BRACE
Law Firm

## September 2019

# DIGEST
# of regulation of the Russian pharmaceutical industry

October 23, 2019

## Dear Colleagues!

We are glad to propose to your attention the Digest of legal regulation of the Russian pharmaceutical industry for September 2019, prepared by BRACE Law Firm. September of 2019 has been distinguished by significant lawmaking activity, as well as the adoption of a number of significant legal acts in the field of the pharmaceutical sector:

- The Board of the Eurasian Economic Commission has developed such important guidelines and legal acts as the Guideline for the preclinical and clinical development of combined drugs, the Guideline for determining the scope of laboratory tests in the examination of drugs, the Procedure for maintaining the nomenclature of dosage forms and a directory of routes for administering drugs.
- The Government of Russia 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.
- The Russian Ministry of Health is proposing for approval a new Procedure for calculating and determining the initial (maximum) price of the contract, and it is also proposed to amend the standard contract for the supply of medicines for medical use to bring it into line with current procurement legislation.
- Federal Law of September 29, 2019 No. 325-FZ stipulates that from January 1, 2020, the tax regime in the form of a single tax on imputed income cannot be applied drugstores.
- The Ministry of Industry and Trade of Russia has approved a standard form of an agreement on the provision of services for the provision of labeling codes to pharmaceutical companies.
- The Ministry of Health of Russia has published a draft plan for approval of the List of Essential and Essential Medicines for Medical Use for 2020.

The above and other important changes to the current legislation, as well as legislative initiatives, can be found in this Digest in more detail.

Sincerely yours,

**BRACE Law Firm**

# 1. Laws, by-laws, legal news

## 1.1. The Eurasian Economic Commission has prepared Guidelines for the Preclinical and Clinical Development of Combined Medicines.

*Recommendation of the Board of the Eurasian Economic Commission of September 2, 2019 N 25 "On the Guideline for the Preclinical and Clinical Development of Combined Medicines"*

This document describes approaches to the preclinical and clinical development of combination drugs (fixed combinations of active substances, fixed dosage combinations of active substances) containing two or more active substances in one dosage form.

The scope 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 product. There are several options for combinations of active ingredients in the combination drug:

- a combined drug in the form of a fixed combination of active substances registered in at least one of the EAEU Member States as monocomponent drugs and used in this combination in world clinical practice as registered drugs;
- a combined drug in the form of a fixed combination of active substances registered in at least one of the EAEU Member States as monocomponent drugs, but not used in this combination in world clinical practice as registered drugs;
- a combined drug in the form of a fixed combination of active substances, consisting of one or more new active substances that have not previously been registered in any of the EAEU Member States as monocomponent or combined medicines, and which have not been used in world clinical practice as registered medicines preparations.

It is supposed to conduct studies of the general toxic properties of the combined active substances, genotoxicity, and carcinogenicity of a combination of active substances.

## 1.2. The EAEU adopted the Guideline for determining the scope of laboratory tests in the examination of drugs.

*Recommendation of the Board of the Eurasian Economic Commission "On the Guideline for determining the scope of laboratory tests in the examination of drugs" dated September 10, 2019 N 28*

The manual contains recommendations on determining the volume 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 Drugs for Medical Use, approved by the Decision of the Eurasian Economic Council Commission dated 03/03/2016 N 78.

Depending on the characteristics of the production of a particular drug, a selection of laboratory tests is performed:

- when examining the registration dossier of a medicinal product manufactured at different production sites (producing bulk pharmaceutical product) using the active pharmaceutical substance of one manufacturer, laboratory tests of samples of pharmaceutical products produced at one production site for all indicators are carried out;
- when examining the registration dossier of a drug produced at one production site (producing bulk pharmaceutical product) using an active pharmaceutical substance of different manufacturers,

laboratory tests of samples of a medicinal product produced at a specified production site using an active pharmaceutical substance of one manufacturer are carried out for all indicators.

- when examining the registration dossier of a drug produced at different production sites (producing “in bulk”) using an active pharmaceutical substance from different manufacturers, laboratory tests of samples produced at one production site using an active pharmaceutical substance from one manufacturer are carried out for all indicators ( excluding biological drugs).

For biological medicinal products – according to all indicators for all sites and using all the declared manufacturers of active pharmaceutical substance.

**1.3. The EAEU approved the nomenclature of dosage forms and the procedure for its maintenance.**

*The decision of the Board of the Eurasian Economic Commission of September 17, 2019 N 158 “On the nomenclature of dosage forms and a directory of routes of administration of drugs”*

Information in the nomenclature is classified by a combined method.

