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DIGEST
of the most significant changes in the regulation of the pharmaceutical industry for 2019

Main news

We bring to your attention the Digest of the most significant changes in the field of regulation of the pharmaceutical industry for 2019.

It should be noted that in 2019, important and significant changes were made to the legislation in the field of drug circulation regarding labeling of drugs, maximum selling prices for Vital and Essential Drugs, as well as the introduction of drugs into civil circulation, etc.

The above and other significant changes can be found in this digest. In forming the digest, we were guided by the influence of various changes on the industry and the difficulties that pharmaceutical market participants may encounter.

Respectfully,

BRACE Law Firm

1. The Board of the Eurasian Economic Commission approved important guidelines and issued recommendations on pharmaceutical activities in the EAEU.

Recommendation of the Board of the Eurasian Economic Commission dated January 29, 2019 N 2 "On the Guide for the Selection of Trade Names of Medicinal Products"

Recommendation of the Board of the Eurasian Economic Commission dated January 29, 2019, N 3 "On the Guidelines for the production of finished dosage forms for the production of finished dosage forms of drugs"

Recommendation of the Board of the Eurasian Economic Commission dated February 12, 2019 N 6 "On the Guidelines for the Selection of Tests and Acceptance Criteria for the Compilation of Specifications for Herbal Raw Materials, Herbal Pharmaceutical Substances (Preparations Based on Medicinal Herbal Raw Materials) and Herbal Medicines"

Recommendation of the Board of the Eurasian Economic Commission of August 6, 2019 N 24 "On the Guidelines for controlling the risks of microbial contamination of medicinal plant materials, herbal pharmaceutical substances (drugs based on medicinal plant materials) and herbal medicines"

Recommendation of the Board of the Eurasian Economic Commission of March 19, 2019 N 10 "On the updated Information Guide of concepts used within the framework of the Eurasian Economic Union in the field of drug circulation"

Recommendation of the Board of the Eurasian Economic Commission of March 12, 2019 N 8 "On the Guidelines for the selection of dosage of drugs"

The Guidelines for the Selection of Trade Names of Medicines establishes an approach to the assessment of trade names of orphan drugs that coincides with the approach to the valuation of trade names for non-organic drugs. To evaluate the trade names of orphan drugs, it is especially important to provide detailed information on the specific conditions under which the drug will be dispensed and used, as well as its target population. In particular, if the trade name of the medicinal product is a newly coined word, it should not be similar to the point of confusion or reproduce another international non-proprietary common name.

The manual for the production of finished dosage forms establishes that the description of the production process should reflect data on critical stages and intermediate products and trace the relationship between pharmaceutical development, the proposed control strategy and validation of the process.

Guidance on the selection of tests and eligibility criteria for preparing specifications for herbal medicines establishes that the specification for finished medicinal forms of herbal medicines should contain: data on the quality of herbal raw materials and (or) herbal pharmaceutical substances (drugs based on herbal raw materials); process description (temperature effect, residual solvents, etc.); profile and stability of active components (composition) during packaging; indication of the series used in preclinical (clinical) trials (safety assessment and determination of effectiveness) (if applicable). Section 5 of the Guide sets out in detail the main tests and acceptance criteria. Also, this document, in addition to standard criteria, contains additional (specific) tests and acceptance criteria.

The Guidelines for controlling the risks of microbial contamination of medicinal plant materials, plant pharmaceutical substances established that when controlling the microbial contamination of the ingress of foreign microorganisms during the growth, cultivation, collection, processing, production, storage and transportation of plant products and herbal medicines, the risks of changes are taken into account pH values, increased humidity during storage, causing the growth of microorganisms. In order to prevent microbial contamination of cultivated plants, the correct growing conditions should be selected and their control ensured.

In order to apply a common terminology in the process of the pharmaceutical market in the EAEU, an informational guide to the concepts used within the Eurasian Economic Union in the field of drug circulation has been updated. For example, the specified directory introduced the decoding of such new concepts (not previously used in the directory) as contains a number of new concepts and definitions to them. For example, such as: “bioseries”, “process validation”, “dose dumping”.

Recommendations on the selection of the dose of drugs establish that when registering drugs in order to reduce registration cases indicating an excessive dosage regimen, when studying them, the smallest dose that has a clear positive effect, or the maximum dose, exceeding which does not lead to an additional increase in the desired positive effect. The most valuable when choosing a starting dose is the knowledge of the shape and location of the population average dose-response curve for the desired effects and unwanted reactions. In determining the dose-effect relationship, diagnostic and therapeutic approaches that affect standard types of studies in each clinical area should be considered.

The above and other most important issues of legal regulation of the pharmaceutical market in the territory of the EAEU Member States are regulated by the above documents.

2. The Eurasian Economic Commission prepared recommendations on the conduct of certain types of clinical and preclinical research and development, as well as an examination of drugs.

