BRACE
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DIGEST
of regulation of pharmaceutical industry

http://brace-lf.com
info@brace-lf.com
+7(499)755-56-50

The Cube business center,
47 Volgogradsky prospekt,
109316, Moscow, Russia»

Brief news

The Federal State Information System for Monitoring the Movement of Medicines from the manufacturer to the end user will be put into operation using labeling (codification) and identification of medicine packages according to the forecast from the website of the Ministry of Economic Development of Russia 04.10.2018.

Additional criteria have been established for excluding a medicine from vital and essential medicines for medical use, a list of expensive medicines, and a list of medicines for providing certain categories of citizens. A new basis for such an exception will be the presentation of a scientifically based recommendation of the chief freelance specialist of the Ministry of Health of the Russian Federation on the results of the analysis of information on the characteristics of the medicine.

When approving the Rules for State Registration and Reregistration of medicines included in the List of vital and essential medicines a number of significant amendments have been made to the new edition.

The Russian Treasury revealed a number of violations of the requirements for the procedure for determining the initial (maximum) contract price in the procurement of medicines for medical use.

The Federal Antimonopoly Service of Russia proposes to establish restrictions on the conclusion of long-term government contracts for the supply of medicines: to establish the possibility of concluding long-term government contracts only for medicines that are protected by patents, if their price is significantly reduced; limit the validity of long-term government contracts to the term of a patent for a medicines or the date of entry into the market of another medicines that has the same indications for use.

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1. Laws, by-laws, legal news

1.1. The rules of information interaction in the implementation of the process of forming a unified database of licenses issued, permits and conclusions (permits) in the field of foreign trade in goods, as well as the procedure for joining this process and regulations for information interaction between the customs authorities of the Eurasian Economic Union member states have been approved.

The decree of the Board of the Eurasian Economic Commission of October 30, 2018 N 179 "On technological documents regulating information interaction in the implementation by means of an integrated information system of foreign and mutual trade of the general process" Formation, maintenance and use of a database of licenses issued, permits and conclusions (permits) in foreign trade in goods", concerning licenses and permits"

A number of important documents were approved that could affect, including the formation of a single database of permits for the import / export of medicines to organizations registered in the member states of the Eurasian Economic Union engaged in pharmaceutical activities, namely:

- The rules of information interaction when implementing the integrated information system of external and mutual trade of the general process "Formation, maintenance and use of a database of licenses issued, permits and conclusions (permits) in the field of foreign trade in goods" regarding licenses and permits established that the authorized bodies of the Eurasian Economic Union Member States ensure the formation and maintenance of national databases of licenses issued and (or) permits x, and transmit it to the Commission (Eurasian Economic Union body that: receives from the competent authorities of the Member States information on the licenses issued, and (or) resolutions of the national database system) as the changes in the national database. The Commission processes information received from the authorized bodies of the Member States and submits to the customs authorities of the Member States information on the issued licenses and (or) permits from the national databases in accordance with the parameters specified in the request.
- Information interaction between the authorized bodies of the Member States and the Commission, as well as between the Commission and the customs authorities of the Eurasian Economic Union Member States is carried out using an integrated information system.
- The procedure for accession to the general process "Formation, maintenance and use of a database of licenses issued, permits and conclusions (permits) in the field of foreign trade in goods" in terms of licenses and permits establishes the basic procedures for joining the Eurasian Economic Union Member States to the general process which includes: informing the Eurasian Economic Union Member State of the Commission on the accession of a new participant to the overall process; introducing changes in the regulatory legal acts of the Eurasian Economic Union Member State to meet the requirements of the technological documents (within 6 months from the date of commencement of the accession procedure); development (revision), if necessary, of an information system and its connection; transfer of information used to implement the general process of forming a database of licenses and permits issued; information interaction testing.

1.2. The Ministry of Economic Development of Russia predicts an increase in the level of protection of citizens from entering the market of counterfeit medicines in the period up to 2024

Forecast of the economic development of the Russian Federation for the period until 2024

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The Cube business center,
47 Volgogradsky prospekt,
109316, Moscow, Russia»

According to this forecast, the Federal State Information System for Monitoring the Movement of medicines from the manufacturer to the end user will be launched using labeling (codification) and identification of medicines packages.