Nomenclature items form a three-level hierarchy. The first step in the classification is the state of the substance. The second step in the classification is the main form of the dosage form. The third step in the classification are dosage forms classified by the following criteria:

- readiness of the dosage form for use;
- type of modified release of active substances;
- route of administration of the drug;
- method of administration of the drug;
- form of application.

Updating information from the nomenclature is carried out by the nomenclature operator when new classification objects are identified and (or) if necessary, changes to the information already included in the nomenclature at least 1 time per month based on:

- appeals of authorized bodies (organizations);
- minutes of meetings with the participation of representatives of authorized bodies (organizations) organized by the department of the Commission, whose competence includes issues of regulation of the circulation of medicines within the EAEU.

**1.4. The Government issued orders for the purchase of drugs of foreign origin.**

*Decree of the Government of Russia dated September 05, 2019 N 19886-r,*
*Decree of the Government of the Russian Federation of September 25, 2019 N 2170-r*

To provide medical assistance to children, the Ministry of Industry and Trade of Russia has been allocated subsidies for the purchase, import, and delivery of psychotropic drugs unregistered in the Russian Federation to provide children in the amount of 11270 packages. In 2019, an order was also made to import into the Russian Federation such unregistered psychotropic drugs as diazepam (rectal solution), clobazam (tablets and capsules), midazolam (oromucosal solution) and phenobarbital (elixir and injection). The specified purchases will have to be carried out by the Moscow State Endocrine Plant Federal State Unitary Enterprise.

**1.5. The Government has approved a procedure for recognizing and assessing the compliance of testing laboratories (centers) with the principles of good laboratory practice.**

*Decree of the Government of the Russian Federation of September 20, 2019 N 1227 “On the recognition and assessment of the conformity of testing laboratories (centers) with the principles of*

*good laboratory practice, consistent with 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, cosmetic products, 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.

The recognition of the conformity 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 conformity assessment procedures of testing laboratories (centers) with the principles of good laboratory practice, consistent with the principles of good laboratory practice of the Organization for Economic Cooperation and Development, are 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, Federal Service for Supervision in the sphere of health, Federal Biomedical Agency and the Federal Agency for Technical Regulation and Metrology.

In order to conduct an inspection, an application is submitted to the monitoring body in an arbitrary form, to which are attached: a list of current and completed non-clinical (preclinical) laboratory tests for 2 years preceding the date of application; non-clinical (preclinical) laboratory research plans; organizational structure of the applicant and testing laboratory (center); documents confirming the qualifications of the staff; list of staff service instructions; information on the training programs used and on the results of staff training; a list of standard operating procedures related to non-clinical (preclinical) laboratory tests or procedures subject to inspection; a list of equipment necessary for conducting non-clinical (preclinical) laboratory research, as well as a floor plan of the testing laboratory (center); a list (s) of non-clinical (preclinical) laboratory research managers and persons who initiated and finances research related to non-clinical (preclinical) laboratory research subject to audit; information about the payment for the preliminary inspection (copy of the payment document); inventory of documents.

**1.6. From January 1, 2020, the tax regime in the form of a single tax on imputed income will not be able to apply when selling drugs.**

*Federal Law of September 29, 2019 N 325-FZ "On Amendments to Parts One and Two of the Tax Code of the Russian Federation"*

With regard to the sale of goods such as shoes, clothing, medicines, subject to mandatory labeling from January 1, 2010, a ban is imposed on the application of a single tax on imputed income.

**1.7. The Ministry of Industry and Trade of Russia has approved a standard form of an agreement on the provision of services for the provision of labeling codes to drug circulation entities.**

*Order of the Ministry of Industry and Trade of Russia dated September 11, 2019 N 3381 "On approval of the standard form of the contract for the provision of labeling codes for drug circulation subjects"*

The basic conditions for the provision of services for the provision of marking codes are established. The size of the fee for the provision of services for the provision of marking codes is 50 kopecks per 1 marking code, excluding VAT. The VAT in the amount stipulated by the tax legislation

of the Russian Federation is paid more than the cost of one marking code. Settlements under the Agreement are made in Russian rubles. All banking expenses when paying for services under the Agreement, including fees payable, shall be borne by the Participant.

The operator does not charge for the provision of labeling codes for drugs for medical use, included in the list of vital and essential drugs for medical use, the maximum selling price of which does not exceed 20 rubles.

This form will enter into force on October 15, 2019.