Recommendation of the Board of the Eurasian Economic Commission dated September 02, 2019 N 25 “On the Guidelines for the Preclinical and Clinical Development of Combined Medicines”

Recommendation of the Board of the Eurasian Economic Commission of September 10, 2019 N 28 “On the Guidelines for determining the scope of laboratory tests in the examination of medicines”

The decision of the Board of the Eurasian Economic Commission dated November 26, 2019 N 202 “On approval of the Guidelines for preclinical safety studies for the purpose of conducting clinical trials and drug registration”

Recommendation of the Board of the Eurasian Economic Commission dated December 17, 2019 N 42 “On the Guidelines for the selection of unstudied drugs for the purpose of conducting clinical trials of drugs”

The Guidelines for the Preclinical and Clinical Development of Combined Drugs describes approaches to the preclinical and clinical development of combined medicines (fixed combinations of active substances, fixed dosage combinations of active substances) containing 2 or more active substances in one dosage form. It is established that the volume and design of preclinical studies performed during the development of a combined drug product depend on the available data on the individual active substances included in the combination, as well as on the intended indication (s) for the use of the combined drug. A description of the combinations of active ingredients in the composition of the combined drug.

The Guidelines for determining the scope of laboratory tests in the examination of medicines contains recommendations for determining the scope of laboratory tests of drug samples for compliance with the requirements of the regulatory document on quality and verification of analytical methods of quality control during registration, amending the registration dossier in accordance with the Rules for Registration and Expertise of Medicines means for medical use, approved by the Decision of the Council of Eurasia Second Economic Commission on November 3, 2016 number 78. The choice made by laboratory tests performed, depending on the nature of the manufacturing of a drug. At the same time, for biological medicinal products, the choice of laboratory tests is made

according to all indicators for all sites and using all the declared manufacturers of the active pharmaceutical substance.

The Guidelines for Preclinical Safety Studies for the purpose of conducting clinical trials and drug registration establishes that clinical trials should be expanded if results are obtained confirming the sufficient safety of the drug in a previous clinical study, as well as if there are additional data from preclinical safety studies that become available as clinical development progresses. The basic set of pharmacological safety studies includes an assessment of the effects on the cardiovascular, central nervous and respiratory systems, which should be carried out before the start of clinical development in accordance with the guidelines for the study of the pharmacological safety of drugs for medical use.

The Guidelines on the selection of non-researchable drugs for the purpose of conducting clinical trials of drugs defines the term “unstudied drugs”. It is established that a medicinal product is unexplored if its use in the process of a clinical trial is not the direct goal of this clinical trial. The document defines the criteria for the selection of unexplored drugs during clinical trials of drugs, the amount of information about unexplored drugs presented in the dossier for obtaining permission to conduct clinical trials. The most commonly used unexplored drugs are drugs registered in accordance with the Rules for Registration and Expertise or registered in any of the Member States where a clinical trial is planned, in accordance with acts included in the EAEU.

These documents play an important role in the regulation on the territory of the EAEU of the procedure for preclinical and clinical trials, as well as an examination of drugs.

3. The government approved a new procedure for introducing drugs into civilian circulation, and the Federal Service for Surveillance in Healthcare gave a number of explanations in this regard.

Decree of the Government of the Russian Federation of November 26, 2019, N 1510 “On the procedure for introducing drugs into medical circulation for medical use” (together with the Rules for the submission of documents and information on drugs for medical use introduced into civilian circulation, the Rules for issuing test reports on the compliance of the first three series or batches of a medicinal product for medical use (except for an immunobiological medicinal product), first produced in the Russian Federation or first e imported into the Russian Federation, quality indicators stipulated by regulatory documents, the Rules for issuing permits for the introduction into civil circulation of a batch or batch of an immunobiological medicinal product, the issuance of an opinion on the conformity of a batch or batch of immunobiological medicinal product to the requirements established during its state registration, the Decision Making Rules on termination of civil circulation of a series or batch of a medicinal product for medical use)

Leaflet on the acceptance of drugs in connection with the entry into force on November 29, 2019, of a new procedure for the introduction of drugs into civil circulation

Letter of the Federal Service for Surveillance in Healthcare dated November 28, 2019, N 01I-2906/19 “On Entering into Civil Turnover”

Federal Law of November 28, 2018, N 449-ФЗ “On Amending Certain Legislative Acts of the Russian Federation on the Issue of Entering into the Civil Circulation of Medicines for Medical Use” was introduced into Federal Law of April 12, 2010, N 61-ФЗ “On Circulation of Medicines” Article 52.1, according to which, with respect to medicines introduced into civil circulation after November 29, 2019, it is necessary to submit to the Federal Service for Surveillance in Healthcare a document of the manufacturer of the medicinal product, confirming giving quality of the drug, and the confirmation of an authorized person manufacturer of medical conformity of the medicinal product requirements

established under its state registration. In fact, the indicated regulatory legal act abolished the mandatory certification of drugs.

The Decree of the Government of Russia adopted in November 2019 specifies the provisions that a manufacturer submits a series or a batch of a medicinal product to the automated information system of the Federal Service for Surveillance in Healthcare through a personal account for each batch or each batch of a medicinal product: manufacturer's document confirming the quality of the drug confirmation of the authorized person of the manufacturer of the conformity of the drug about the drug requirements established during its state registration.

