BRACE
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DIGEST
of regulation of pharmaceutical industry

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Brief news

In September 2018, a number of important acts were adopted at the EAEU level: The EEC Board approved the Guidelines for the Preparation of a Regulatory Document on the Quality of a Medicinal Product, the Classifier of Dose Measurement Units and Concentrations of Active Substances in Medicinal Products, the Guideline for the Quality of Medicines for Inhalation and Nasal Medicinal Products drugs. Accepted Recommendation “On the Quality Guide for Medicines for Inhalation and Nasal Medicines”

Roszdravnadzor listed typical mistakes of drug manufacturers, as well as persons importing drugs into the territory of Russia: inconsistency of information on drugs received in civil circulation with data from the state register of drugs, data specified in the declarations of conformity and certificates of conformity, unreliability of data, also violation of the deadlines for the provision of information.

FAS Russia extended the period of informing drug manufacturers about the size of wholesale mark-ups, as well as a number of explanations on the calculations.

Among legislative initiatives, it is necessary to mention a proposal to strengthen patent protection of the state registration of drugs by the Ministry of Healthcare, namely, when performing state registration of drugs for medical use, providing the applicant with information on the existing intellectual property rights to the claimed drug, and also confirming that registration of the drug does not violate rights of third parties to intellectual property. For failure to submit a registration certificate of a medicinal product to a biotechnological or orphan drug to conduct clinical trials of a reconstituted medicinal product, administrative liability may be introduced.

The Russian Ministry of Healthcare proposed to impose a fine in the amount of 100,000 rubles for the holder or owner of the registration certificate of a medicinal product for a biotechnological or orphan drug to another legal entity intending to carry out state registration of a replicated medicinal product, samples of a reference medicinal product for clinical research. Also, the Ministry of Health of Russia is proposing to introduce the obligation for medical organizations to exercise internal control over the direction of drug safety, as well as sending messages to Roszdravnadzor in order to monitor the safety of drugs on identified cases of side effects not indicated in the instructions for use of the drug, serious adverse reactions and unforeseen unwanted reactions when using drugs, including those that served as the basis eat for prescribing drugs.

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1. Laws, by-laws, legal news

1.1. Guidelines for the preparation of a regulatory document on the quality of the medicinal products approved.

The decision of the Board of the Eurasian Economic Commission from 07.09.2018 N 151

The document specifies the structure of a regulatory document on the quality of a medicinal product, which includes the title page, the composition of the medicinal product, specification, description of methods and tests, description of packaging, marking, storage conditions and shelf life. A separate annex to the Guidelines for the preparation of a regulatory document on the quality of a medicinal product includes detailed requirements for the preparation of specifications, a description of approaches to the development of a single set of specifications.

1.2. The classification of dosage units and concentrations of active ingredients in the composition of medicinal products rugs is approved.

The decision of the Board of the Eurasian Economic Commission from 07.09.2018 N 150

This classification method will be applied when registering funds in the Eurasian Economic Union, as well as during the operation of the Eurasian Economic Union reference information system.

1.3. The guide for the quality of medicinal products for inhalation and nasal medicinal products is approved.

Recommendation N 17, dated September 7, 2018, "On the Guidelines for the quality of Medicinal Products for Inhalation and Nasal Medicinal Products"

The Guide for the Eurasian Economic Union Member States is recommended to be applied 6 months after the date of publication on the Eurasian Economic Union website when conducting research, examining, forming registration dossiers of inhalation medicinal products and nasal medicinal products. The manual contains such information requirements for consumers of medical workers as: qualitative and quantitative composition, dosage, precautionary measures, etc.

This document contributes to the creation of a unified policy for medicinal products in this category. The Guide for the Eurasian Economic Union Member States is recommended to be applied 6 months after the date of publication on the Eurasian Economic Union website when conducting research, examining, forming registration dossiers of inhalation medicinal products and nasal medicinal products. The manual contains such information requirements for consumers of medical workers as: qualitative and quantitative composition, dosage, precautionary measures, etc.

This document contributes to the creation of a unified policy for medicinal products in this category.

