BRACE
Law Firm

June 2019

DIGEST
of regulation of the Russian pharmaceutical industry

July 11, 2019

Dear Colleagues!

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

In June 2019, the Federal Law dated 06.06.2019 No. 134-FZ was adopted, which established the list of cases when pharmaceutical companies are obliged to reduce the maximum selling prices for drugs from the VED list.

Mandatory price reductions will be in the following cases:

- price reduction in foreign currency for the drug in the country of origin and (or) in the countries in which the drug is registered and (or) to which it is supplied by the manufacturer;
- price reductions for reference drugs (for appropriately replicated, biosimilar (biosimilar) drugs);
- exceeding the maximum selling price for the first reproduced, biosimilar (biosimilar) foreign-made drug over the manufacturer's maximum selling prices for the second reproduced biosimilar (biosimilar) drug;
- exceeding the maximum selling price for the first reproduced, biosimilar (biosimilar) drug of the manufacturer of the Eurasian Economic Union member state over the maximum selling prices of the manufacturer for the second reproduced biosimilar (biosimilar) medicine of the manufacturer of the EAEU member state.

The Federal Antimonopoly Service of Russia also clarified that when delivering drugs from the VED list to the medical organization, it is not prescribed to include the retail mark-up in the price of the drug, neither by the current legislation in the circulation of drugs, nor by the law in the procurement of goods, works, services for state and municipal needs.

The Accounts Chamber of Russia published a Report on the results of an expert-analytical event “Monitoring the development of the system of state and corporate procurement in the Russian Federation for 2018”, within which important recommendations were made regarding the improvement of procurement legislation (including procurement of medicines).

The above, as well as other equally important legislation changes are reflected in this digest in more detail.

Sincerely yours,

BRACE Law Firm

1. Laws, by-laws, legal news

1.1. On June 7, 2019 the Federal Law came into force, which introduces conditions under which manufacturers of vital and essential drugs are obliged to reduce the maximum selling prices for such drugs.

Federal Law of June 06, 2019 N 134-FZ "On Amendments to the Federal Law" On Circulation of Medicinal Products" regarding state regulation of prices for medicinal products included in the list of vital and essential medicinal products"

The Law establishes the obligation to reduce the marginal selling price of drugs included in the List of the Vital and Essential Drugs.

Mandatory price reductions will be in the following cases:

- price reduction in foreign currency for the drug in the country of origin and (or) in the countries in which the drug is registered and (or) to which it is supplied by the manufacturer;
- price reductions for reference medicinal products in accordance with clause 1 of this part (for corresponding generic, biosimilar (biosimilar) medicinal products);
- exceeding the maximum selling price for the first reproduced, biosimilar (biosimilar) foreign-made drug over the manufacturer's maximum selling prices for the second reproduced biosimilar (biosimilar) drug;
- exceeding the maximum selling price for the first reproduced, biosimilar (biosimilar) drug of the producer state of a member of the Eurasian Economic Union over the maximum selling prices of the manufacturer for the second reproduced bioanalogue (biosimilar) medicinal product of the manufacturer of the EAEU member state.

It is important to note that the frequency of price reductions has not been established. Therefore, a reduction statement may be filed several times during the year when the above conditions occur.

In other cases, in the period 2019-2020 reregistration of previously registered maximum selling prices for all drugs is obligatory.

We suppose that the introduction of such changes in the current legislation on the one hand, can have a beneficial effect on the reduction of prices for medicines. On the other hand, without a clear study of the mechanism of price reduction with the establishment of reasonable terms for such a reduction, such innovations may lead to the fact that some manufacturers may leave the Russian market.

1.2. The Federal Antimonopoly Service of Russia posted an explanation of the procedure for forming selling prices for narcotic and psychotropic drugs included in the Vital and Essential Drugs List.

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

The document is posted by the Federal Antimonopoly Service of Russia on the official website on June 26, 2019 and contains the following clarifications. When delivered to the Vital and Essential Drugs medical organization, there is no provision for the inclusion of the retail mark-up in the price of a drug, neither by the current legislation in the field of drug circulation, nor by the law in the field of procurement of goods, works, services for state and municipal needs.

At the same time, clause 5.6 of the Methodology for establishing by the executive authorities of the subjects of the Russian Federation of limits for wholesale markups and limits for retail markups to actual sale prices set by drug manufacturers for drugs included in the List of Vital and Essential Drugs approved by order of the Federal Tariff Service of Russia dated December 11, 2009 N 442-a, prescribes that the vital and essential drugs for which wholesale organizations and retail trade organizations carry to additional costs associated with the special conditions of their transportation and storage (narcotic and psychotropic drugs) are separated from the total volume of realized Vital and Essential Drugs into a separate group for which the executive authorities of the constituent entities of the Russian Federation set the size of the premiums, taking into account the additional costs of their implementation. The decision on this issue is made by the executive authority of the subject of the Russian Federation independently.