The importer, before entering the drug into civil circulation, submits to the automated information system of the Federal Service for Surveillance in Healthcare through the personal account for each series or each batch of the drug: a certificate of the manufacturer of the drug, certifying the compliance of the imported drug with the requirements of the pharmacopoeial article, and in the absence pharmacopeia article requirements of regulatory documentation; confirmation of the representative of the importer, authorized by the foreign manufacturer of medicines, the compliance of the imported medicinal product with the requirements established during its state registration.

In case of failure to submit these documents, a decision is made to terminate the civil circulation of drugs, which is executed by order of the Federal Service for Surveillance in Healthcare within 5 business days after the receipt of information confirming the actual presence in the civil circulation of a series or batch of a drug.

The Federal Service for Surveillance in Healthcare has clarified that since November 29, 2019, organizations that manufacture drugs in the Russian Federation or import drugs into the Russian Federation enter information into the personal account of the external information resource of the automated information system of Federal Service for Surveillance in Healthcare.

If the applicant already has a personal account in the automated information system of the Federal Service for Surveillance in Healthcare, then additional registration is not required.

The legality of finding a series (batch) of a medicinal product can be checked on the official website of the Health Inspectorate www.roszdravnadzor.ru. The search is possible by several details, including the trade name, series number, manufacturer, country of production.

Information on the permits of the Federal Service for Surveillance in Healthcare for the introduction of a series (batch) of immunobiological medicinal product into civil circulation is also posted on the Federal Service for Surveillance in Healthcare website under the heading “Electronic Services”/“Information on drugs received in civil circulation in the Russian Federation”.

If there is no information on the Federal Service for Surveillance in Healthcare website on the introduction of a series (batch) of a medicinal product into civil circulation, you should contact the territorial body of the Federal Service for Surveillance in Healthcare to consider the need for control measures.

4. The Russian Government has approved the procedure for recognition and assessment of the conformity of testing laboratories (centers) with the principles of good laboratory practice of the Organization for Economic Cooperation and Development.

Decree of the Government of the Russian Federation of September 20, 2019 N 1227 “On the Recognition and Assessment of Conformity of Testing Laboratories (Centers) with the Principles of Good Laboratory Practice, Corresponding to the Principles of Good Laboratory Practice of the Organization for Economic Cooperation and Development”

Testing laboratories (centers) that conduct non-clinical (preclinical) laboratory studies of objects contained in pesticides, cosmetics, medicines for medical use, medicines for veterinary use, food and feed additives, as well as in industrial chemicals, are entitled to voluntarily submit an application to the monitoring body in order to obtain or confirm the status of compliance of the testing laboratory (center) with the principles of good laboratory practice.

Recognition of compliance of the testing laboratory (center) with the principles of good laboratory practice is carried out according to the results of the preliminary and complete inspection.

The recognition and assessment of conformity of testing laboratories (centers) with the principles of good laboratory practice, corresponding to the principles of good laboratory practice of the Organization for Economic Cooperation and Development, is ensured by the Ministry of Health of the Russian Federation, the Ministry of Industry and Trade of the Russian Federation, the Ministry of Agriculture of the Russian Federation, and the Federal Service for Supervision in the field of consumer protection and human well-being, Federal d Service for Veterinary and Phytosanitary Supervision, the Federal Service for Surveillance in Healthcare, Federal Biomedical Agency and the Federal Agency for Technical Regulation and Metrology.

5. The Federal Service for Surveillance in Healthcare approved the Regulation on the Commission for the Quality of Immunobiological Medicines, the form for authorizing the introduction of a medicinal product produced in Russia or imported into the country, and also approved the Procedure for assessing the volume of quality tests of immunobiological medicines.

The order of the Federal Service for Surveillance in Healthcaredated November 29, 2019 N 8967 "On the Commission of the Federal Service for Supervision of Healthcare on the quality of immunobiological drugs" (together with the "Regulation on the Commission of the Federal Service for Supervision of Healthcare on the quality of immunobiological drugs")

The order of Federal Service for Supervision of Health Care of Russia dated November 29, 2019 N 8966 "On approval of the form for authorizing the introduction into civil circulation in the Russian Federation of a series or batch of an immunobiological drug produced in the Russian Federation or imported into the Russian Federation and the form of a conclusion on the compliance of a series or batch of an immunobiological drug with the requirements established at its state registration"

Order of Federal Service for Supervision of Health Care of Russia dated December 17, 2019 N 9452 "On approval of the Procedure for assessing the volume of tests of the quality of immunobiological drugs by the Commission of the Federal Service for Supervision of Healthcare on the quality of immunobiological drugs"

The composition of the Commission for the Quality of Immunobiological Medicines (hereinafter - the Commission) is approved by the head of the Federal Service for Supervision of Health in the amount of at least 10 people.

The Commission has the right: to involve independent experts in the field of production and quality control of immunobiological drugs; request and receive information necessary for work from federal executive bodies, organizations engaged in the production of immunobiological drugs in the Russian Federation, organizations importing immunobiological drugs into the Russian Federation, and other subjects of immunobiological drug circulation.

