BRACE
Law Firm

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DIGEST
of regulation of the Russian pharmaceutical industry

June 14, 2019

Dear Colleagues!

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

This month, the Eurasian Economic Commission specified certain provisions of the instructions for completing customs declarations. This specification includes, inter alia, the provisions regarding the filling of customs declarations when handling medicinal products on the territory of the EAEU.

The Government of the Russian Federation has established a fee for the provision of drug labeling codes and a standard cost for the provision of medicines for disabled children in 2019.

The Federal Antimonopoly Service of Russia provided explanations of cases when the supply price for vital and essential drugs can exceed the manufacturer's maximum selling price, including VAT, as well as clarify the calculation features of the maximum sale prices for drugs included in the List of essential and essential drugs.

The Ministry of Health of Russia distinguished itself by a very active legislative activity in May 2019. The Ministry proposed to introduce post-registration measures in respect of drugs, which established the impossibility of the applicant submitting complete data on the efficacy and safety of the drug (it was decided to establish the reasons for such impossibility). In addition, the Ministry of Health of Russia is proposing to improve prescription forms in order to facilitate their electronic circulation. The most noteworthy is the development by the Ministry of Health of Russia of the procedure for the presentation of samples of biomedical cell product, cell line (cell lines), medical devices, pharmaceuticals, pharmaceutical substances, substances that are part of the biomedical cell product used in the examination of the quality of biomedical cell product.

It is also worth noting the formation in May of 2019 of judicial practice, which is remarkable because the courts gave quite detailed justifications for their position regarding the grounds for bringing to administrative responsibility for turnover of medicinal products.

Sincerely yours,

BRACE Law Firm

1. Laws, by-laws, legal news

1.1. Amendments have been made to the instructions of the Commission of the Customs Union governing the procedure for filling in customs declarations.

The Decision of the Board of the Eurasian Economic Commission of 21 May 2019 N 83 "On Amendments to the Decisions of the Commission of the Customs Union and the Board of the Eurasian Economic Commission"

This document introduces amendments to the Decision of the Commission of the Customs Union dated May 20, 2010 N 257 "On Instructions for Completing Customs Declarations and Forms of Customs Declarations", which determines that for the Kyrgyz Republic and the Russian Federation, medicinal products that are classified according to the legislation of the Kyrgyz Republic and the Russian Federation Federation, respectively, to vital and essential medicines, are declared as one product, if they have the same name, dosage form, dosage u and release form.

At the same time, in the Republic of Belarus, the Republic of Kazakhstan, the Kyrgyz Republic and the Russian Federation, goods containing intellectual property included in the national customs register of intellectual property of a member state of the Union, in which these goods are placed under the customs procedure, are declared separately from goods not containing intellectual property.

It should be noted that the specified document comes into force on February 1, 2020.

1.2. From October 1, 2019, it will be possible to procure medicines without determining the initial (maximum) contract price.

Federal Law of 01.05.2019 N 71-FZ "On Amendments to the Federal Law "On the Contractual System in the Field of Procurement of Goods, Work, and Services for Providing State and Municipal Needs"

In cases when a state or municipal customer does not have the opportunity to determine the exact amount of drugs required for procurement, it will be possible to indicate the maximum value of a contract price with obligatory designation in a procurement documentation of the condition that payment is made at the price of a unit of the drug based on the quantity of goods delivered but in an amount that is not higher than the maximum value of the contract price.

If a subject of a contract, for a conclusion of which is a tender or auction, is the supply of goods necessary for a normal livelihood (including emergency medical care or medicines), a bidder is offered a twenty-five contract price and more percent lower than the initial (maximum) contract price, the initial sum of prices of commodity units, which is twenty-five percent or more lower than the initial (maximum) contract price, such participant is Packs are obliged to provide the customer with a justification of the proposed contract price, the sum of prices of commodity units. A letter of guarantee from the manufacturer indicating the price and quantity of the goods supplied, 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 can be attributed to the justification.

1.3. The standard of costs for the provision of medicines for children with disabilities in 2019 has been established.

Government Decree of 21 May 2019 N 628 "On the establishment of a standard of financial costs per month per citizen receiving state social assistance in the form of social services for providing medical products according to medical assistance standards (medical assistants) according

to medical prescriptions products, as well as specialized medical nutritional products for disabled children, for 2019"

From June 8, 2019, the rate of financial expenses per month per citizen receiving state social assistance in the form of social services to ensure in accordance with the standards of medical care according to the doctor's (paramedic) prescriptions with drugs for medical use, medical products, as well as specialized medical products food for children with disabilities will be 860,6 rubles. It should be noted that in 2018 the specified standard was the standard was 826,3 rubles.