1.4. The list of the IV List of Narcotic Drugs, Psychotropic Substances and their Precursors has been added, approved by the Decree of the Government of the Russian Federation of 06.30.1998 N 681.

Decree of the Government of the Russian Federation of 28.03.2018 N 337 "For amendments to some acts of the Government of the Russian Federation in connection for improvement of control over the trafficking of precursors of narcotic drugs and psychotropic substances" (entered into force on September 27, 2018)

All tables of the List of precursors whose turnover in the Russian Federation is limited and for which control measures are established in accordance with the legislation of the Russian Federation and international treaties of the Russian Federation (List IV) are supplemented by new precursors All

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tables of the List of precursors whose turnover in the Russian Federation is limited and for which control measures are established in accordance with the legislation of the Russian Federation and international treaties of the Russian Federation (List IV) are supplemented by new precursors.

1.5. The list of medicinal products that are prescribed for medical care for children with type I mucopolysaccharidosis has been approved.

Public discussions of the draft order of the Ministry of Health "On approving the standard of specialized medical care for children with type I mucopolysaccharidosis (enzyme replacement therapy)" ended in September 2018. The project approves the list of medicinal products for medical use that are assigned to this category of patients according to the instructions for use of the medicinal products and pharmacotherapy group on anatomical, therapeutic and chemical classification recommended by the World Health Organization. And also takes into account the method of administration and use of the medicinal products. Appointment and use of medicinal products for medical use that are not included in this standard are allowed in case of medical indications.

1.6. The Federal Healthcare Surveillance Service has listed common mistakes of medicinal products.

Letter dated August 12, 2018 N 01I-2222/18 "On the information that must be provided to Federal Service for Surveillance in Healthcare"

The Federal Healthcare Surveillance Service draws attention to the fact that drug manufacturers and individuals who import medicinal products into the Russian Federation need to provide information according to the procedure for selectively monitoring the quality of medicines for medical use, approved by the Order of the Federal Healthcare Surveillance Service dated 07.08.2015 N 5539. Responsibility for failure to provide this information is provided for in Art. 19.7.8 Administrative Code.

The letter informs that organizations that are obliged to transfer this information gain access to the Automated Information System of Federal Healthcare Surveillance Service. In this letter, Federal Healthcare Surveillance Service makes reference to typical violations during the submission of information. Among such violations, the following are distinguished: inconsistency of information on medicinal products received in civil circulation with the data of the state register of medicinal products, data indicated in the declarations of conformity and conformity certificates, inaccuracy of data, as well as violation of established deadlines for providing information.

It's supposed that this letter will have a positive impact on reducing the number of violations of the requirements for the provision of information about medicines to Federal Healthcare Surveillance Service.

1.7. The Federal Antitrust Service extended the period for informing drug manufacturers about the size of wholesale mark-ups and clarified the settlement procedure.

Letter of the Federal Antitrust Service of Russia dated September 03, 2018 N AC / 70030/18

The deadline for providing information on the preservation of the limits of wholesale mark-ups that are included in the vital and essential medicines data has been extended to November 12, 2018 for technical reasons.

It's clarified that the calculation of gross profit in the reporting period is made from the difference between the weighted average selling price of medicinal products and the weighted average actual selling price of the manufacturer. To exclude from the calculation of the planned amount of surcharges when medicinal products are sold below the acquisition price, negative values of gross profit are not taken into account when summing up the values for each medicinal product.

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1.8. The Ministry of Finance explained the procedure for determining the VAT rate when importing medicines into the Russian Federation for which the registration certificate expired.

Letter of the Ministry of Finance of Russia of September 13, 2018 N 03-09-19 / 65511

Medicinal products that do not have registration certificates, including due to the expiration of the registration certificate, the value added tax rate of 10 percent does not apply. Taxation of such medicinal products is made at the rate of value added tax of 18 percent.