The decision to determine the scope of the quality tests of the immunobiological medicinal product of a particular name and manufacturer (taking into account the dosage form and dosage) is

carried out by the Commission in accordance with the procedure for assessing the volume of quality tests of immunobiological drugs

The Commission takes decisions by an open vote by a simple majority.

The procedure for assessing the volume of tests of the quality of immunobiological drugs established that from January 12, 2020, the assessment of the volume of tests of the quality of immunobiological drugs is carried out in relation to immunobiological drugs, the data on which are entered in the State Register of Medicinal Products and entered into civil circulation in the Russian Federation, information about which are contained in the automated information system of the Federal Service for Surveillance in Healthcare Eden.

The decision to determine the scope of the quality tests of the immunobiological medicinal product of a specific name and manufacturer (taking into account the dosage form and dosage) is carried out by the Commission on the basis of the analysis of the quality of such drugs submitted to the Commission annually until March 1.

Based on the available information, the Commission annually, no later than April 1 of the year following the last, holds a meeting and decides to determine the scope of the quality tests of the immunobiological medicinal product of a specific name and manufacturer (taking into account the dosage form and dosage) and the frequency of immunobiological drug tests for all indicators of approved regulatory documentation.

6. In 2019, a number of legal acts were adopted, as well as clarifications were given by the Federal Monopoly Service of Russia regarding the introduction of the obligation of Vital and Essential Drugs manufacturers to reduce marginal selling prices for such drugs.

Federal Law of June 06, 2019, N 134-ФЗ "On Amendments to the Federal Law "On the Circulation of Medicines" regarding state regulation of prices for medicines included in the list of vital and essential medicines"

Clarification on the formation of a wholesale organization having structural divisions of retail sales prices for narcotic and psychotropic vital drugs when they are delivered to a medical organization (from letters of the Federal Monopoly Service of Russia dated February 28, 2019 N RP / 15603/19 and April 29, 2019 N CA / 36600/19)"

Decree of the Government of the Russian Federation of December 16, 2019 N 1683 "On amendments to some acts of the Government of the Russian Federation regarding state registration and re-registration of maximum selling prices for drugs included in the list of vital and essential drugs"

Federal Law of June 06, 2019, N 134-ФЗ introduces a legal norm on the need to reduce the maximum selling price for medicines included in the List of Essential and Essential Medicines.

Mandatory price reduction will be in cases:

- reduction in the price in foreign currency of the drug in the country of manufacture and/or in countries in which the drug is registered and/or supplied by the manufacturer;
- reduction of prices for reference medicines for the corresponding reproduced, bio-analog (biosimilar) medicines in the country of the manufacturer and (or) in the countries in which the drug is registered and (or) which is supplied by the manufacturer;
- excess of the maximum selling price for the first reproduced, bio-analog (biosimilar) drug of foreign manufacture over the maximum selling price of the manufacturer for the second reproduced, bio-analog (biosimilar) drug calculated in accordance with the methodology approved by the Government of the Russian Federation;

- excess of the maximum selling price for the first reproduced, bio-analog (biosimilar) medicinal product of a producer of a EAEU member state over the maximum selling price of a producer for a second reproduced bio-analog (biosimilar) medicinal product of a producer of a EAEU member state calculated in accordance with the methodology approved by the Government of the Russian Federation.

The Federal Antimonopoly Service of Russia clarifies that when delivering drugs from the Vital and Essential Drug List to a medical organization, it is not envisaged to include a retail mark-up in the price of a medicinal product either by the current legislation in the field of the circulation of medicines or by legislation in the field of procurement of goods, work, services to meet state and municipal needs. To medical organizations that do not have pharmacy organizations in their structure, narcotic and psychotropic drugs are dispensed with overhead requirements. In this case, it is permissible to take into account the costs of wholesale organizations that have in their structure a pharmacy organization through which these drugs are dispensed on invoice requirements.

It is important to note that in December 2019, amendments were made to the Rules of state registration and re-registration of maximum selling prices of manufacturers of drugs included in the list of vital and essential drugs. These changes establish that the mandatory re-registration of maximum selling prices for medicines is carried out with the preservation of the last registered (re-registered) maximum selling prices for immunobiological medicines, medicines containing narcotic drugs and psychotropic substances produced by the Member States of the Eurasian Economic Union, as well as medicines in the price segment up to 100 rubles.

An application for mandatory re-registration in 2019-2020 of the registered maximum selling price of a manufacturer for a reference medicinal product included in the list of vital and essential medicines must be submitted by the holder or owner of the registration certificate of the reference medicinal product within 40 business days from the date of entry into force of the decision The Government of the Russian Federation of December 16, 2019 N 1683.

For drugs used in pediatric practice (for which the maximum selling price is not registered), the calculation of the maximum selling price is carried out in accordance with the requirements established for reference medicines. In this case, the maximum difference between the minimum registered maximum selling price of a medicinal product and the maximum selling price of a medicinal product submitted for state registration, calculated on the basis of the unit cost of the active substance, may not exceed 90 percent.