1.4. Approved a fee for the provision of drug labeling codes.

Decree of the Government of the Russian Federation dated 08 May 2019 N 577 "On Approval of the Amount of Payment for Rendering Services for the Provision of Marking Codes Necessary for Forming Identification Means and Ensuring Monitoring of the Movement of Goods Subject to Mandatory Marking by Identification Means, and also on the procedure for its collection"

The specifics of the procedure for charging for the provision of marking codes are defined in the contract concluded between the operator and the participant. The Ministry of Industry and Trade of Russia approves the standard form of the contract.

The amount of payment for the provision of services for the provision of marking codes necessary for the formation of means of identification and ensuring monitoring of the movement of goods subject to mandatory marking by means of identification will be 50 kopecks per 1 code of labeling excluding VAT. It does not charge for the provision of labeling codes for drugs for medical use, included in the list of vital and essential drugs, the maximum selling price of the manufacturer does not exceed 20 rubles.

1.5. The procedure for recording and declaring the volume of production, circulation, and use of the pharmaceutical substance of ethyl alcohol (ethanol), as well as the production of alcohol-containing drugs and (or) alcohol-containing medical devices, entered into force.

Decree of the Government of the Russian Federation of April 20, 2019 N 472 "On the procedure for recording and declaring the volume of production, turnover and (or) use of the pharmaceutical substance of ethyl alcohol (ethanol), as well as the production, manufacture and (or) turnover (except for retail sale) of alcohol-containing medicines drugs and (or) alcohol-containing medical devices and on amending the Decree of the Government of the Russian Federation of June 19, 2006 N 380" (together with the "Rules for recording the production, turnover and (or) use of pharmaceutical ethyl alcohol (ethanol), as well as the production, manufacture and (or) turnover (excluding retail sale) of alcohol-containing drugs and (or) alcohol-containing medical products, "Rules for the submission of declarations on the production, turnover and (or) use pharmaceutical substance of ethyl alcohol (ethanol), as well as the production, manufacture and (or) turnover (excluding retail sale) of alcohol-containing drugs and (or) alcohol-containing medical devices")

The accounting procedure introduces the obligatory declaration of the volume of production of alcohol-containing drugs. The declaration is subject to submission via telecommunication channels in the form of an electronic document signed by a reinforced qualified electronic signature of the head. The duty to determine the format and form of declarations is assigned to the Ministry of Finance of Russia.

The procedure for eliminating inaccuracies and incompleteness of the information presented in the declarations has been settled. If the organization finds in the current reporting period assumptions of inaccuracies and errors in the declarations already submitted, it will be necessary to submit corrective declarations before the deadline for filing the declaration for the quarter following the

reporting quarter. Correcting declarations should contain a justification of the reasons for the mistakes made or non-reflection or incomplete reflection of the information in previously filed declarations.

1.6. On May 7, 2019 the standard of specialized medical care for senile asthenia entered into force.

Order of the Ministry of Healthcare N 190n dated April 2, 2019 "On approval of the standard of specialized medical care for senile asthenia"

The List of drugs for medical use registered in Russia, indicating the average daily and course doses has been established. In particular, the daily dose is determined for such drugs as colecalciferol; apixaban; rivaroxaban; teriparatide; glucosamine; diacerein; alendronic acid; denosumab; fentanyl; tramadol; pregabalin; memantine.

1.7. The Federal Antimonopoly Service of Russia clarified on the use of wholesale mark-ups when making deliveries within the framework of state (municipal) contracts of medicines included in the Vital and Essential Drugs List.

Letter of the Federal Antimonopoly Service of the Russian Federation on May 13, 2019 N NATS/38800/19 "On the use of wholesale mark-ups in the delivery of vital and essential drugs to the government (municipal) contracts"

The Vital and Essential Drugs Price may exceed the registered maximum selling price of the manufacturer including VAT (not more than the maximum wholesale premium set in the subject of the Russian Federation) if the supplier is not a manufacturer and at the same time:

• if, when making procurements to meet federal needs, the size of the initial (maximum) contract price does not exceed 10 million rubles;

• if, when making procurements to meet the needs of a constituent entity of the Russian Federation, the size of the initial (maximum) contract price does not exceed the amount established by the highest executive body of the government of the constituent entity of the Russian Federation.

