BRACE
Law Firm

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DIGEST
of regulation of the Russian pharmaceutical industry

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Dear Colleagues!

We are glad to bring to your attention the latest digest of regulation of the Russian pharmaceutical industry in February 2019, prepared by the BRACE Law Firm.

It should be noted an increase in legislative activity in February 2019, as well as the adoption of a number of important innovations in the legislation governing pharmaceutical activity.

The Board of the Eurasian Economic Commission approved the Guidelines for the selection of tests and eligibility criteria for the preparation of specifications for medicinal plant raw materials, plant pharmaceutical substances (preparations based on medicinal plant materials) and medicinal plant preparations containing general principles for the preparation of specifications and methods for selecting criteria.

Since February 2019, such documents as the Standard of primary health care for children with Juvenile arthritis with the systemic onset and the Procedure for Issuing permits for importation into the Russian Federation of a specific batch of an unregistered biomedical cellular product and a form of Permits for Importation into the Russian Federation of a specific batch of unregistered biomedical cell product.

The Ministry of Health of Russia approved the criteria for the formation of the list of alcohol-containing drugs included in the state register of drugs. In addition, the Ministry of Health of Russia proposed drafts of regulatory legal acts that establish additional requirements for documents submitted for state registration of drugs and establish a standard of monthly costs per citizen receiving social assistance in the form of provision of medicines.

It is also important to note that February was marked by an important judicial precedent affecting the protection of drug patent holders.

Sincerely,

BRACE Law Firm

1. Laws, by-laws, legal news

1.1. The Board of the Eurasian Economic Commission approved the Guideline for the selection of tests and acceptance criteria for the preparation of specifications for medicinal plant materials and medicinal herbal preparations.

Recommendation of the Board of the Eurasian Economic Commission dated February 12, 2019 N 6 "On the Guideline to the selection of tests and acceptance criteria for the preparation of specifications for medicinal plant raw materials, plant pharmaceutical substances (products based on medicinal plant materials) and medicinal plant preparations"

The Guideline contains general principles for the preparation of specifications for medicinal plant raw materials, herbal pharmaceutical substances (medicinal plant medicinal products) and medicinal herbal preparations for their registration in accordance with the Rules for Registration and Expertise of Medicines for Medical Use approved by the Council of the Eurasian Economic Commission dated November 03, 2016 N 78.

The member states of the Eurasian Economic Union are recommended to apply this Guideline after 6 months from the date of publication of the Recommendation on the official website of the Eurasian Economic Union.

It is established that the acceptance criteria in the specifications should be established and justified on the basis of data and results obtained in the analysis of the series used for preclinical (clinical) studies or on the basis of information from relevant literature sources.

Specification for medicinal plant raw materials should contain: botanical characteristics of medicinal plants; macro- and microscopic characteristics, phytochemical characteristics; biological (geographic) variability data; information about the conditions of cultivation, collection, drying; data on chemical processing before and after collection (pesticides, fumigants); description of the profile of the components of the composition of medicinal plant materials and their stability.

The specification for the finished dosage forms of medicinal herbal preparations should contain: data on the quality of medicinal plant raw materials and (or) plant pharmaceutical substances (preparations based on medicinal plant raw materials); description of the process (temperature effect, residual solvents, etc.); profile and stability of the active components (composition) during packaging; the indication of the series used in preclinical (clinical) trials (safety assessment and determination of efficacy) (if applicable).

Section 5 of the Guideline establishes in detail the basic tests and acceptance criteria. Also the document, in addition to standard criteria, contains additional (specific) tests and acceptance criteria.

We believe that this document significantly specifies the necessary requirements for the selection of tests and eligibility criteria for the preparation of specifications.

1.2. From March 10, 2019, the Procedure for issuing a permit for importing a specific batch of an unregistered biomedical cell product into the Russian Federation came into force.

Decree of the Ministry of Health of Russia dated January 30, 2019 N 31n "On approval of the procedure for issuing permits for import into the Russian Federation of a specific batch of an unregistered biomedical cellular product and the form of permission for import into the Russian Federation of a specific batch of an unregistered biomedical cellular product"

The document establishes that in order to obtain an appropriate permit, subjects of treatment of biomedical cellular products send the following documents or information to the Ministry of Health of Russia (hereinafter the Ministry):

- application for a permit;