Also, the Ministry of Health and the Federal Antimonopoly Service will now be empowered to make an independent decision on the mandatory re-registration of the maximum selling price for a drug.

We believe that the introduction of such changes in the current legislation, on the one hand, can lead to lower prices for drugs. On the other hand, due to the very short time frames for such a decline, such innovations may lead some manufacturers to leave the Russian market.

7. Amendments to the legislation governing investment activities in the framework of special investment contracts have entered into force.

Federal Law of August 2, 2019, N 290-ФЗ "On Amendments to the Federal Law" On Industrial Policy in the Russian Federation "with regard to the regulation of special investment contracts"

Federal Law of August 2, 2019, N 269-ФЗ "On Amendments to Parts One and Two of the Tax Code of the Russian Federation"

Recall that the mechanism of special investment contracts provides for the obligation of the investor to create or modernize or master the production of industrial products on the territory of the Russian Federation, on the continental shelf of the Russian Federation, in the exclusive economic zone of the Russian Federation, and the other side of the contract represented by the Russian Federation or subject of the Russian Federation term of the contract is obliged to implement measures to stimulate activities in the industry (within the direction of the contract).

According to the amendments, the Federal Law "On Industrial Policy in the Russian Federation" is supplemented by Chapter 2.1, which specifies that, in accordance with the special investment contracts, technology is introduced or developed and introduced, the use of which is necessary for the implementation of production and technological operations. The list of modern technologies is compiled and updated by the Government of the Russian Federation. Now a mandatory requirement is established that a special investment contract should include a list of incentive measures for industrial activity applied to the investor, provided that he fulfills obligations under such a contract. At the same time, such a contract does not include a list of incentive measures that the investor can take in accordance with the measures provided for by current legislation, regardless of the contract. Also, for participants in the competitive selection for concluding a special investment contracts, a duty is established before submitting applications to coordinate with the subject of the Russian Federation and the municipality the place of production of this or that industrial product and provide information on this approval as part of the application for participation in the competitive selection.

For contracts with an investment volume of up to 50 billion rubles, the term of the investment contract is extended to 15 years, and if the investment exceeds the specified amount, the contract can be concluded for up to 20 years.

For taxpayers participating in special investment contracts, the tax rate payable to the federal budget is set at 0 percent during the period of application of the reduced tax rate payable to the budget of the constituent entity of the Russian Federation. As a general rule, zero rates can be established if more than 90% of the investor's income is made up of a special investment contract. Innovations in the Tax Code introduce the possibility of separate accounting of investor income.

At the same time, a reduction in the tax rate to be credited to the budgets of the constituent entities of the Russian Federation can also be carried out up to 0 percent. Such a reduced rate is applied, starting from the tax period in which the first profit from the implementation of the investment project was received, until the reporting (tax) period in which the organization loses its taxpayer status as a participant in the special investment contract, but no later than the reporting (tax) period in which the total amount of expenses and lost revenues of the budgets of the budget system of the Russian Federation related to the application of incentive measures exceeded 50 percent of the volume of capital investments a national project, the size of which is stipulated by the contract.

We believe that these measures will have a beneficial effect on attracting large investors, including in the pharmaceutical market.

8. The circle of persons to whom the wholesale drug trade organizations can sell drugs has been expanded, and the term for maintaining the status of a member of 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 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 member state of the Organization for Economic Cooperation and Development to foreign legal entities, individual entrepreneurs who are participants and the project in accordance with the Federal Law of June 29, 2015 N 160-ФЗ "On the International Medical Cluster and Amending Certain Legislative Acts of the Russian Federation". 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. The international medical cluster is being created in the territory determined by the highest executive body of state power of the city of federal significance of 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 20 (instead of the previously established 10) years from the date of conclusion of an agreement with them or from the date of early termination of the agreement, liquidation or reorganization of the project participant, termination of activity of an 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 budget of the budget system of the Russian Federation. Previously, medical assistance could be provided to project participants with permits for medical activities issued in the Russian Federation.

9. In 2019, it became possible to formulate electronic prescriptions for drugs containing narcotic drugs and psychotropic substances.

Federal Law of July 29, 2017 N 242-ФЗ "On Amending Certain Legislative Acts of the Russian Federation on the Use of Information Technologies in the Field of Health Care"

Now, prescriptions containing the prescription of narcotic drugs or psychotropic substances are issued on special forms on paper or are formed with the consent of the patient or his legal representative in the form of electronic documents signed using an enhanced qualified electronic signature of the attending physician or paramedic, midwives who are assigned the functions the attending physician, and the appropriate medical organization.