All medicines will be covered by individual labeling from January 1-st, 2020. This will ensure safety and protect citizens from counterfeit medicines.

The formation of a common medicines market within the framework of the Eurasian Economic Union will continue. The guide for the quality of medicines for inhalation and nasal medicines is approved.

1.3. Dietary supplement in the form of chewing marmalade related to food.

Recommendation Decision of the Board of the Eurasian Economic Commission of October 30, 2018 N 171 "On the classification of biologically active food supplements in the form of chewing marmalade in accordance with the single Commodity Nomenclature of Foreign Economic Activity of the Eurasian Economic Union"

Biologically active food supplement in the form of chewing marmalade, consisting of sugar and (or) sugar syrups, gelling agents, vitamins, mineral substances intended for a balanced addition to children's nutrition is classified according to the Commodity Nomenclature for Foreign Economic Activity of the Eurasian Economic Union, approved by the Decision of the Eurasian Economic Commission. dated July 16, 2012 N 54 of heading 2106 (Food products not elsewhere specified or included).

1.4. The Amendments to the rules for the formation of lists of medicines.

Decree of the Government of the Russian Federation of October 29, 2018 N 1283 “On Amendments to the Rules for the Formation of the List of medicines for medical use and the minimum assortment of medicines required for rendering medical care”

These documents have been added to the fact that the lists of medicines are formed taking into account the results of clinical testing of methods of prevention, diagnosis, treatment and rehabilitation. Such a criterion for the formation of lists as a criterion of therapeutic equivalence to medicines with a similar mechanism of pharmacological action is recognized as invalid.

Additional criteria have been established to exclude a medicines from the list of vital and essential medicines for medical use, the list of expensive medicines, and the list of medicines for providing certain categories of citizens. A new basis for such an exception will be the presentation of a scientifically based recommendation of the chief freelance specialist of the Ministry of Health of the Russian Federation on the results of the analysis of information on the characteristics of the medicines. In the event that the manufacturer’s maximum selling price for a medicines is not registered within 6 months after the inclusion of a medicines in the list of essential medicines, this medicines should be excluded from the list.

The specified decree of the Government of the Russian Federation settled the issue of the inclusion in the lists of combined medicines. It has been established that combined medicines are included in the lists if the results of a comprehensive assessment prove their advantage in use and cost compared to single-component medicines. With such inclusion of combined medicines, all the single-component medicines registered in the Russian Federation, which make up such a combination, are subject to simultaneous inclusion.

As a new reason for rejecting the proposal to include a medicines in the lists is the submission of documents for which the commission this year decided to refuse to include (exclude) a medicines.

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1.5. The rules for state registration and reregistration of the maximum selling prices for medicines included in the list of vital and essential medicines set by medicines manufacturers are set forth in the new edition.

Decree of the Government of the Russian Federation of October 08, 2018 N 1207 "On Amendments to Decisions of the Government of the Russian Federation of October 29, 2010 N 865 and September 15, 2015 N 979"

When approving the Rules for State Registration and Reregistration of medicines included in the List of vital and essential medicines a number of significant amendments have been made to the new edition. In particular, the changes affected the state registration of the sale prices of reproduced medicines by the manufacturers of the Eurasian Economic Union Member State. Now, for all manufacturers specified in the registration certificate of medicines, a single maximum selling price of medicines is established for each dosage form, dosage and total quantity in the secondary (consumer) package without taking into account the form of release. When registering the selling price for the reproduced medicines, the corresponding coefficient shall be applied in relation to the registered maximum selling price of the manufacturer for the reference medicines in accordance with the Methodology for calculating the maximum selling prices for medicines included in the vital and essential medicines list when they are registered with the state and reregistration, approved by the Decree of the Government of the Russian Federation of September 15, 2015 N 979. Specified technique has also undergone substantial changes and now states that the price of generic medicines may not exceed registered price of the original medicines.

Another important change is the need to conduct an economic analysis when submitting documents for registration or reregistration of prices. These powers are vested in the Federal Antimonopoly Service.

Significant changes have been made in parts of the procedure for reregistering medicines prices upwards. For manufacturers registered under the law of the Eurasian Economic Union Member States, for such reregistration, it is necessary to submit a calculation of the increase in the cost of raw materials and materials in terms of the cost of production and sale of a medicines, copies of contracts confirming the increase in the cost of raw materials and materials associated with an increase in tariffs for heat, gas, etc., as well as the calculation of the increase in depreciation.