- a copy of the agreement (contract), annexes and (or) additions to it, and in the absence of an agreement (contract) - a copy of another document confirming the intentions of the parties;
- certificate of the manufacturer of the biomedical product certifying the compliance of the imported biomedical cell product with the requirements of the regulatory documentation for the biomedical cell product;
- specification for biomedical cell product;
- information on the main state registration number and tax identification number of the applicant;
- in case of import of a specific batch of an unregistered biomedical cellular product intended for carrying out the biomedical examination and (or) preclinical studies, substantiation of the quantity of the imported biomedical cellular product;
- in case of importing a specific batch of an unregistered biomedical cell product intended for conducting clinical trials of a biomedical cell product: justification of the quantity of the imported biomedical cell product; information about the Ministry's permission to conduct a clinical trial of a biomedical cell product; copies of documents confirming the proper labeling of a biomedical cellular product, determining their intended use exclusively in clinical studies;
- in case of import of a specific batch of an unregistered biomedical cellular product intended for the provision of medical care to a particular patient for health reasons: information on the full name and address of the federal institution in which the patient is given medical care; the conclusion of the consultation of doctors of the federal institution, in which medical assistance is provided to a specific patient with an indication of the amount of the biomedical cell product to be imported into the Russian Federation.

The specified legal act approved the form of the relevant permit. Attention should be paid to the fact that the validity of the procedure for issuing permits for importing a specific batch of an unregistered biomedical cell product into the Russian Federation is limited on April 30, 2019 in accordance with paragraph 3 of the Government of Russian Federation Decree N 1229 of October 16, 2018 "On the introduction of a temporary order of import into Russia Federation of biomedical cellular products.

1.3. On February 5, 2019, a new standard of primary medical care for children with juvenile arthritis came into force.

Order of the Ministry of Health of Russia of December 29, 2018 N 953n "On approval of the standard of primary health care for children with juvenile arthritis with systemic onset"

This document establishes a different List of drugs for medical use registered in Russia, indicating the average daily and course doses, different from the List approved by the Order of the Russian Ministry of Health dated 09 November 2012 N 777n.

The standard draws attention to the fact that the prescription and use of drugs for medical use, medical devices and specialized medical foods that are not part of the standard of medical care are allowed in the case of medical indications (idiosyncrasy, for health reasons) by a decision of the medical board.

1.4. On the territory of advanced socio-economic development "Mendeleevsk" provides for the production of medicines.

Decree of the Government of Russian Federation dated February 12, 2019 N 123 "On the creation of the territory of advanced socio-economic development "Mendeleevsk"

The Decree of the Government of Russia on the territory of advanced socio-economic development "Mendeleevsk" provides, inter alia, for such an economic activity as the production of medicines and materials used for medical purposes.

During the first year after the legal entity was included in the register of residents of the territory of advanced socio-economic development, the minimum amount of capital investments of the resident of the territory of priority development carried out within the framework of an investment project implemented by the specified resident in respect of relevant economic activities are 2.5 million rubles and the minimum number of new permanent jobs created as a result of the investment project implementation is 10 units.

1.5. The Ministry of Finance of Russia provided explanations regarding the preservation of preferential VAT rates in respect of a number of goods, works, and services.

Letter of the Ministry of Finance of the Russian Federation dated February 07, 2019 N 03-01-11 / 7176

The Ministry explains that since January 1, 2019, an increase in the VAT rate from 18 to 20 percent has been introduced. At the same time, VAT benefits in the form of exemption from VAT, as well as a reduced VAT rate of 10 percent, which are applied to social goods (services), a number of food products, children's goods, as well as medicines and medical products, remain.

1.6. The Government of the Russian Federation has approved the procedure for forming a list of alcohol-containing drugs, whose production activities do not cover the Federal Law “On State Regulation of the Production and Turning of Ethyl Alcohol, Alcohol, and Alcohol-Containing Products, and on Limiting the Consumption (Drinking) of Alcohol Products”.

Decree of the Government of the Russian Federation of February 28, 2019 N 201 “On Approval of the Rules for Forming the List of Alcohol-Containing Drugs, for the production, production and (or) turnover of which are not covered by the Federal Law “On state regulation of production and turning of ethyl alcohol, alcohol and alcohol-containing products and about limiting consumption (drinking) of alcohol products"

The list is compiled on the basis of the proposals submitted to the Ministry of Health of the Russian Federation (for medicinal products for medical use) and the Ministry of Agriculture of the Russian Federation (for medicinal products for veterinary use) to include (exclude from the list) alcohol-containing medicinal drugs (with attached documents and information) on paper with a copy attached in electronic form (on electronic media information).