10. The Russian government approved a number of changes regarding the production of alcohol-containing medicines.

Decree of the Government of the Russian Federation of February 28, 2019 N 201 "On approval of the Rules for the formation of a list of alcohol-containing drugs, the production, manufacture and (or) turnover of which is not covered by the Federal Law "On State Regulation of the Production and Turnover of Ethyl Alcohol, Alcohol, and Alcohol-Containing Products and on the restriction of consumption (drinking) of alcoholic beverages"

Decree of the Government of the Russian Federation of February 28, 2019 N 217 "On amendments to the Regulation on licensing the production of medicines"

The compilation of the list of alcohol-containing drugs for the production, manufacture and (or) circulation of which is not covered by the Federal Law "On State Regulation of the Production and Turnover of Ethyl Alcohol, Alcohol, and Alcohol-Containing Products and on the Limitation of Consumption (Drinking) of Alcoholic Products" sent to the Ministry of Health of the Russian Federation (for medicines for medical use) and the Ministry of Agriculture of the Russian Federation (for medicines for veterinary use) proposals for the inclusion in the list (deletion) of alcohol-containing

drugs (with the relevant documents and information) on paper with a copy in electronic form (on electronic information).

Alcohol-containing drugs that do not meet the above criteria or drugs for which there is information about the cancellation of state registration and its exclusion from the state register of drugs are subject to exclusion from the list.

For license applicants for the production of alcohol-containing drugs, additional requirements are currently being met, such as:

- on equipping containers for receiving the pharmaceutical substance of ethyl alcohol (ethanol) or ethyl alcohol with automatic means for measuring and recording the concentration and volume of anhydrous alcohol in the pharmaceutical substance of ethyl alcohol (ethanol) or in ethyl alcohol, the volume of the pharmaceutical substance of ethyl alcohol (ethanol) or ethyl alcohol in accordance with the equipment scheme of the specified equipment, containing information about the specified equipment, automatic means, and communications in accordance with the list information established by the Federal Service for Regulation of the Alcohol Market, as well as with the technical documentation of the manufacturer of automatic means for these means;
- on equipping equipment for accounting the volume of turnover and use of the pharmaceutical substance of ethyl alcohol (ethanol) or ethyl alcohol for the production of alcohol-containing drugs, as well as in the production of other drugs using the pharmaceutical substance ethyl alcohol (ethanol) or ethyl alcohol with technical means of fixation and transfer of information on the volume of production and turnover of ethyl alcohol (ethanol), alcoholic and alcohol-containing products to a single state a military automated information system for recording the volume of production and turnover of ethyl alcohol, alcoholic and alcohol-containing products.

11. A new type of administrative responsibility has been introduced for untimely entering data into the system for monitoring the movement of drugs or entering data that are unreliable. In addition, a number of important changes were made to the Code of Administrative Offenses of the Russian Federation

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

Federal Law of July 18, 2019 N 180-ФЗ "On Amendments to the Code of the Russian Federation on Administrative Offenses"

In 2019, the Code of Administrative Offenses of the Russian Federation introduced article 6.34, which provides that for late entry of data into the system for monitoring the movement of drugs for medical use or entering inaccurate data, a fine on officials in the amount of 5,000 to 10,000 rubles shall be imposed; for legal entities - from 50,000 to 100,000 rubles. In this case, individual entrepreneurs in the event of such violations are liable as legal entities. This regulatory legal act establishes that the absence of an identification tool (QR code) on the packaging of a medicinal product entails a fine on officials in the amount of 5,000 to 10,000 rubles; for legal entities - from 50,000 to 100,000 rubles. Along with the imposition of a fine, both for officials and legal entities, such sanction as confiscation of administrative offenses is also applicable.

In addition, part 1 of article 24.81 of the Code of Administrative Offenses of the Russian Federation 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 persons with disabilities to access

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. Such an offense shall entail the imposition of an administrative fine on officials in the amount of 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.

12. From April 7, 2019, new forms of prescription forms for medicines came into force.

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 medicines approved by Order of the Ministry of Health of Russia dated January 14, 2019 N 4н"

The Ministry of Health of the Russian Federation reports that the production of new prescription forms requires time. In this regard, the transition to new prescription forms should be carried out only from January 1, 2020.

13. A number of explanations are given regarding the drug labeling experiment, and a fee has been set for the provision of drug labeling codes.

Recommendations for participants in the experiment on labeling with identification tools and monitoring the turnover of certain types of drugs for medical use (together with "Characteristics of identification tools, requirements for structure and format, including the procedure for obtaining and using labeling codes and generating group codes", "Information requirements provided by the state information systems of federal executive bodies to the monitoring system, as well as to information transmitted of the monitoring system"), approved by RZN October 2, 2019

Decree of the Government of the Russian Federation dated May 08, 2019 N 577 "On approving the number of fees for the provision of marking codes necessary for the formation of identification tools and monitoring the movement of goods subject to mandatory marking by identification means, as well as the procedure for its collection"

The participants in the experiment on labeling with identification tools and monitoring the turnover of certain types of drugs for medical use (hereinafter - the Experiment) on the part of drug circulation entities are determined on the basis of voluntary registration in the monitoring system.