If the supplier is not a manufacturer of a medicinal product, but when making purchases to meet federal needs, the initial (maximum) contract price exceeds 10 million rubles, and when making purchases to meet the needs of a constituent entity of the Russian Federation, the municipal needs of the initial (maximum) contract price exceed which is established by the highest executive body of state power of a constituent entity of the Russian Federation, the price of the supply of vital and essential drugs cannot exceed the registered maximum selling price of the manufacturer VAT. In this case, the supplier has the right to apply a wholesale premium to the manufacturer's actual selling price (the manufacturer's actual selling price for the medicinal product, in this case, should be lower than the registered selling price limit) provided that the delivered drug price does not exceed the manufacturer's registered selling price limit including VAT.

1.8. The Federal Antimonopoly Service of Russia explained the procedure for applying certain provisions of the Methodology for calculating the maximum selling prices for drugs included in the Vital and Essential Drugs list by drug manufacturers during their state registration.

Letter of the Federal Antimonopoly Service of Russia dated 14 May 2019 N AC/39362/19 "On the Procedure for Applying Certain Provisions of the Methodology for the Calculation of the Maximum Sale Prices for Medicinal Products Included in the List of Essential and Essential Medicines during their state registration and reregistration, approved Decree of the Government of the Russian Federation of September 15, 2015 N 979"

The Federal Antimonopoly Service of Russia gave explanations that if a reference drug with a single dosage and total quantity in a secondary (consumer) package has several price limits (for example, in different primary packages, with different bar codes, etc.), then the minimum of the registered marginal prices, taking into account its latest re-registration (decline).

In the absence of a reference medicinal product (or the price for it is not registered), the Federal Antimonopoly Service of Russia considers it appropriate to use a similar approach in determining the maximum price, which is provided for determining the price of the reference medicinal product.

To calculate the maximum price, a medicinal product is used that coincides in accordance with the International Nonproprietary Name, dosage form, dosage and has a maximum value of one dosage form. At the same time, if several limit prices are registered for such a drug, then for each consumer package (taking into account the latest re-registration (reduction) of price), a reduction factor is calculated and, based on these reduction factors, the arithmetic average reduction factor is calculated.

1.9. The Ministry of Health of Russia gave additional explanations regarding the procedure for applying new prescription forms.

Letter of the Ministry of Health of Russia dated May 20, 2019 N 1127/25-4 "On New Forms of Prescription Forms for Drugs"

The Office recalls that the letter of the Ministry of Health of the Russian Federation dated April 04, 2019 N 25-4/I/2-2885 allowed the use of the remnants of previously prepared prescription forms of the "old sample" until December 31, 2019.

It is reported that pharmaceutical organizations are not forbidden to dispense medicines according to prescriptions drawn up on prescription forms of the "old sample" of form N 148-1/y-06 (l) and N 148-1 / y-04 (l), taking into account the validity of these recipes.

Recipes for barbituric acid derivatives, combination drugs containing codeine (its salts), other combination drugs that are subject to quantitative accounting, drugs that have anabolic activity in accordance with the main pharmacological effect can be drawn up for a course of treatment of not more than 60 days. In the case when the course of treatment is more than 30 days, the inscription "For Special Purpose" is additionally added to the recipes on paper, certified by the medical worker's signature and stamped by the medical organization "For Recipes", in the recipes in the form of an electronic document the note "For Special Purpose", with a certified qualified electronic signature of a medical worker and a person authorized to certify documents on behalf of the medical organization.

2. Drafts of regulatory legal acts

2.1. The Ministry of Health of Russia proposes to take measures to accelerate the state registration of drugs with the consolidation of compliance with post-registration measures for the drug manufacturer.

Draft Federal Law "On Introducing Amendments to the Federal Law "On Circulation of Medicinal Products" regarding the implementation of state registration of medicinal products for medical use with the establishment of post-registration measures"

The draft law proposes to allow for state registration of medicinal products (with the exception of medicinal products that are replicated or biosimilars (biosimilar) if the applicant cannot provide complete data on the efficacy and safety of the medicinal product if such impossibility is due to such reasons as:

- indications for use, for which the drug is intended to be used, are so rare that the applicant cannot reasonably expect to receive comprehensive confirmation of the evidence of efficacy and safety;
- with existing scientific research methods, full information on the efficacy or safety of a drug cannot be provided;
- obtaining information about the efficacy or safety of a drug will be contrary to generally accepted principles of medical ethics;
- indications for the use of a medicinal product are intended therapy for previously incurable diseases and (or) given its significant therapeutic advantages compared with existing methods of treatment.