The specified regulatory legal act establishes that alcohol-containing drugs registered in the Russian Federation in the prescribed manner and included in the state register of drugs that meet one or more of the following criteria are subject to inclusion in the list:

- the volume of consumer packaging (packaging) does not allow their use as a substitute for alcoholic beverages;
- the retail price of the alcohol-containing drug, when compared in comparable volumes for consumer packaging (packaging) and ethyl alcohol content is higher than the retail price for alcoholic beverages;
- the functional purpose of the alcohol-containing drug in accordance with the instructions for its use is not related to its ingestion, except for drugs with the international non-proprietary name "ethanol" at the stage of their production in all liquid dosage forms and dosages.

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

The specified document is currently approved but has not been officially published. Entry into force of the Resolution of the Government of Russia is planned after 7 days from the date of its official publication.

1.7. The Russian Government approved amendments to the regulations on licensing the production of medicines in terms of the production of alcohol-containing medicines.

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

Additional requirements are spread on applicants for licenses for the production of alcohol-containing drugs, such as:

- on equipping of containers for accepting 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, a 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 tools and communications in accordance with the list information established by the Federal Service for the regulation of the alcohol market, as well as with the technical documentation of the manufacturer of automatic funds for these funds;
- on equipment for recording the volume of trafficking and the use of the pharmaceutical substance of ethyl alcohol (ethanol) or ethyl alcohol for the production of alcohol-containing medicines, as well as in the production of other medicines using the pharmaceutical substance of ethyl alcohol (ethanol) or ethyl alcohol by means of fixation and transferring information on the volume of production and circulation of ethyl alcohol (ethanol), alcoholic and alcohol-containing products to a single state vein automated information system for recording the volume of production and turnover of ethyl alcohol, alcoholic and alcohol-containing products.

2. Drafts of legal acts

2.1. The Russian Ministry of Health proposes for approval a list of diagnostic tools procured through subsidies from the federal budget for detecting and monitoring the treatment of persons infected with human immunodeficiency viruses, including in combination with hepatitis B viruses and (or) C, in the subjects of the Russian Federation.

Draft Decree of the Ministry of Health of Russia "On approving the list of diagnostic tools procured through subsidies from the federal budget to identify and monitor the treatment of persons infected with human immunodeficiency viruses, including in combination with hepatitis B viruses and (or) C in the subjects of the Russian Federation"

The list includes, among other things, Reagent and Reagent Kits for the determination of antibodies to HIV-1 and HIV-2 and the HIV-1 p24 antigen in human biological material in the absence of special laboratory equipment using the method of an unassisted enzyme immunoassay or chromatographic analysis, as well as Standard Serum Panels, containing / not containing antibodies / antigen to HIV-1 and HIV-2 for conducting input quality control.

2.2. The Russian Ministry of Health has been asked to approve a list of diagnostic tools procured through subsidies from the federal budget to identify, determine the sensitivity

of Mycobacterium tuberculosis and monitor the treatment of people with multidrug-resistant tuberculosis in the regions of the Russian Federation.

Draft Order of the Ministry of Health of Russia "On approving the list of diagnostic tools procured through subsidies from the federal budget to identify, determine the sensitivity of Mycobacterium tuberculosis and monitor the treatment of people with multidrug-resistant tuberculosis in the Russian Federation"

This list includes reagents for the isolation and amplification of deoxyribonucleic acid of the Mycobacterium tuberculosis complex from samples and cultures isolated from human biological material by the method of a polymerase chain reaction with the determination of mutations associated with the resistance of Mycobacterium tuberculosis to reserve tuberculosis drugs.

2.3. The Ministry of Health proposes to declare invalid the procedure for monitoring movement and registration in the subjects of the Russia of drugs intended to provide persons with hemophilia, cystic fibrosis, pituitary nanism, Gaucher disease, malignant neoplasms of lymphoid, hematopoietic and related tissue, multiple sclerosis

Draft Order of the Ministry of Health of Russia "On the invalidation of the order of the Ministry of Health of the Russian Federation dated December 21, 2016 N 983n "On approval of the procedure for monitoring movement and registration in the subjects of the Russian Federation of drugs intended to provide persons with hemophilia, cystic fibrosis, pituitary nanism, disease Gaucher, malignant neoplasms of lymphoid, hematopoietic and related tissues, multiple sclerosis, persons after organ and (or) tissue transplantation, up to SIC to the authorized bodies of executive power of subjects of the Russian Federation received the results of the monitoring data and matching applications authorized by the executive authorities of the Russian Federation on the redistribution of drugs among the subjects of the Russian Federation"

The proposal is justified by the fact that on January 1, 2019, the Government of the Russian Federation dated December 26, 2011 N 1155 "On the procurement of medicines intended to provide persons with hemophilia, cystic fibrosis, pituitary nanism, Gaucher disease, malignant neoplasms of lymphoid, hematopoietic and related tissues, multiple sclerosis, persons after transplantation of organs and (or) tissues", in fulfillment of which the Order of December 21, 2016 N 983n was adopted.