As part of the information interaction, the monitoring system exchanges information with state information systems of interested executive bodies, including through the infrastructure that provides information and technological interaction of information systems used to provide state and municipal services and perform state and municipal functions in electronic form. The monitoring system interacts with the following information systems: a single register of licenses for the production of medicines; a unified register of licenses, including licenses issued by state authorities of the constituent entities of the Russian Federation in accordance with the transferred authority to license certain types of health care activities; unified state information system in the field of healthcare; unified state register of legal entities; unified state register of individual entrepreneurs; state register of accredited branches, representative offices of foreign legal entities; automated information system of the Federal Service for Surveillance in Healthcare (automated information system of the Federal Service for Surveillance in Healthcare); Unified automated information system of customs authorities; information systems of drug circulation entities.

An application for participation in the Experiment on a voluntary basis is executed in the monitoring system in electronic form.

When transferring drugs between subjects of circulation of drugs, it is allowed to provide information to the monitoring system both by the subject of circulation of drugs carrying out the transfer of drugs and by the entity taking the drugs.

The fee for the provision of services for the provision of marking codes necessary for the formation of means of identification and monitoring the movement of goods subject to mandatory marking by means of identification will be 50 kopecks per 1 marking code excluding VAT. At the same time, no fee is charged for the provision of labeling codes for medicines for medical use included in the list of vital drugs, the maximum selling price of the manufacturer of which does not exceed 20 rubles.

14. From October 1, 2019, it became possible to purchase medicines without determining the Initial maximum price of the contract.

Federal Law of May 01, 2019 N 71-ФЗ "On Amendments to the Federal Law "On the Contract System in the Sphere of Procurement of Goods, Work, and Services to Ensure State and Municipal Needs"

In cases where the state or municipal customer does not have the opportunity to determine the exact amount of medicines required for purchase, it will become possible to indicate the maximum value of the contract price with the obligatory indication in the procurement documentation of the condition that payment is made at the unit price of the medicine based on the number of goods delivered but in an amount not exceeding the maximum value of the contract price.

In addition, the specified Federal Law determines that if the subject of the contract for the conclusion of which a tender or auction is held in the supply of goods necessary for normal life support (including funds for emergency medical assistance or medicines), and the bidder proposes the price of the contract (or the sum of unit prices) is 25 percent or lower than the initial (maximum) contract price, the initial sum of unit prices, such a procurement participant must justify the customer with the offer the estimated price of the contract, the sum of unit prices. Such a justification may include a letter of guarantee from the manufacturer indicating the price and quantity of the delivered goods, documents confirming the availability of goods from the procurement participant and other documents confirming the possibility of delivery at the proposed price, the sum of prices of units of goods.

15. The possibilities of obtaining a social tax deduction in the amount of the cost of drugs purchased by taxpayers at their own expense have been expanded, the Ministry of Finance of Russia has given explanations regarding the procedure and grounds for receiving the deduction.

Federal Law of June 17, 2019, N 147-ФЗ "On Amending Part Two of the Tax Code of the Russian Federation"

Letter of the Ministry of Finance of Russia dated June 13, 2019 N 03-04-05/43139

If previously a social tax deduction could be received by a taxpayer in the amount of the cost of medicines for medical use, listed in the List of medicines approved by Decree of the Government of the Russian Federation of March 19, 2001 N 201, appointed by the attending physician and acquired by the taxpayer at his own expense.

Now the cost of medicines subject to accounting in order to obtain a tax deduction is not limited to this list. A deduction is now granted on the cost of any medication prescribed by your doctor.

The Ministry of Finance clarifies that the prescription form N 107-1/y with the stamp “For the tax authorities of the Russian Federation, Taxpayer Identification Number” is the basis for obtaining a deduction for medicines.

16. The Government of Russia has established the rules for the clinical study of donated blood

Decree of the Government of the Russian Federation of June 22, 2019 N 797 “On approval of the Rules for the collection, storage, transportation and clinical use of donated blood and its components and on the invalidation of certain acts of the Government of the Russian Federation”

It was found that it is unacceptable to introduce into the container with donated blood and (or) its components any medications or solutions, except for a 0,9 percent sterile sodium chloride solution.

To ensure the safety of the clinical use of donated blood, traceability of data on the donor, donations, prepared donor blood and (or) its components, consumables (containers, reagents, solutions, drugs), donor blood samples, modes of storage and transportation of donated blood and (or) its components, recipient blood samples, work performers, as well as on compliance with safety requirements for the work performed on preparation, transportation, storage and clinical the use of donated blood and (or) its components.

17. The Ministry of Health of Russia has developed a memo for parents of children in need of medications containing psychotropic substances, containing recommendations for obtaining unregistered non-Russian territory medications.

The memo is published on the official website of the Ministry of Health of the Russian Federation

The memo consists of two sections: for those parents whose children already have a doctor’s opinion and a protocol of the council of the federal medical organization on the need to prescribe psychotropic drugs unregistered in the Russian Federation (such as diazepam, clobazam, midazolam, phenobarbital); for parents of children who, apparently, need these drugs because the prescribed registered drugs for the treatment of epilepsy were ineffective and/or it is necessary to use a pediatric form of a psychotropic drug (elixir, rectal solution, oromucosal solution), but the conclusions of medical commissions and there are no protocols of federal councils yet.