Foreign manufacturers provide copies of invoices for a specific medicines and information confirming the manufacturer's sale prices for the medicines in foreign countries, copies of customs declarations for the supply of the medicines, and information confirming the manufacturer's prices for the medicines in foreign countries.

1.6. The Russian Treasury draws attention to the identified violations of the requirements for determining the initial (maximum) contract price in the procurement of medicines for medical use.

The Letter of the Treasury of Russia of October 08, 2018 N 07-04-05/21-21405 "On the direction of summary information on the results of control measures"

The Russian Treasury indicates such violations of the Procedure for determining the initial (maximum) contract price, contract price concluded with a single supplier (contractor, performer) when purchasing medicines for medical use, approved by Order N 871n of the Ministry of Health of the Russian Federation dated October 26, 2017 (hereinafter Order), as: the calculation of the initial (maximum) contract price with ignoring the value added tax and the wholesale mark-up; when calculating the initial (maximum) contract price, the prices of the units of the medicines planned to be

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purchased are installed fully or partially without applying the methods of determining the price of a medicines unit, and when repurchasing the prices of units of medicines are not the following minimum prices, but the average values of the prices of the units planned to be purchased medicines in violation of article 3 of the Order.

In view of the above, state customers are recommended to pay special attention to compliance with the requirements of the Procedure in order to avoid the above violations.

2. Drafts of legal acts

2.1. The Ministry of Health of Russia proposes amendments to Federal Law N 61-FZ of April 12, 2010, on the circulation of funds, with regard to the procedure for the reregistration of vital and essential medicines.

The draft federal law "On Amendments to Federal Law "On Circulation of Medicines" in terms of price regulation for medicinal products included in the list of vital and essential medicines"

The bill additionally states that the registered maximum selling price of a manufacturer for a medicines may be reregistered upwards no more than once a year on the basis of an application to be filed no later than October 1 of each year, and a mandatory reregistration of those registered prior to the entry into force of the limit producer prices for medicines included in the list of vital and essential medicines in 2018 – 2019. The procedure for such reregistration is established by the Government of the Russian Federation.

Presumably, the proposed amendments additionally fix at the federal level the norms introduced by the Government Decree of October 08, 2018 N 1207 "On Amendments to the Decisions of the Government of the Russian Federation of October 29, 2010 N 865 and September 15, 2015 N 979".

2.2. The Federal Private Service of Russia proposes to make changes to part 29 of article 34 of the Law on the contract system.

Public discussions on the commencement of the development of the draft Federal Law "On Amendments to part 29 of article 34 of the Federal Law "On the contract system in the area of procurement of goods, works and services for state and municipal needs"

It is proposed to establish restrictions on the conclusion of long-term government contracts for the supply of medicines, including establishing the possibility of concluding long-term government contracts only for medicines protected by patents, subject to a significant reduction in prices for such medicines, limiting the duration of long-term government contracts to the duration of the patent for a medicines or date of entry into the market of another medicines having the same indications for use.

Such a proposal by the Federal Antimonopoly Service of Russia motivates it with the need to prevent unreasonable restriction of competition when generic medicines appear, increase the effectiveness of budget expenditures, encourage market entry of generic medicines, as well as other medicines that have the same indications for use, lower prices for medicines that do not have analogues.

2.3. The list of biotargets for the development of similar in pharmacotherapeutic action and improved analogues of innovative medicines for the development of similar in pharmacotherapeutic action and improved analogues of innovative medicines can be supplemented.

Draft order of the Ministry of Industry and Trade of the Russian Federation and the Ministry of Health of the Russian Federation "On amending the list of biotargets for the development of similar in

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pharmacotherapeutic action and improved analogues of innovative medicines approved by order of the Ministry of Industry and Trade of the Russian Federation and the Ministry of Health of the Russian Federation dated May 19, 2016 N 1605/308n

It is proposed to supplement the list with a biopeduct of AGE / RAGE with nosology: diabetic nephropathy, diabetic cataract, diabetic retinopathy, diabetic mononeuropathy, diabetic polyneuropathy, diabetic peripheral angiopathy.

