BRACE
Law Firm

August 2019

DIGEST
of regulation of the Russian pharmaceutical industry

September 11, 2019

Dear Colleagues!

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

During the indicated period the Board of the Eurasian Economic Commission adopted the Guidelines for controlling the risks of microbial contamination of medicinal plant materials and herbal medicines, as well as the Guidelines for the assessment and control of DNA-reactive (mutagenic) impurities in medicines and setting limits on potential carcinogenic risk. These legal acts are designed to improve the quality of medicines in circulation in the territory of the Eurasian Economic Union.

Important amendments to the current Russian legislation, aimed at increasing the investment attractiveness of the Russian market for large investors by providing them with special preferences and introducing tax benefits when concluding and implementing special investment contracts, were adopted.

Some new requirements have been introduced for the content of the registration dossier for immunobiological drugs for veterinary use.

One of the most important legislative initiatives is the proposal to approve a standard form of a contract for charging fees for providing marking codes.

The Ministry of Health of Russia proposed the adoption of a new procedure for determining the interchangeability of drugs for medical use.

The above, as well as other equally important innovations and legislative initiatives, can be found in more detail below.

Sincerely yours,

BRACE Law Firm

1. Laws, by-laws, legal news

1.1. The Eurasian Economic Union has adopted the Guidelines for controlling the risks of microbial contamination of herbal raw materials, herbal pharmaceutical substances and herbal medicines.

Recommendation of the Board of the Eurasian Economic Commission "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" dated August 6, 2019, N 24

This document is used in the production and examination of the quality of plant products and herbal medicines approved for circulation in the territories of the Member States of the Eurasian Economic Union (hereinafter – the EAEU).

It is 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 in pH, increased humidity during storage, causing the growth of microorganisms, are taken into account. In order to prevent microbial contamination of cultivated plants, the correct growing conditions should be selected and their control ensured. Direct use in the cultivation of plants as a fertilizer of human excrement, as well as wastewater, is not allowed.

The chosen method of reducing microbial contamination should have a minimal effect so as not to entail undesirable changes in the chemical composition and physical properties that affect the quality of the finished drug. In addition, it should be proved that there are no hazardous degradation products formed during processing after applying one or another decontamination method. Other regulatory requirements for assessing the microbial contamination of a herbal medicinal product are established depending on the quality of the starting materials, the production process, their purpose and are justified during the validation study.

The above and other rules aimed at controlling the risks of microbial contamination are developed in detail in the above document, which will enter into force on February 08, 2010.

1.2. The EAEU adopted the Guidelines for the Assessment and Control of DNA Reactive (Mutagenic) Impurities in Medicines and Establishing the Limits of Potential Carcinogenic Risk.

Recommendation of the Board of the Eurasian Economic Commission "On the Guidelines for the Assessment and Control of DNA-Reactive (Mutagenic) Impurities in Medicines and Establishing the Limits of Potential Carcinogenic Risk" dated August 6, 2019, N 23

It has been established that the purpose of this Guidelines is to ensure the application of a unified methodology for the identification, categorization, qualification, and control of mutagenic impurities in the composition of pharmaceutical substances and drugs to limit the potential carcinogenic risk they create. However, this document does not apply to pharmaceutical substances and drugs intended for the treatment of advanced cancer.

The guidelines establish that the allowable intake of mutagenic impurities is based on established risk assessment strategies. The acceptable risk in the early phase of development is established at a theoretically calculated level of mutagenic impurities, leading to the occurrence of tumors in humans with a frequency of approximately 1 case per 1,000,000. The acceptable increase in carcinogenic risk for new drugs at later stages of development and for registered drugs is

established at a theoretically calculated level of occurrence of tumors in humans with a frequency of 1 case per 100,000.

Presumably, this document should provide a slight increase in carcinogenic risks, which will improve the quality of medicines.

The specified document shall enter into force on February 08, 2021. The requirements of the Guidelines do not apply to medicines registered in accordance with the EAEU law before the above date for the start of application of the Guidelines.

1.3. The Ministry of Health of Russia has clarified the ratio of the names of dosage forms included in the list of Vital and Essential Drugs and the names of dosage forms to be indicated in applications for state registration of medicines.

Letter of the Ministry of Health of Russia dated July 31, 2019, N 25-1/I/2-6859

The Office explains that one of the reasons for the adoption of this legal act was the receipt of a large number of requests regarding the ratio of dosage forms of drugs named in the List of Vital and Essential Drugs for 2019, approved by Decree of the Government of the Russian Federation dated December 10, 2018 N 2738- p with a list of names of dosage forms of drugs for medical use, approved by Order of the Ministry of Health of Russia on July 27, 2016 N 538n.

As a result, the Ministry of Health of Russia cited in tabular form the ratios of the dosage forms given in the above documents. In particular, such a dosage form as “compressed gas” from the list of Vital and Essential Drugs correlates with the dosage form “medical compressed gas”, “tablets, sustained-release, coated tablets”, correspond to the dosage form “coated tablets”, and others.