In particular, if you have a doctor’s report and transportation of the drug (for example, when you go to the cottage), you must have with you either a doctor’s report or a protocol from the federal council or a receipt for the drug. The drug is given for three months. Therefore, 2.5 months after receiving the drug, you must consult your doctor and inform about the need to receive the medicine for the next three months. In the absence of an appropriate opinion of the medical commission, it is necessary to contact the polyclinic at the place of residence or another medical organization that provides specialized medical care for children in the "neurology" profile or palliative medical care in order to obtain an opinion. If necessary, the attending physician in the district clinic or other medical organization where the child is being observed can refer the child to a specialized medical organization, including a hospital, for additional examination and / or to consider the availability of indications for the use of a psychotropic drug not registered in the Russian Federation drug and dose selection.

We believe that this memo can help patients and their parents quickly navigate in the order they receive the necessary medications, as often this requires a detailed analysis of the current legislation, which can cause difficulties and significantly increase time costs.

18. Significant changes have been made to the law on the circulation of medicines, which will enter into force in 2020.

Federal Law of December 27, 2019, N 475-ФЗ "On Amending the Federal Law "On the Circulation of Medicines" and the Federal Law "On Amending the Federal Law "On the Circulation of Medicines"

Federal Law of December 27, 2019, N 462-FZ "On Amending the Federal Law "On the Circulation of Medicines" and the Federal Law "On Amending the Federal Law "On the Circulation of Medicines"

Changes have been made regarding the disclosure of the meaning of the terms "generic drug" and "reference drug". Particular attention is paid to equivalence in terminology. In particular, the term "bioequivalence" was introduced, which means achieving comparable indicators of the rate of absorption, the degree of entry to the site of action, and the rate of excretion of one or more active substances with pharmacological activity when using drugs for medical use that have one international non-patented (chemical or group) name, in equivalent dosages and with the same method of administration. A reference drug is a drug that is used to evaluate bioequivalence or therapeutic equivalence, quality, effectiveness and safety of a reproduced drug or a bio-analog (biosimilar) drug (bio-analog). The original medicinal product is used as a reference medicinal product for medical use either, if the original medicinal product is not registered or is not in circulation in the Russian Federation and is not in circulation in foreign countries, the reproduced medicinal product or bio-analog (biosimilar) drug (bio-analog) which is first registered among those in circulation in the Russian Federation, bioequivalence or therapeutic equivalent The relevance, quality, effectiveness and safety of which were evaluated in relation to the original medicinal product, as well as the quality, effectiveness, and safety of which are confirmed by the results of pharmacovigilance and checks of compliance of drugs in civil circulation with the established requirements for their quality. As a reference medicinal product for veterinary use, a medicinal product for veterinary use, registered in the Russian Federation on the basis of the results of preclinical studies of drugs and clinical studies of drugs confirming its quality, effectiveness, and safety, is used. A reproduced drug is a medicine for medical use that has a qualitative composition and quantitative composition of active substances in an equivalent dosage form equivalent to a reference medicine, or a medicine for veterinary use that has the same as a reference medicine, qualitative composition and quantitative composition of active substances in the same dosage form, bioequivalence or therapeutic whose equivalence to the corresponding reference medicinal product is confirmed by relevant studies.

It is envisaged to allow the import into Russia of a specific batch of unregistered drugs containing narcotic drugs or psychotropic substances to provide medical care according to the vital indications of a particular patient or group of patients, if there is a decision of the medical commission of the medical organization on the inefficiency or impossibility of using other registered patients medicines, including those containing other active substances, and the need for delivery of a certain unregistered medicinal product with an indication of its international non-proprietary (or chemical, or grouping) name, form of release and quantity. The list of diseases and conditions and related medications containing narcotic drugs and psychotropic substances, in order to import them in accordance with the requirements of this part, is approved by the authorized federal executive body.

These changes come into force on March 1, 2020.

On January 1, 2023, a decision to cancel the state registration of a medicinal product and its deletion from the state register of medicines is taken if the holder or holder of the registration certificate of the medicinal product for medical use has not been presented within six months from the

date of suspension of the use of the medicinal product for medical use to the authorized body the documents (information in the documents) necessary for the examination of the registration dossier for a medicinal product in order to determine the interchangeability of a medicinal product for medical use, as well as in the event that an application is not submitted to amend the documents contained in the registration dossiers for registered medicinal products for medical use, in relation to the information specified in the instructions for medical use the use of drugs, within forty business days from the date of placement by the authorized body of information on the need to make instructions th for medical use of the drug changes to the information about the indications and contraindications for use for applying medicament identified side effects, adverse reactions when applying a medicament.

Delayed implementation of the labeling of drugs used in a number of nosologies. Medicinal products for medical use intended to provide persons with hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, malignant neoplasms of lymphoid, hematopoietic and related tissues, multiple sclerosis, persons after transplantation of organs and (or) tissues produced before December 31, 2019 years, as well as other medicinal products for medical use, produced before July 1, 2020, are subject to storage, transportation, leave, sale, transfer, use without application means of identification prior to the expiry of their validity.

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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 industrial practice is “Health care and pharmaceutics”.

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