3. Judicial and other law enforcement practice

3.1. The Supreme Court of the Russian Federation sent for a new trial a case of refusal to write off an accrued penalty.

Determination of the Supreme Court of the Russian Federation of October 30, 2018 N 305-ЭС18-10724 in case N A41-83159/2017

The Ministry of Health of the Moscow Region sent a claim for payment of the penalty because it decided that the contractor violated the delivery time of the medicine Goserelin to provide certain categories of citizens. In response, the executor asked to write off the accrued penalty on the basis of part 34 of Section 34 of the Law on the Contractual System in force at the time of execution of the contract. Satisfying the requirement of the ministry, the courts of two instances proceeded from the confirmation of the fact of late delivery.

However, the Supreme Court of the Russian Federation concluded that the lower courts did not take into account that the rule of art. 6.1, which was in force during the conclusion and execution of the contract. 94 of this law, it was provided that in cases and in the manner determined by the Government of the Russian Federation, the customer provides deferment of payment of penalties (fines, penalties) and (or) writes off the accrued amounts of penalties (fines, penalties). The procedure for writing off accrued sums of penalties was established Government Decree of the Russian Federation N 190, according to which the customer is obliged to provide a deferment of payment of penalties (fines, penalties) and (or) write off the accrued sums of penalties (fines, penalties) in the event that the supplier (contractor, executor) of all obligations stipulated in the contract, except for warranty obligations. The conclusion of the court of appeal about the absence of circumstances that are the basis for the cancellation of the penalty, contrary to the actual circumstances of the case and the arguments of the appeal. In connection with the above, the case is sent for a new consideration.

3.2. The Novgorod Department of the Federal Antimonopoly Service of Russia acknowledged a justified complaint in connection with the indication in the procurement documentation characteristics of the goods, which indicate the products of a single manufacturer and non-conformity of the goods to the catalog of goods, works and services for state and municipal needs.

The decision of the Novgorod Department of the Federal Antimonopoly Service of Russia of October 17, 2018

The subject of purchase was a balloon catheter with a medicines coating. The controlling authority concluded that the procurement documentation indicated on a specific manufacturer due to the fact that the technical task contains the unique characteristics of this balloon catheter, such as: catheter length, the presence of a medicines coating, the length and diameter of the balloon. At the same time, the indication in the name of the object of purchase “A balloon catheter with a medicinal coating” does not correspond to the catalog of goods, works and services for state and municipal needs, which provides for another name of the goods required by the customer: standard". The

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description of the object of purchase includes redundant characteristics of the product (the release of the medicines substance, the length of the catheter, etc.) that are not covered by the description of the object of purchase contained in the catalog of goods, works and services for state and municipal needs.

In practice, the evaluation of the indication in the documentation on the procurement of the characteristics of the goods supplied, corresponding only to the goods of one manufacturer, is carried out by the controlling authority in each case individually. Significant influence is indicated by such factors as the compliance of the subject of procurement of catalog of goods, works and services for state and municipal needs, as well as violations by the state customer of the Law on the contract system.

3.3. The Omsk Department of the Federal Antimonopoly Service of Russia acknowledged the complaint of the procurement participant to be justified, since the requirements established in the terms of reference of the auction documentation do not allow the procurement participants to offer an interchangeable medicines.

The decision of the Omsk Department of the Federal Antimonopoly Service of Russia of 05.10.2018 N 03-10.1/311-2018

According to clause 1 of the technical part of the auction documentation for delivery, the medicines International Nonproprietary Name Tobramycin with the characteristics specified by the Customer was required, namely: a solution for intravenous and intramuscular administration of 40 mg / ml, 2 ml - ampoules (5) - blister (2). Analysis of the instructions of the state register of medicines showed that the medicines International Nonproprietary Name: Tobramycin with established characteristics, namely: a solution for intravenous and intramuscular administration of 40 mg / ml, 2 ml - ampoules (5) - blister (2) corresponds to a single manufacturer - Teva Pharmaceutical Plant Co. Ltd. The remaining medicines with the International Nonproprietary Name: Tobramycin have a different dosage form. The characteristics of this product are given to the specific manufacturer.

In this regard, the supervisory authority concluded that the requirements established in the technical specifications of the auction documentation do not allow the procurement participants to be offered a medicines interchangeable within the International Nonproprietary Name Tobramycin.