1.4. A set of amendments to the legislation governing investment activities in the framework of special investment contracts entered into force.

Federal Law of August 2, 2019, N 290-FZ “On Amendments to the Federal Law “On Industrial Policy in the Russian Federation” concerning the regulation of special investment contracts”

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

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 a subject of the Russian Federation during term of the contract is obliged to implement measures to stimulate activities in the industry (in the framework of contract).

According to the amendments, the Federal Law “On Industrial Policy in the Russian Federation” is supplemented by Chapter 2.1, according to which the Special Investment Contract implements or develops the technology, the application 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 special investment contract should include a list of incentive measures for industrial activity applied to the investor, provided that he fulfills the obligations under such a contract. The contract does not include a list of incentive measures that the investor can take following the measures provided by applicable law, regardless of the contract. Also, for participants in the competitive selection for concluding a Special Investment Contract, a duty is established before submitting applications to coordinate with the subject of the Russian Federation and the municipality the place of production of a particular 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 set if more than 90% of the investor's income is made up of a special investment contract. Innovations in the Tax Code of Russia introduce the possibility of separate accounting of investor income.

Moreover, 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 applies from the tax period in which the first profit from the implementation of the investment project was received to the reporting (tax) period in which the organization loses its taxpayer status as a participant in a special investment contract, but no later than the reporting (tax) period in which the aggregate the number 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 insulating the 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.

1.5. Amendments have been made to the legal acts regulating the circulation of medicines for veterinary use.

Federal Law of August 2, 2019, N 297-FZ "On Amending Certain Legislative Acts of the Russian Federation Regarding the Regulation of the Circulation of Medicines for Veterinary Use"

Now, the Federal State Supervision in the Field of Medicinal Products Circulation also includes carrying out control purchases to verify that the pharmaceutical business entities comply with the rules of good pharmacy practice of medicines for veterinary use.

Officials of the state oversight body are empowered to conduct test purchases of drugs for veterinary use.

The registration dossier during state registration of immunobiological drugs for veterinary use should contain information about the strain, including its name, information about the origin, its properties, characteristics and place of deposit. Also, upon registration, it is required to provide a document containing the name of the pharmaceutical substance, its structure, general properties. At the same time, information on impurities and specifications for a pharmaceutical substance, the results of an analysis of a series of pharmaceutical substances, and stability data are not presented during state registration of immunobiological drugs for veterinary use. Also, information on the use of new excipients is no longer required for these medicines, but additional information must be provided on the state registration of genetically modified organisms intended for release into the environment.

The holder or owner of the registration certificate of a medicinal product for veterinary use is required to submit a report on the results of pharmacovigilance once every six months within two years after state registration of the drug in the Russian Federation, then annually for the next three years and then once every three years.

2. Drafts of regulatory legal acts

2.1. The Ministry of Health has developed a draft Procedure for determining the interchangeability of drugs for medical use.

Draft Decree of the Government of the Russian Federation "On Approving the Procedure for Determining the Interchangeability of Medicines for Medical Use, the Form of Conclusion of the Federal State Budget Institution of the Ministry of Health of the Russian Federation, Created to Enforce the Authority of the Ministry to Issue Permits for Clinical Trials of Medicinal Products for Medical Use and (or) on state registration of medicines for medical of applications, interchangeability or interchangeable drugs for medical use"

The project proposes new regulation instead of the Decree of the Government of the Russian Federation of October 28, 2015, N 1154 "On the procedure for determining the interchangeability of drugs for medical use".

It is proposed to introduce a legal norm that, within the framework of one international non-proprietary (or chemical, or grouping) name, drugs are combined into separate groups, within each of which drugs are interchangeable. A reproduced medicinal product (bio-analogous (biosimilar) medicinal product (bio-analog)), registered according to the results of bioequivalence or therapeutic equivalence studies, is interchangeable with its reference medicinal product, and the reference medicinal product is interchangeable with the indicated reproduced (biosimilar) drug.

This document establishes that drugs in various dosage forms can also be used interchangeably if there are no clinically significant differences according to the results of expert studies.

Information on the interchangeability of medicinal products for medical use within the framework of one international non-proprietary (or chemical, or grouping) name for the purpose of including it in the list of interchangeable medicinal products for medical use is submitted by the expert institution to the Ministry every month no later than the twentieth of a month, together with conclusions drawn up on the specified calendar date.

2.2. The Ministry of Industry and Trade of Russia has developed a draft standard form for a contract for the collection of marking codes.

Draft order of the Ministry of Industry and Trade of the Russian Federation "On approval of the standard form of the contract for charging fees for providing marking codes"

According to the draft of this agreement, the operator is obliged under the applications of the participant (the person requesting the marking codes) to form the number of marking codes and provide them to the participant, and the participant is obliged to pay for the services of providing marking codes on the terms of the Agreement.