**1.8. The Russian Government approved the permissible shares of foreign labor in various sectors of the economy.**

*Decree of the Government of the Russian Federation of September 30, 2019 N 1271 "On establishing for 2020 an allowable share of foreign workers used by business entities engaged in certain types of economic activity in the Russian Federation"*

For the retail sale of medicines in specialized stores (pharmacies), a share of 0 percent of the total number of employees has been established. At the same time, such business entities must bring the number of employed foreign workers into compliance with the standards established by the Government of Russia by January 1, 2020.

## 2. Drafts of regulatory legal acts

**2.1. The Ministry of Health has developed a proposal to amend the Regulation on the system for monitoring the movement of drugs for medical use.**

*Draft Decree of the Government of the Russian Federation "on amendments to the Regulation on the system for monitoring the movement of drugs for medical use", approved by Decree of the Government of the Russian Federation of December 14, 2018 N 1556 "On approval of the Regulation on the system for monitoring the movement of drugs for medical use"*

The draft version sets out a definition of the term "tertiary (transport) packaging of a medicinal product", which according to the draft is a packaging used for storage, transportation and movement of a medicinal product between drug circulation entities, combining sets of secondary (consumer packaging) medicines (in in case of their absence - primary packages of drugs) or tertiary (transport) packages of drugs of a lower level Nost.

The draft of the indicated legal act proposes that the issuer of identification means after receiving the marking code converts it into an identification means, ensures its application on the secondary (consumer) packaging of the medicinal product (and in its absence – on the primary packaging of the medicinal product) or on a material carrier (label ) and no later than the date of putting into circulation a medicinal product, on the packaging (label) of which an identification tool is applied, converted from the corresponding labeling code whether not later than the date of delivery of drugs to the place of arrival on the territory of the Russian Federation during the production of drugs outside the territory of the Russian Federation (with the exception of drugs imported from the EAEU member states), or before importation of drugs into the pharmaceutical warehouse in Russia drugs outside the territory of the Russian Federation in relation to drugs imported from the EAEU member states, transfers to the monitoring system information on applying the means of identification.

It is proposed to establish cases of cancellation of marking codes and denial of registration in the monitoring system.

In particular, marking codes are canceled in the following cases: marking codes received by the issuer of identification means within the framework of one application containing identification codes

are not included in the information on applying identification means converted from the corresponding marking codes; the payment deadline for providing the marking code has been violated; the deadline for the transfer of information to the monitoring system on the application of identification means has been violated.

Registration in the monitoring system of information on applying identification means may be refused in the following cases: the absence of identification codes specified in the information on applying identification means in the registry of identification means of the operator of the monitoring system; submission by the issuer of identification means of information on the application of identification means upon expiration; the monitoring operator does not have information about the emission registration device, with which information was transmitted to the monitoring system; lack of confirmation of payment of marking codes.

**2.2. The Ministry of Health proposes to change the standard form of the contract for the supply of drugs.**

*Draft order of the Ministry of Health of the Russian Federation "On amendments to the Model contract for the supply of medicines for medical use, approved by order of the Ministry of Health of October 26, 2017, N 870n"*

According to the explanatory note to the project, in order to bring the Model Contract into line with the current legislation of the Russian Federation, taking into account the amendments made to the Federal Law dated 05 April 2013 N 44-FZ "On the contract system in the field of procurement of goods, works, services for the provision of state and municipal needs", Decree of the Government of the Russian Federation of August 30, 2017 N 1042 "On approval of the Rules for determining the amount of the fine charged in case of improper performance by the customer, non-performance or non-performance the execution by the supplier (contractor, executor) of the obligations stipulated by the contract (with the exception of the delay in the fulfillment of obligations by the customer, supplier (contractor, executor), on amending the resolution of the Government of the Russian Federation of May 15, 2017 N 570 and invalidating the resolution of the Russian Government Federation of November 25, 2013 N 1063".

The project proposes to introduce the variability of supply (on request or in accordance with the contract).

It is also established that a penalty is charged for each day of delay by the Supplier for fulfillment of the obligation stipulated by the contract, starting from the day following the expiration of the period for fulfillment of the obligation established by the contract, in the amount of one three hundred valid on the date of payment of the key interest rate of the Central Bank of the Russia from the contract price, reduced by an amount proportional to the volume of obligations stipulated by the contract and actually fulfilled by the Supplier, unless the law The Government of Russia has established a different procedure for calculating interest. Recall that the current edition indicates the accrual of interest on the refinancing rate.