In addition, the explanations indicate that medical organizations that do not have pharmacy organizations in their structure are given narcotic and psychotropic drugs according to the invoice requirements. In this case, it is acceptable to take into account the costs of wholesale organizations that have a pharmacy organization in their structure through which these drugs are dispensed according to the invoice requirements.

1.3. The Accounts Chamber of Russia based on an analysis of public procurement in 2018 made recommendations to simplify a number of procedures for such procurement.

Report on the results of the expert-analytical event "Monitoring the development of the system of state and corporate procurement in the Russian Federation in 2018"

The report notes the inefficiency of a number of government procurement due to the fact that such procurement requires both the costs of potential procurement participants and the additional costs of customers. In particular, the report notes that according to the analysis of experts of the All-Russian Popular Front "For Fair Purchases", the application of the calculation method of the Initial (Maximum) Contract Price approved by order N 871n of the Ministry of Health of Russia leads to an increase in the number of repeated drug procurement procedures, since every fourth the procedure takes place without the participants of the procurement due to errors made in the method of calculating the Initial (maximum) price of the contract.

In this regard, it is proposed to:

- establish responsibility for banks to the procurement participant for non-compliance with its requirements for timely blocking of funds in order to secure applications for participation in electronic procurement;
- ensure the adoption of a regulatory legal act on pricing regulation in the implementation of procurement with the ability to automatically calculate the initial (maximum) prices of government contracts;
- include in the procedure for drafting acts of the President of the Russian Federation or the Government of the Russian Federation on the determination of a single supplier (contractor, performer) to provide justification for the need to attract subcontractors, mandatory coordination of such acts with the Federal Treasury and the federal executive authorities concerned in their sectoral competence.

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

Federal Law of 17 June 2019 N 147-FZ "On Amendments to Part Two of the Tax Code of the Russian Federation"

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

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

Now the cost of medicines to be taken into account in order to obtain a tax deduction is not limited to the specified list. Now the deduction is granted on the cost of any medications prescribed by the attending physician.

The Ministry of Finance of Russia explains that the basis document for the deduction for medicines is prescription form N 107-1 / y with a stamp "*For tax authorities of the Russian Federation, Taxpayer Identification Number*".

1.5. Changes in the list of precursors entered into force.

Decree of the Government of the Russian Federation of February 22, 2019 N 182 "On Amendments to certain acts of the Government of the Russian Federation in connection with the improvement of control over the circulation of the precursors of narcotic drugs and psychotropic substances"

From list I, the restrictions will not depend on the concentration of these substances. In addition, "1-hydroxy-1-methyl-2-phenylethoxy sulfate" is excluded from this list.

In Table I of the precursors from List IV are included: - 2-bromo-1-phenylpentan-1-one; - 1- (2,5-Dimethoxyphenyl) -2-nitroprop-1-ene; - Despropionyl-3-methylfentanyl; - Despropionyl-ortho-methylfentanyl; - (2-Methoxyphenyl) acetone; - 1-phenylpentan-1-one; - 2-Nitro-1- (2-fluorophenyl) prop-1-ene. Table 1 of this list includes "1- (4-methylphenyl) propan-1-one".

1.6. Roscosmos approved the list of goods purchased from small and medium-sized businesses.

The list of goods, works, services procured from small and medium-sized businesses, approved by order of the State Corporation "Roscosmos" dated June 13, 2019 N 179

This list includes medicinal products and materials used for medical purposes.

1.7. Government of Russia establishes rules for clinical research of donor blood

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

It has been established that it is unacceptable to introduce into the container with donor blood and (or) its components any drugs or solutions, except for 0.9% sterile sodium chloride solution.

To ensure the safety of the clinical use of donor blood, traceability of data on the donor, donations, harvested donor blood and/or its components, consumables (containers, reagents, solutions, drugs), donor's blood samples, storage modes and transportation of donor blood should be ensured. (or) its components, blood samples of the recipient, contractors, as well as compliance with the safety requirements of the work performed on the procurement, transportation, storage and clinical the use of blood and (or) its components.