Payment of services for the provision of marking codes is carried out by the participant transferring advance payments to the operator's bank account until the registration (entry) in the Monitoring System for the Movement of Medicines information on applying the identification tool.

2.3. The Ministry of Agriculture of Russia proposes to amend the Procedure for certification of an authorized person of a manufacturer of medicines for veterinary use.

Draft order of the Ministry of Agriculture of Russia "On Amendments to the Procedure for Certification of an Authorized Person for a Manufacturer of Medicinal Products for Veterinary Use, approved by Order of the Ministry of Agriculture of Russia of April 20, 2017 N 192"

The specified draft resolved the issue of transferring the time of certification, as well as the non-appearance of the certified person. A one-time transfer of time for the certified person to pass the test of knowledge control is allowed no more than ten working days in the event of a preliminary (no later than one day) written notification to the Certification Commission about the impossibility of appearing to pass the test of knowledge control with an indication of the reason.

It is proposed that in case the certified person fails to appear on the test control of knowledge without prior notification of the Certification Commission, as well as in case of transfer of the time for passing the test knowledge control with the subsequent absence of the certified person to test knowledge control by the Certification Commission, a decision is made to refuse certification as an authorized person of the manufacturer.

2.4. The Ministry of Finance of Russia proposes to approve the procedure for assessing the reliability of accounting for the volume of production, turnover and (or) use of the pharmaceutical substance of ethyl alcohol (ethanol) for the production of alcohol-containing drugs and (or) alcohol-containing medical devices.

Draft Order of the Ministry of Finance of Russia "On approving the procedure for evaluating the reliability of accounting for the volume of production, turnover and (or) use of the pharmaceutical substance of ethyl alcohol (ethanol) for the production of alcohol-containing drugs and (or) alcohol-containing medical products in the production process of other drugs and (or) medical products, as well as the production, manufacture and (or) turnover (excluding retail) of alcohol-containing drugs and (or) alcohol-containing medical products"

Formulas are established for evaluating the reliability of volume accounting. Namely, for organizations engaged in the production of a pharmaceutical substance of ethyl alcohol (ethanol), such indicators are provided as: the volume of such a pharmaceutical substance, measured by a measuring instrument for a reporting period of time (days) after the end of the last technological operation related to its production, before being stored or for use, in decalitres; as well as the volume of the specified pharmaceutical substance, obtained according to the primary accounting documents of the organization after the end of the last technological operation related to its production, before being transferred to storage or for use for the reporting period of time.

2.5. The Ministry of Finance of Russia proposes for approval a draft order establishing standards for natural attrition in the production, circulation and (or) use of the pharmaceutical substance of ethyl alcohol (ethanol) or alcohol-containing drugs and medical devices.

Draft Order of the Ministry of Finance of Russia "On the approval of the norms of natural loss in the production, turnover and (or) use of the pharmaceutical substance of ethyl alcohol (ethanol), as well as in the production and (or) turnover (except for retail sale) of alcohol-containing drugs and (or) alcohol-containing medical products

The said document proposes to establish the rate of natural loss in the production of the pharmaceutical substance of ethyl alcohol (ethanol) equal to 2,21% (as a percentage of the amount of anhydrous alcohol); the rate of natural loss during the purchase, storage, delivery, transportation and (or) use of the indicated pharmaceutical substance is equal to (in containers not exceeding 1 liter in the spring and summer period 0,024%, in the autumn and winter period 0,008%), (in containers over 1000 liters in the spring-summer period of 0,065%, in the autumn-winter period of 0,016%); the rate of natural loss in the production of alcohol-containing drugs and (or) alcohol-containing medical devices, equal to 2,21% for alcohol solutions.

3. Judicial and law enforcement practice

3.1. The Federal Service for Intellectual Property stood on the side of the VITA Pharmacy Chain in the issue of recognizing the grant of legal protection to a trademark, similar to the extent of confusion with the trademark of the pharmacy network, completely

invalid.

The decision of the Federal Service for Intellectual Property of August 9, 2019, on application N 2016727904

The Federal Service for Intellectual Property decided that the popularity and current market reputation of the VITA group of companies as a pharmacy network make it possible for consumers to be misled about the person providing the services marked with the contested trademark as originating from the said group of persons, which is not true. As a rule, when establishing the ability of a sign to mislead a consumer, information about trademarks is considered, the provision of legal protection to which is invalidated because the actions of the copyright holder are an act of unfair competition and abuse of law.

If you have any questions regarding this digest, please contact us:
✓ info@brace-lf.com
✓ +7(499)755-56-50

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”.

We provide legal assistance in the field of legal support of commercial activities, dispute resolution and litigation, antitrust law, public and corporate procurement, international trade law and some other areas.