2. Drafts of legal acts

2.1. It is planned to strengthen legislatively the patent protection of the state registration of medicinal products by the Ministry of Health of the Russian Federation

Draft federal law "On Amendments to the Federal Law "On Circulation of Medicines"

On September 7, 2018, at the initiative of the Ministry of Health of the Russian Federation, a bill was submitted for public condemnation, which is designed to harmonize the norms of the current Russian legislation with the requirements of the Eurasian Economic Union legislation. According to Annex 2 of the Registration Rules for the registration of medicines (bringing the registration dossier of a medicinal product in accordance with the requirements of the acts constituting the law of the Eurasian Economic Union), having a patent issued in accordance with the legislation of the Eurasian Economic Union member state. The applicant submits a certified copy of such patent or license agreement that gives the right to manufacture and sale of a registered medicine product. The applicants submit a letter stating that the intellectual rights of third parties, protected by a patent or transferred under a license, are not violated in connection with the registration of a medicinal product.

However, due to the absence of such rules in Russian legislation, in practice in the Russian Federation, generic registration was carried out before the expiration of the patent. In fact, in such a situation, the protection of the rights of the patent owner is possible only in a court of law. Due to the length of disputes and large losses, it became necessary to resolve this issue at the legislative level.

The draft federal law "On Amendments to the Federal Law "On Circulation of Medicines" provides for the registration of medicinal products the need to provide information on the existing intellectual property rights to the declared medicinal product, as well as confirming that the registration of the medicinal product does not violate the third-party intellectual property rights.

For failure to submit a registration certificate of a medicinal product to a biotechnological or orphan medical product to conduct clinical trials of a reconstituted medicinal product, administrative liability may be introduced. For failure to submit a registration certificate of a medicinal product to a biotechnological or orphan medical product to conduct clinical trials of a reconstituted medicinal product, administrative liability may be introduced.

2.2. Administrative responsibility may be specified for failure to submit a registration certificate of a medicinal product of a biotechnological or orphan medicinal product for conducting clinical trials of a replicated medicinal product.

Draft Federal Law "On Amendments to the Administrative Code"

The Ministry of Health of Russia has an important initiative that will affect the interests of pharmaceutical manufacturers made. September 25, 2018 submitted for public debate, which will last until October 9, 2018.

The project proposes to introduce Article 6.34 into the Administrative Code, which establishes a fine in the amount of 100,000 rubles for the holder or owner of the registration certificate of a

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medicinal product for a biotechnological or orphan drug to another legal entity intending to carry out state registration of a replicated medicinal product, samples of a reference medicinal product for conducting clinical research.

These innovations can shorten the time-to-market for medicinal products of reproducible medicinal products. This will enable the conduct of clinical studies during the four-year ban on the state registration of reproduced drugs, which is calculated from the date of state registration of the reference medicinal product.

2.3. The Ministry of Healthcare of Russia proposes to approve the requirements for the organization and conduct of quality control and safety of medical activities.

Draft Order "On approval of requirements for the organization and conduct of quality control and safety of medical activities"

On September 21, 2018, the Ministry of Healthcare of Russia prepared a document according to which the duty of internal control by medical organizations in the direction of drug safety is introduced. Monitoring is planned in the form of an assessment of the quality, reasonableness and effectiveness of diagnostic and treatment activities, including prescription of drugs, as well as sending messages to the Federal Service for the Supervision of Healthcare to monitor the safety of drugs on identified cases of side effects that are not specified in the instructions for use of the drug, serious adverse reactions and unforeseen adverse reactions when using drugs, including those that served as the basis for prescribing drugs.

2.4. On September 25, 2018, the public discussion of the project on the approval of the rules for organizing the provision of medicines for medical use and the rules for maintaining the federal register of persons under the 7 Nosology Program was completed.

Draft Resolution of the Government of the Russian Federation "On Approval of the Rules for Organizing the Provision of Medicines for Medical Use and Rules for Maintaining the Federal Register of Persons with hemophilia, pituitary nanism, Gaucher's disease, malignant neoplasms of lymphoid, hematopoietic and related tissues, multiple sclerosis, hemolytic uremic syndrome, juvenile arthritis with systemic onset, mucopolysaccharidosis i, ii and vi types, after organ and / or tissue transplantation"

Currently, the document is undergoing anti-corruption expertise. If the document is accepted, the authorized bodies will be obliged to enter the relevant information in the Federal Register within 5 working days from the date of treatment of the patient with this diagnosis. Forms will be approved to provide data on prescribed medications intended for this category of patients.

