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**GOVERNMENT OF THE RUSSIAN FEDERATION**

ORDER

of June 1, 2021 No. 853

MOSCOW

**On Approval of the Rules on Importing Medicines for Medical Use into the Russian Federation and Invalidation of Certain Acts and Individual Provisions of Certain Acts of the Government of the Russian Federation**

In accordance with Part 1 of Article 47 of the Federal Law on Circulation of Medicines, the Government of the Russian Federation **hereby orders**:

1. To approve the attached:

Rules on Importing Medicines for Medical Use into the Russian Federation;

List of Inoperative Acts and Individual Provisions of Acts of the Government of the Russian Federation.

1. This Order shall come into force on September 1, 2021.

The Rules approved by this Order shall remain valid until September 1, 2027.

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| Chairman of the Government of the Russian Federation |  | М. Mishustin |
|  | Stamp:CENTRAL OFFICE OF THE GOVERNMENT OF THE RUSSIAN FEDERATION \* DEPARTMENT OF DOCUMENTATION SUPPORT \* OF THE GOVERNMENT OF THE RUSSIAN FEDERATION \* No.1 |  |

APPROVED BY

Order of the Government of the Russian Federation

of June 1, 2021 No. 853

**RULES**

**on Importing Medicines for Medical Use into the Russian Federation**

1. These Rules set out the procedure for the importation into the Russian Federation of medicines for medical use, with the exception of medicinal products for providing humanitarian aid (assistance) or emergency relief (hereinafter - ‘medicines’).

These Rules shall not apply to the importation of narcotic drugs, psychotropic substances and their precursors included in section 2.12 ‘Narcotic Drugs, Psychotropic Substances and Their Precursors’ of the list of goods subject to the approval-based procedure for importing into and (or) exporting from the customs territory of the Eurasian Economic Union (Appendix No. 2 to Decision of the Board of the Eurasian Economic Commission of April 21, 2015 No.30 on Non-Tariff Regulation Measures), in the list of narcotic drugs, psychotropic substances and their precursors subject to control in the Russian Federation approved by Order of the Government of the Russian Federation of June 30, 1998 No.681 on Approval of the List of Narcotic Drugs, Psychotropic Substances and Their Precursors Subject to Control in the Russian Federation, and in the nomenclature of potent and poisonous substances that are not precursors of narcotic drugs and psychotropic substances subject to the procedure for importing into and exporting from the Russian Federation approved by Order of the Government of the Russian Federation of March 16, 1996 No.278, which nomenclature has been approved by Order of the Government of the Russian Federation of August 3, 1996 No.930.

1. The following legal entities are allowed to import medicines into the Russian Federation:
	1. manufacturers of medicines for the purpose of inhouse production of medicines;
	2. wholesalers of medicines;
	3. foreign developers of medicines and foreign manufacturers of medicines or other legal entities acting on behalf of the developer of a medicine for the purpose of conducting clinical trials of the medicinal product, registering and carrying out expert examination of medicines intended for circulation in the Russian Federation or in the common market of medicines within the Eurasian Economic Union, carrying out state registration of the medicinal product, including the pharmaceutical substance in the state register of medicines and performing quality control of medicines, provided that the Ministry of Health of the Russian Federation has issued a conclusion (approval) in accordance with Decision of the Board of the Eurasian Economic Commission dated May 16, 2012 No.45 on a Single Form of a Conclusion (Approval) for the Import, Export and Transit of Certain Goods Included in the Single List of Goods to Which Non-Tariff Regulation Measures Apply in Trade with Third Countries and the Methodical Guidelines for Filling the Form (hereinafter a ‘conclusion’);
	4. research centers, higher education institutions and manufacturers of medicines for the purpose of development, research, control of safety, quality and effectiveness of the medicines, provided that a conclusion has been issued;
	5. medical organizations and organizations specified in subparagraphs a-d of this paragraph for the purpose of providing life-saving medical care to a particular patient or giving medical care to a limited group of patients with a rare and (or) especially severe pathology, provided that a conclusion has been issued.
2. A specific batch of registered and (or) unregistered medicines intended for clinical trials of medicinal products, a specific batch of unregistered medicinal products for expert examination of medicines for the purpose of registration and expert examination of the medicines intended for circulation in the Russian Federation or in the common market of medicines within the Eurasian Economic Union, for performance of state registration of the medicinal products, inclusion of the pharmaceutical substance in the state register of medicines, a specific batch of unregistered medicines for the purpose of providing life-saving medical care to a particular patient (hereinafter a ‘specific batch of medicines’) may be imported into the Russian Federation on the basis of the conclusion on an application of legal entities specified in subparagraphs a-e of paragraph 2 of these Rules.

