal product in a package intended for circulation on the territory of foreign states, including the need to conduct drug quality tests.

2.6. Federal Service for Surveillance in Healthcare proposes to approve the list of documents required by pharmacies for the online sale of prescription medicinal products.

Draft Order of Federal Service for Surveillance in Healthcare "On Approval of the List of Documents Confirming the Compliance of a Pharmacy Organization with the Requirements Granting the Right to Remotely Retail Sale of Medicinal Products for Medical Use, Dispensed by Prescription for a Medicinal Product"

So, the pharmacy organization must have documents confirming the availability of equipped premises for storing formed orders, including:

- confirming the availability on the right of ownership or on other legal grounds of premises for the storage of generated orders with specification of numbers (in accordance with technical plan);
- confirming the availability of such equipment as air conditioning systems, cold rooms and (or) refrigerators, ventilation systems, thermohygrometers (psychrometers), or other equipment used to record temperature and humidity in the premises.

It is planned to impose on pharmacies the obligation to provide information confirming the existence of a website and a mobile application (if any) or an agreement with a legal entity that owns an aggregator website. In addition, they must have documents confirming that they have their own courier service with the necessary equipment that provides temperature control, or an agreement with intermediaries who will deliver orders.

3. Law Enforcement

3.1. The Moscow Arbitration Court brought the pharmacy to administrative responsibility for the sale of expensive subsidized medicines.

Award of the Moscow Arbitration Court dated January 31, 2023 in case N A40-235026/22-94-1789

During the inspection of the trading floor of the pharmacy organization located at the address: Moscow, st. Nizhnyaya, d. 5, officials of the Territorial Authority found medicines in the cabinet (in bags) and in the refrigerator, on the packages of which there were price tags indicating the name of the pharmacy organization, among which medicines were also found with intentionally damaged individual marking codes. Thus, it is not possible to establish the legality of the origin of these medicinal products, since the individual labeling codes of these medicinal products cannot be identified.

In addition, Federal Service for Surveillance in Healthcare identified medicinal products dispensed to patients on preferential prescriptions, as well as medicinal products that are in the status of "*retired for medical use*".

The court sided with the supervisory authority and ruled on bringing to administrative responsibility in the amount of 1,000,000 rubles. This decision was upheld by the Court of Appeal.

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About Us

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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.