At the same time, the approval of such registration is carried out when the applicant is assigned the obligation to comply with such post-registration measures as:

- use of the drug exclusively in medical organizations subordinated to the federal executive body in the field of health care, providing medical care in a hospital;
- the inclusion of certain measures in the risk management system to ensure the safe use of the drug and the establishment of requirements for filing reports of suspicious and undesirable reactions;
- completion of the program of clinical (post-registration) studies within the designated time frame - studies of various aspects of the safety and efficacy of a drug, the results of which allow a re-evaluation of the ratio of the expected benefit to the possible risk of using the drug;
- annual confirmation of the state registration of the drug for the completion of clinical (post-registration) studies;
- inclusion in the instructions for medical use of the drug, labeling of the primary and secondary packaging of the medicinal product treatment, containing information that the existing characteristics of the drug are insufficient to confirm certain aspects of its effectiveness or safety.

2.2. The Ministry of Health of Russia proposes to change the procedure for prescribing drugs and the form of prescription forms for drugs.

Draft Order of the Ministry of Health of Russia "On Amendments to Appendices to the Order of the Ministry of Health of the Russian Federation dated January 14, 2019 N 4n "On Approval of the Order of Prescribing Drugs, Prescription Forms For Drugs, and Designing the Forms of These Forms, their Accounting and Storage"

In connection with the introduction of the possibility of fulfilling prescriptions for medicinal products in the form of electronic documents, the Ministry suggests that in the form of the prescription form N 148-1/y-04 (l) provide a place for applying a bar code. This innovation is due to the need to improve the quality of preferential drug supply.

It is also proposed in the recipes on paper to produce the inscription "For Special Purpose", certified by the signature of the medical worker and stamped by the medical organization "For Recipes", recipes in the form of an electronic document, to be marked "For Special Purpose", with an enhanced qualified electronic signature of the medical worker and a person authorized to certify documents on behalf of a medical organization. These marks are recommended to be applied in the case when the course of treatment is more than 30 days extra.

2.3. The Ministry of Health of Russia has developed a draft Procedure for presenting samples of a biomedical cell product, cell line (cell lines), medical devices, pharmaceuticals, pharmaceutical substances, substances that are part of a biomedical cell product, used in the

examination of the quality of a biomedical cell product.

Draft Order of the Ministry of Health of Russia "On Approval of the Procedure for Submission of Samples of Biomedical Cellular Product, Cell Line (Cell Lines), Medical Devices, Pharmaceuticals, Pharmaceutical Substances, Substances That Are Part of the Biomedical Cellular Product Used for Examining the Quality of the Biomedical Cell Product for examination of the quality of the biomedical cellular product and the invalidation of the order of the Ministry of Health of the Russian Federation on October 20, 2017 N 841n "On approval of the Procedure for presenting samples of a biomedical cell product, cell line (cell lines), medical devices, drugs, substances that are part of the biomedical cell product used in the examination of the quality of biomedical cell product, for carrying out examination of quality of a biomedical cellular product"

The draft Order establishes that for the examination of the quality of the biomedical cellular product the applicant within sixty working days from the date of receipt from the federal state budgetary institution under the jurisdiction of the Ministry of Health of Russia and ensuring the fulfillment of the authority of the Ministry for issuing permits for conducting clinical trials of biomedical cellular products notifications

On receipt of the relevant assignment of the Ministry of Health of Russia, it provides samples of a biomedical cell product to an expert institution for quality examination.

The submission of these samples is carried out in an amount necessary to reproduce the methods of quality control of a biomedical cellular product, which is determined by the expert institution and is indicated in the notification.

Upon receipt of the specified samples, the expert institution shall issue to the applicant a document confirming receipt of the specified samples, and within a period not exceeding three working days from the date of their receipt notify the Ministry of this on paper or in the form of an electronic document and shall be indicated in the notification.

In case of failure of the biomedical cellular product samples submitted to the expert institution expert, the expert has the right to ask the head of the expert institution the question of submitting additional samples to him.

2.4. The Ministry of Industry and Trade of Russia is proposing amendments to some of the Regulations on the system for monitoring the movement of medicines for medical use.