Medicines may be imported into the Russian Federation for the purposes specified in paragraph 5 of these Rules.

1. It is prohibited to import into the Russian Federation falsified, poor-quality, counterfeit medicines.
2. Medicinal products for medical use may be imported into the Russian Federation for personal use and other non-commercial purposes without a conclusion if they are intended for:
	1. personal use by individuals arriving in the Russian Federation. In such a case, medicinal products containing potent and (or) toxic substances included, respectively, in the list of potent substances for the purposes of Article 234 and other articles of the Criminal Code of the Russian Federation and in the list of poisonous substances for the purposes of Article 234 and other articles of the Criminal Code of the Russian Federation approved by Order of the Government of the Russian Federation of December 29, 2007 No.964 on Approval of Lists of Potent and Poisonous Substances for the Purposes of Article 234 and Other Articles of the Criminal Code of the Russian Federation and Large Amounts of Potent Substances for the Purposes of Article 234 of the Criminal Code of the Russian Federation shall be imported into the Russian Federation on presenting documents (certified copies of or certified extracts from the documents) confirming that the specified medicinal products have been prescribed to the individual, unless the medicinal products are registered in the Russian Federation and sold in the Russian Federation without a prescription. These documents (certified copies of or certified extracts from the documents) must contain information on the name and quantity of the prescribed medicinal product. If such documents (certified copies of or certified extracts from the documents) are made in a foreign language, they shall be accompanied by a notarized translation into the Russian language;
	2. use by employees of the diplomatic corps or representatives of international organizations accredited in the Russian Federation;
	3. treatment of passengers and transport crew members, train crews and drivers of vehicles arriving in the customs territory of the Eurasian Economic Union (in the first aid kits of these vehicles in a limited number determined by the legislation of the state of their registration);
	4. treatment of participants in official international cultural, sports events and participants of international expeditions.
3. For a legal entity specified in paragraph 2 of these Rules (hereinafter the ‘applicant’) to receive a conclusion, the applicant shall submit to the Ministry of Health of the Russian Federation, using the federal state information system Unified Portal of State and Municipal Services (Functions) (hereinafter the ‘Unified Portal’) in the form of an electronic document signed with an electronic signature (a simple electronic signature, or an enhanced qualified electronic signature, or an enhanced unqualified electronic signature for which the verification key certificate is created and used in the infrastructure that ensures information and technology interaction between information systems used to provide state and municipal services in electronic form, in accordance with the procedure established by the Government of the Russian Federation), an application (indicating the name of the medicinal product and (or) pharmaceutical substance, pharmaceutical form, dosage, concentration, filling amount, name of the manufacturer of the medicinal product and (or) pharmaceutical substance, country of manufacture of the medicinal product and (or) pharmaceutical substance) (hereinafter the ‘application’) accompanied by the following documents in electronic form (a package of electronic documents):
	1. the draft conclusion;
	2. substantiation of the quantity of imported medicinal products and (or) pharmaceutical substances. The substantiation of the quantity of imported medicines for the purpose of development, research, safety and quality control, and effectiveness of medicines shall be based on the flow chart of production process of the medicine and the material balance (production formulation) compiled according to the data from industrial regulations (technological instructions) for the production of medicines or a draft thereof and presented in the form of extracts from industrial regulations (technological instructions) or drafts thereof, extracts from normative documents (normative document on quality) or drafts thereof, containing information on the quantity of the medicine required to conduct quality tests by relevant indicators, references to Pharmacopoeial monographs of the State Pharmacopoeia, Pharmacopoeial monographs of the Pharmacopoeia of the Eurasian Economic Union or foreign pharmacopoeias and calculations of the expert institution that conducts expert examination of medicines. The substantiation of the quantity of medicinal products imported for the purpose of conducting clinical trials of the medicinal product shall be based on the conditions of use of the medicinal product within the framework of the clinical trial and presented in the form of information on the dosage regimen, doses, concentrations, filling amounts, frequency of administration, duration of use of the medicinal product in the clinical trial, the number of trial subjects, or other documents confirming the need to import the medicinal product in the declared quantity;
	3. copies of the agreement (contract), annexes and (or) addenda thereto, and in the absence of an agreement (contract), copies of another document confirming the intentions of the parties (in the case of participation of 2 or more parties);
	4. copies of documents confirming the quality of the medicinal product (unless the medicinal product is imported for the purpose of providing life-saving medical care to a particular patient or giving medical care to a limited group of patients with a rare and (or) especially severe pathology) and (or) pharmaceutical substances issued by the manufacturer of the medicines or other organization authorized to confirm the quality of medicines in accordance with the legislation of the country of origin of the medicine, specifying indicators (characteristics) and the place of manufacture of this medicine;
	5. in the case of importing a specific batch of registered and (or) unregistered medicines intended for clinical trials of medicinal products, copies of documents (package designs and (or) photographs) confirming the proper labeling of the medicines as intended for use exclusively in clinical trials;
	6. in the event that the medicinal product is imported to provide life-saving medical care to a particular patient:

a copy of the protocol of the conclusion of a medical commission or a council of doctors of a federal institution (a medical commission or a council of doctors of a structural subdivision of a scientific or educational federal institution) where medical care is provided to the patient, signed by the head of the institution (the head of the structural subdivision of the scientific or educational federal institution, a person acting as the head of the institution, or an authorized person occupying a position not lower than the head of the structural subdivision of the scientific or educational federal institution, their deputy responsible for matters of organizing medical care) on the prescription of the unregistered medicinal product to the patient for providing life-saving medical care (indicating the trade name or international non-proprietary name, pharmaceutical form, dosage and quantity of the unregistered medicinal product and justification of the need for its import) or a request filed by an authorized executive body of the constituent entity of the Russian Federation on the need to import the unregistered medicinal product for the purpose of providing life-saving medical care to this particular patient with a copy of the protocol of the decision of the medical commission or the council of doctors of the institution of the constituent entity of the Russian Federation where the medical care is provided to the patient signed by the head of the institution or by a person acting in lieu of them on the prescription of the unregistered medicinal product to the patient for the purpose of providing life-saving medical care (indicating the trade name or international non-proprietary name, pharmaceutical form, dosage and quantity of the unregistered medicinal product);

a copy of the passport or birth certificate of the patient to whom the unregistered medicinal product is prescribed for the purpose of providing life-saving medical care.

It is not allowed to re-submit the above protocols of decisions of medical commissions or councils of doctors, if a conclusion has already been issued on them earlier (except for decisions of medical commissions or councils of doctors prescribing the medicinal product for life or long-term therapy for the condition).

1. Importation of a medicinal product not registered in the Russian Federation for the purpose of giving medical care to a limited group of patients with a rare and (or) especially severe pathology shall be carried out on the basis of a conclusion prepared in accordance with a relevant act of the Government of the Russian Federation, which specifies the legal entity importing the unregistered medicinal product into the Russian Federation, the international non-proprietary names of the medicinal products, their pharmaceutical forms, strengths, quantities to be imported, and the disease (condition) of the patients included in the group for which the medicinal product is imported.

The legal entity specified in the act of the Government of the Russian Federation shall, within 3 business days of the date of its publication, submit an application to the Ministry of Health of the Russian Federation through the Unified Portal together with the documents specified in subparagraphs a and c of paragraph 6 of these Rules. The application shall indicate the number and date of the act of the Government of the Russian Federation.

The submitted documents shall be considered and a decision on them shall be made in accordance with paragraph 9 of these Rules.