2.5. May be represented by the right to receive subsidies for Russian producers of goods that have the exclusive right to the appellation of origin of goods.

Draft Government Decree "On Amendments to the Rules for the provision of subsidies to Russian Manufactures to finance part of the costs associated with registration of intellectual property on foreign markets"

On September 27, 2018, the project entered for an independent anti-corruption expertise according to the data of the Federal portal of draft regulations.

The draft Decree proposes to fill the gap in the law in that the provision of subsidies for Russian producers of goods that have the exclusive right to designate the place of origin of goods is not currently provided.

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In addition, the project provides for the expansion of the rules for compensation of costs for the preparation of an application for registration of an exclusive right to the appellation of origin, as well as for payment of fees stipulated by the normative legal acts of national patent offices related to filing, considering applications and issuing certificates on the exclusive right to the appellation of origin of goods and (or) the geographical indication.

3. Judicial and other law enforcement practice

3.1. The establishment by the public customer of the requirements for the dosage of purchased goods is legal if it is justified by the need to ensure the safety of patients.

Determination of the Supreme Court of the Russian Federation of 06.09.2018 N 309-KG18-13516 in case N A76-12088 / 2017

Submitted by the decisions of the courts of lower instances, which recognized the prescription of the antitrust authority as illegal, in the opinion of which there was a violation during the procurement, expressed in indicating in the auction documentation the right to conclude contracts for the specific dosage required for the delivery of goods (“Antibacterial medicinal products Cefoperazone + Sulbactam").

The Supreme Court decided that the requirements for the dosage of the medicinal product fully meet the needs of the customer, as they are associated with ease of use and the need to ensure the safety of patients because of its specific. Differences in achieving a clinically comparable therapeutic effect, which depends on the dosage of the medicinal product, especially the pharmacological properties and principles of application, indicate the impossibility of replacing it with medicinal products with dosage options in a multiple amount.

It should be noted that the validity of the procurement with the designation of requirements for the dosage of the supplied medicinal products is evaluated by the antitrust authorities and the courts on an individual basis, which leads to the presence of a variety of judicial and administrative practices.

3.2. The rejection of the application of the participant due to the incompleteness of the information on compliance with the requirements for procurement is recognized as illegal.

Determination of the Supreme Court of the Russian Federation of September 14, 2017 N 310-KG18-13912 in case N A36-7353 / 2017

The decisions of the lower courts are upheld and refused to transfer the case to the Judicial Board on Economic Disputes of the Supreme Court of the Russian Federation. Arguments of the customer about the ambiguity of the formulations contained in the submitted application for participation in the electronic auction were deemed unfounded.

According to the case file, when reviewing and evaluating the said application, the auction commission decided that it did not meet the requirements of the auction documentation, since the information provided in the auction participant’s declaration of its compliance with the requirements set forth in clauses 3–9 of part 1 of article 31 of the Federal Law of April 5, 2013 N 44-FZ “On the contract system in the field of procurement of goods, works, services for meeting state and municipal needs” (hereinafter referred to as the Law on the Contract System) allows for its ambiguous interpretation and do not decipher as amended the Law on the Contract System introduced by the Federal Law of 28.12.2016 N 489-ФЗ, namely: 1) the information provided for in paragraph 7 of Part 1 of Article 31 of the Law on the Contract System of the absence of from a procurement participant - an individual or from a manager, members of a collegial executive body, a person performing the functions of the sole executive body, or the chief accountant of a legal entity - party to the

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procurement of a conviction for economic crimes and / or crimes under articles 289, 290, 291, 291.1 of the Criminal Code of the Russian Federation; 2) information provided for in clause 7.1 of Part 1 of Article 31 of the Law on the Contract System.

The court decided that this federal law does not contain the obligatory condition that each clause of Article 31 of the Federal Law “On the Contract System” must be deciphered and prescribed separately in the application.