**2.3. The Ministry of Industry and Trade proposes to approve some standard forms of contracts to accompany the labeling of drugs by foreign manufacturers.**

*Draft order of the Ministry of Industry and Trade of the Russian Federation "On the approval of a standard form of an agreement on the provision of a device for registration of emissions to drug circulation entities (foreign legal entities) by providing remote access to it free of charge"*

*Draft order of the Ministry of Industry and Trade of the Russian Federation "On approval of the standard form of the contract for the provision of a device for registration of emissions to drug circulation entities (foreign legal entities)"*

The purpose of the development of projects is the legal regulation of legal relations of the provision by the operator of a monitoring system for free of charge of devices for registering emissions by transferring identification means to issuers (foreign manufacturers of medicines).

The explanatory note to the project states that the equipment of issuers of identification means with emission registration devices is carried out by the operator of the monitoring system free of charge.

**2.4. The Ministry of Health has developed a new project for determining the initial (maximum) price of the contract.**

*Draft Order of the Ministry of Health of the Russian Federation "On approval of the procedure for determining the initial (maximum) price of a contract, the price of a contract concluded with a single supplier (contractor, contractor), the initial unit price of a product, work, service when purchasing medicines for medical use"*

The project proposes to declare invalid the order of the Ministry of Health of the Russian Federation dated October 26, 2017 N 871n "On approval of the procedure for determining the initial (maximum) price of a contract, the price of a contract concluded with a single supplier (contractor, contractor), when purchasing medicines for medical application", as well as the order of the Ministry of Health of the Russian Federation of June 26, 2018 N 386n "On Amendments to the Procedure for Determining the Initial (Maximum) Price of the contract price to be concluded with a single supplier (contractor, executor), for the procurement of drugs for medical use", approved by order of the Russian Federation Ministry of Health on 26 October 2017.

The project proposes that reference prices will be calculated 2 times a year as of April 1 and October 1 of the current year within the same name (international non-proprietary name, in the absence of such a name - by group or chemical name).

It is specified that when calculating the Initial (maximum) contract price, the prices of previously concluded contacts are excluded from the calculation, such as: for the supply of medicines that are not in circulation; contracts concluded as a result of failed purchases or using anti-dumping measures.

Given the fact that this project is previously detailed in comparison with the current legal acts regulating the procedure for establishing the initial (maximum) price of a contract, we believe that this project will be further developed.

**2.5. The Ministry of Health of Russia proposes amendments to the procedure for prescribing drugs.**

*Draft Order of the Ministry of Health of the Russian Federation "On Amendments to the Order of the Ministry of Health of the Russian Federation dated January 14, 2019 N 4n "On the Approval of the Procedure for Prescribing Medicines, Forms of Prescription Forms for Medicines, the Procedure for Formulating the Forms, Recording and Storage"*

Amendments to the Order of prescribing drugs will allow you to issue a prescription for a drug that is not registered in the Russian Federation, if necessary, its individual application for health reasons on the basis of a decision of the council of the federal specialized medical organization, or the institution of the Russian Academy of Medical Sciences, or the institution of a subject of the Russian Federation, in which medical care is provided to a particular patient, in the absence of an alternative treatment method.

The draft document provides for an increase in the duration of prescriptions issued on the prescription form of form N 148-1 / y-04 (l) and intended for dispensing drugs to citizens who have reached retirement age, people with disabilities of the first group, children with disabilities, and also citizens suffering from chronic diseases requiring a long course of treatment, up to 180 days from the date of registration.

It is assumed that the changes envisaged by the draft Order to the design procedure and form of prescription form N 148-1/y-04 (l) intended for dispensing drugs to citizens entitled to preferential drug provision will make it possible to produce prescription form N 148-1 / u-04 (l) using computer technology with the application of a bar code and organize automated accounting of such recipes in pharmacy and medical organizations.

**2.6. The Ministry of Health has published a draft of the List of Essential and Essential Medicines for Medical Use for 2020.**

*Draft List of Vital and Essential Medicines for Medical Use for 2020*

The List is planned to be supplemented with new items in an amount of 25. These include the immune serum Palivizumab, psycholeptic Kariprazin, anti-viral drugs Pibrentasvir, Grazoprevir + Elbasvir, etc.

## 3. Judicial and law enforcement practice

**3.1. The Federal Antimonopoly Service of Russia has applied sanctions for the pharmaceutical company to ignore the previously imposed fines.**

*Information of the official website of the Federal Antimonopoly Service of the Russian Federation of September 11, 2019*

The force of Part 1 of Article 20.25 of the Code of Administrative Offenses of the Russian Federation of failure to pay an administrative fine on time entails the legal consequences: the imposition of a new fine in half. So, due to non-payment by non-payment of Vesta Pharm LLC, a fine of 2 598 169.08 rubles previously assigned for participation in the anti-competitive agreement, the Federal Antimonopoly Service of Russia was charged with an additional fine of double the amount of the appointed and unpaid on time.

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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”.

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.