Draft Resolution of the Government of the Russian Federation "On Amendments to the Regulations on the System for Monitoring the Movement of Medicinal Preparations for Medical Use"

It is proposed to make amendments to the Regulation on the system of monitoring the movement of medicines for medical use, approved by the Government of the Russian Federation dated December 14, 2018 N 1556 to supplement the Regulations by the procedure for charging the labeling code in accordance with the Government Decree of May 08, 2019 N 577 Attached to supplement the cases of denial of registration in the monitoring system of information on the application of identification tools for such reasons as:

- absence of serial global identification numbers of the trade unit specified in the notification (report) on the application of identification tools in the register of identification tools of the monitoring system operator;
- submission by the issuer of means of identification of a notification (report) on the application of means of identification after a specified period of time;
- the monitoring operator's lack of information about the emission registration device, using which the notification (report) was transmitted to the monitoring system;

- the lack of confirmation of payment of marking codes converted into identification means, on the application of which the issuer of identification means sends a notification (report) to the monitoring system.

Also, a proposal was made to reduce to 44 characters the length of an electronic signature, which is part of the cryptographic protection.

2.5. The Ministry of Health of Russia has published a list of applications that have been documented for the inclusion of drugs in the List of Vital and Essential drugs.

Information on the results of consideration of proposals for inclusion in the lists of drugs (https://www.rosminzdrav.ru)

It is assumed that the List of Vital and Essential drugs by 2020 will be supplemented by 27 positions. These drugs are supposed to include drugs with the following international non-proprietary names: insulin lispro, Macittentan, Pegvisomant, Vinflunin, Elotuzumab, Netakimab, etc.

3. Judicial and law enforcement practice

3.1. The court confirmed the illegality of the use of instruments for measuring the temperature of domestic use during storage of medicines. However, recognizing the lawful mitigation of punishment applied to the subject of an administrative offense.

Resolution of the Sixteenth Arbitration Court of Appeal dated May 17, 2019, in case N A63-23543/2018

In the process of checking by the Federal Service for Supervision in the field of health, it was revealed that the entrepreneur to ensure compliance with the storage conditions of drugs that require protection from elevated temperature, uses refrigerators that do not have an integrated measuring device, verified in the prescribed manner, to monitor the temperature. To control the parameters of air in refrigerators, household thermometers TB-225, produced by LLC First Thermometer Plant, were used, which do not have calibration (verification is not provided by the manufacturer).

Thus, the court concluded that when measuring drugs should be used specialized devices for measuring temperature.

At the same time, according to the court of appeal, the court of the first instance, taking into account the nature and circumstances of the offense and the fact that the subject of the offense is a small business, came to the correct conclusion about the possibility of sentencing in the form of a warning. The sanction of clause 4 of Article 14.1 of the Code on Administrative Offenses of the Russian Federation provides for the imposition of an administrative fine on persons engaged in entrepreneurial activities without forming a legal entity in the amount of from four thousand to eight thousand rubles or administrative suspension of activity for up to ninety days. However, in accordance with Article 4.1 Administrative Code may apply a milder punishment. In this connection, the appellate court rejected the argument of the body of the Federal Service for Supervision in the field of health concerning the necessity of imposing a fine.

3.2. The court decided that the offense, expressed in the non-recording of data on the release of drugs in the register of transactions related to the circulation of drugs, applies special periods of limitation of administrative responsibility.

Resolution of the Sixteenth Arbitration Court of Appeal dated May 17, 201 in case N A63-23543/2018

According to the pharmacy organization, bringing to administrative responsibility should not have been made on the motive of the expiration of the term of bringing to administrative responsibility.

In particular, according to the subject of the administrative offense, the sold drugs should have been reflected in the Journal on the day of sale of the indicated drugs. In this case, there is a clear date for committing an administrative offense, to which the general three-month period for bringing to justice applies. The application to the specified offense of special limitation periods for bringing to administrative responsibility is unreasonable and inadmissible.

However, the court rejected this argument on the basis of the fact that the register is kept for a year, while the journal must contain the daily consumption of the medicinal product, indicating separately according to the prescriptions issued by medical personnel and the requirements of medical organizations. In this connection, the argument is rejected that the failure to add information on the sale of a medicinal product to the journal is considered accomplished the next day after its actual sale. Failure to make entries on receipt and expenditure of controversial drugs does not relieve from the need to keep the specified journal in a proper manner during the year, including taking into account the need for storage together with the journal of receipt and expenditure documents in the manner recorded in the journal. According to the court, when entering a pharmacy and selling a medicinal product, a record of it, including receipt and expenditure documents, should be recorded in the log book and these records should be in the log during the entire period of logging.

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About us

BRACE Law Firm renders legal services to manufacturers and distributors of medicines, medical products, dietary supplements and other health organizations on issues of Russian and international law.

Our main industry 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 and a number of other areas.