2.4. The Ministry of Health proposes to make changes to the procedure for determining the initial (maximum) contract price.

Draft Order of the Ministry of Health of the Russian Federation "On amendments to the procedure for determining the initial (maximum) contract price, contract price, concluded with a single supplier (contractor, performer) when purchasing medicines for medical use, approved by Order of the Ministry of Health of the Russian Federation of October 26 2017 N 871n"

It is proposed to provide that the application of reference prices by customers will be carried out if the relevant information is placed in the United procurement information system due to the fact that in 2019 it is planned to switch to the calculation and use of reference prices for medicines for medical use, for which interchangeability is defined.

2.5. The Ministry of Industry and Trade of Russia proposes to provide for the issuance of a document that confirms that the production of a pharmaceutical substance is carried out in accordance with the requirements of GMP

The draft federal law "On amendments to article 5 of the Federal Law "On the circulation of medicines"

The draft law provides for the possibility of issuing a document that confirms that the production of a pharmaceutical substance is carried out in accordance with the requirements of the rules of good manufacturing practice, and is to be submitted at the request of the authorized body of the country into which the pharmaceutical substance is imported. The main goal of this draft law is to improve export-import operations with pharmaceutical substances and bring the current Russian legislation in line with the law of the EEU.

2.6. The Ministry of Health has proposed to supplement the requirements for the application for registration of medicines.

The draft federal law "On amendments to article 18 of the Federal Law "On the circulation of medicines"

Draft law touches upon the issue of preventing the violation of exclusive rights during the state registration of drugs. In the application for state registration of a medicinal product, it is proposed to provide information on the availability of exclusive rights relating to a medicinal product to inventions certified by patents issued by the federal executive body on intellectual property or patents that are valid in the Russian Federation in accordance with international treaties of the Russian Federation, as well as information on the availability of exclusive trademark rights relating to the drug, supporting evidence for the trademark.

When adopting this draft law, a written confirmation of the applicant should be attached to the said application that the state registration of the medicinal product does not violate the exclusive rights of third parties for inventions and trademarks and copies of patents and certificates certifying the exclusive rights to inventions and trademarks.

2.7. The Ministry of Health proposes to establish a standard of monthly costs per citizen receiving social assistance in the form of provision of medicines.

Draft Resolution of the Government of the Russian Federation "On the establishment of a standard of financial expenses per month per citizen receiving state social assistance in the form of social welfare services in accordance with the standards of medical care according to the prescriptions of the doctor (paramedic) drugs for medical use, medical products, as well as specialized medical nutritional products for disabled children, for 2019"

The draft of the Decree of the Government of Russia establishes for 2019 the rate of financial expenses per month per citizen receiving state social assistance in the form of social welfare services in accordance with the standards of medical care for prescription drugs issued by a doctor (medical assistant) applications, medical products, as well as specialized medical nutritional products for children with disabilities, and the amount of 861.8 rubles.

3. Judicial and law enforcement practice

3.1. The Court on Intellectual Property Rights upheld the decision of the lower court on obliging the person who committed patent infringement to file with the Ministry of Health an application to cancel the state registration of the drug Gefitinib.

The decision of the court for intellectual property rights dated February 28, 2019, case N A40-106405/2018

The court defended the interests of the company AstraZeneca UK LIMITED and upheld the Resolution of the Ninth Arbitration Court of Appeal of 20.20.2018 by which Jodas Expoim LLC was obliged to submit to the Ministry of Health a statement about the cancellation of the state registration of the drug Gefitinib and submit a statement of exclusion from the state register producer prices for medicines included in the list of essential and essential medicines, information on state registration oh the selling price of the manufacturer for the drug. This legal entity was also prohibited from carrying out actions aimed at registering a medicinal product containing Gefitinib in the Russian Federation and maximum selling prices for the medicinal product prior to the expiration date of the patent.

This judicial precedent may have an important impact on the protection of the rights and legitimate interests of drug manufacturers, since there have been previous cases when courts passed decisions not in favor of exclusive rights holders on the grounds that the state registration of generics before the expiration of a patent expired in the circulation of the drug after the expiration of the patent.