1.8. The President of Russia approved the Health Care Development Strategy until 2025.

Presidential Decree of June 06, 2019 N 254 "On the Strategy for the Development of Health Care in the Russian Federation for the Period up to 2025"

This strategy provides for the improvement of mechanisms for the provision of medicines to citizens, as well as the pricing mechanism for medicines; further implementation of the information-analytical system of monitoring and control in the procurement of medicines, as well as in order to reduce the volume of falsified and poor-quality medicines and medical products.

2. Drafts of regulatory legal acts

2.1. The Ministry of Industry and Trade of Russia proposes to amend the procedure for labeling certain types of drugs.

Draft federal law "On Amendments to Article 4 of the Federal Law" On Amendments to Certain Legislative Acts of the Russian Federation on the issue of putting into civilian circulation of drugs for medical use"

The bill proposes to exclude medical gases from the system of monitoring the movement of drugs for medical use.

The justification for submitting a draft for consideration is due to the fact that, in accordance with the provisions of the 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 Medicinal Drugs for Medical Use", the information contained in the identification tool is applied by methods inseparable from packaging.

In the production of compressed medical gases for the primary packaging, recycled packaging is used (cylinder), there is no secondary packaging. For cylinders that are recyclable, the presence on the marked surface of the previous identification means will not allow to achieve the uniqueness of the encoded information. The explanatory note to the draft law explains that there is no international experience in labeling gases with medical identification means. In accordance with EU Directive 2016/161, medical gases are not subject to mandatory labeling.

2.2. The Ministry of Health of Russia is proposing to adopt guidelines for the provision of disabled children with essential medicines.

Draft Order of the Ministry of Health of Russia "On approval of guidelines for the implementation by the state authorities of the subjects of the Russian Federation of the authority to organize providing citizens included in the Federal Register of persons eligible for state social assistance, medicines, medical products for disabled children"

The draft Methodological Recommendations provide that municipal authorities of the constituent entities of the Russian Federation in the field of health protection submit to the state authorities of the constituent entities of the Russian Federation in the field of health protection applications for the supply of medicines for medical use, medical devices, specialized foods for children with disabilities with the application justifications for their volume.

The need (scope of supply) for drugs is determined by taking into account clinical recommendations (treatment protocols) and the average course dose of the drug based on the monthly actual need of patients for drugs and the need to form a minimum stock for 3-4 months.

A citizen who has the right to receive social services may refuse to receive them by applying with the appropriate application to the territorial body of the Pension Fund of the Russian Federation, which makes a monthly cash payment.

It is allowed to refuse to receive a set of social services in full, to refuse to receive one of the social services and to refuse to receive any two social services.

2.3. Public discussions have begun on the draft Order of the Ministry of Health of Russia, which proposes amendments to the procedure for prescribing narcotic drugs.

The draft Order of the Ministry of Health of Russia "On Amendments to the Order of the Ministry of Health of the Russian Federation of August 1, 2012 N 54n "On approval of the form of prescription forms containing the purpose of narcotic drugs or psychotropic substances, their production, distribution, registration, accounting and storage, and also design rules""

It is proposed to introduce special requirements for obtaining a prescription for narcotic and psychotropic drugs in the form of an electronic document signed with the use of a reinforced qualified electronic signature of a medical professional.

At the same time, in order to ensure the availability of medicines to palliative patients, it is proposed to eliminate the need for a prescription to be certified by the signature of the head of a medical organization or the head of a structural unit of a medical organization or a person authorized by the head of a medical organization. And also it is supposed to include the norm allowing to issue a prescription for narcotic drugs or psychotropic substances at home.

3. Judicial and law enforcement practice

3.1. The state budgetary institution of health care of the Sverdlovsk region "Regional blood transfusion station" was fined in connection with the conclusion of an antimonopoly agreement.

The Sverdlovsk Department of the Federal Antimonopoly Service of Russia fined the State Budgetary Institution of Health Care of the Sverdlovsk Region "Regional Blood Transfusion Station" for 4.85 million rubles.

As noted on the official website of the Federal Antimonopoly Service of Russia, the anti-competitive agreement, by which most purchases were made from one legal entity, led to "*the inability to acquire tick-borne encephalitis immunoglobulin by other buyers and, thereby, to restrict competition in the commodity market*".

Nevertheless, we believe that this decision is not final and will be challenged in court in the future.

3.2. Approved list of instructions of the President of Russia on the results of the program "Direct Line with Vladimir Putin"

According to the results of this program, a list of instructions was approved, according to which top officials of the constituent entities of the Russian Federation were recommended to ensure timely procurement of medicines to ensure preferential categories of citizens and promptly send information about purchased medicines and their balances to medical and pharmacy organizations.

If you have any questions regarding this digest, please contact us:
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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 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.