1. For the purpose of issuing a conclusion, the applicant may, on its own initiative, submit copies of the certificate of state registration and certificate of registration with a tax authority, as well as copies of the approval of the Ministry of Health of the Russian Federation to conduct a clinical trial of the medicinal product (in case of importing a specific batch of medicines intended for clinical trials of medicinal products). The Ministry of Health of the Russian Federation may not demand that the applicant submits copies of these documents.
2. The Ministry of Health of the Russian Federation shall, within 5 business days of the date of receipt of the documents specified in paragraphs 6 and 7 of these Rules:
	1. verify the completeness and accuracy of the information contained in the documents submitted by the applicant, and if the applicant has not submitted a copy of the Ministry’s approval to conduct a clinical trial of the medicinal product (in the case of importing a specific batch of medicines intended for clinical trials of medicinal products) and check whether the specified approval has been issued to the applicant using the data from the register of issued approvals to conduct clinical trials of medicinal products;
	2. request and receive from the Federal Tax Service, through an interdepartmental information exchange process, information on whether the applicant’s details are entered in the Unified State Register of Legal Entities and whether the applicant is registered with a tax authority, if the applicant has not submitted copies of the certificate of state registration and certificate of registration with a tax authority;
	3. make a decision to issue a conclusion or to refuse to issue a conclusion indicating the reasons for such refusal;
	4. send to the applicant’s account on the Unified Portal in the form of an electronic document signed with an enhanced qualified electronic signature the conclusion or give notice of refusal to issue the conclusion, indicating the reasons for such refusal.
3. Refusal to issue a conclusion shall not prevent the applicant from resubmitting the documents and information in accordance with paragraph 6 of these Rules once the reasons that served as the grounds for refusal have been eliminated.
4. No fee shall be charged for issuing a conclusion.
5. The following circumstances shall be the grounds for refusal to issue a conclusion:
	1. the documents submitted by the applicant for the purpose of obtaining a conclusion contain incomplete or inaccurate information;
	2. the medicine for medical use declared for importation into the Russian Federation is prohibited for medical use in the territory of the Eurasian Economic Union;
	3. the legal entity that has submitted the application and documents for the purpose of obtaining a conclusion in accordance with paragraph 7 of these Rules is not indicated in the relevant act of the Government of the Russian Federation as a person authorized to import medicinal products not registered in the Russian Federation for the purpose of giving medical care to a limited group of patients with a rare and (or) especially severe pathology.
6. The Ministry of Health of the Russian Federation shall keep a register of issued conclusions in electronic form in accordance with its own procedure, which register shall be for informational purposes only.
7. The information contained in the conclusions shall be submitted by the Ministry of Health of the Russian Federation to the customs authorities in electronic form, through a unified system of interdepartmental electronic information exchange, on a weekly basis, but not later than the first business day of a calendar week.
8. Organizations that have imported into the Russian Federation medicinal products for the purpose of providing life-saving medical care to a particular patient, as well as organizations that have imported a medicinal product not registered in the Russian Federation for the purpose of giving medical care to a limited group of patients with a rare and (or) especially severe pathology shall, within 10 business days of receipt of the medicinal products by the medical organization that provides medical care to the patient, notify the Ministry of Health of the Russian Federation in the form of an electronic document signed with an electronic signature (a simple electronic signature, or an enhanced qualified electronic signature, or an enhanced unqualified electronic signature).

APPROVED BY

Order of the Government of the Russian Federation

of June 1, 2021 No. 853

**LIST**

**of Inoperative Acts and Individual Provisions of Acts of the Government of the Russian Federation**

1. Order of the Government of the Russian Federation of September 29, 2010 No.771 on the Procedure for Importing Medicines for Medical Use into the Russian Federation (Collected Legislation of the Russian Federation, 2010, No.41, Article 5235).
2. Order of the Government of the Russian Federation of June 3, 2011 No.441 on Amending Certain Acts of the Government of the Russian Federation on the Import of Medicines for Medical Use into the Russian Federation (Collected Legislation of the Russian Federation, 2011, No.24, Article 3494).
3. Paragraph 4 of the amendments to be made to the acts of the Government of the Russian Federation on the provision of state services in the field of circulation of medicines approved by Order of the Government of the Russian Federation of December 5, 2011 No.1001 on Amending Certain Acts of the Government of the Russian Federation on the Provision of Public Services in the Field of Circulation of Medicines (Collected Legislation of the Russian Federation, 2011, No.50, Article 7390).
4. Paragraph 128 of the amendments to be made to the acts of the Government of the Russian Federation on matters relating to activities of the Ministry of Health of the Russian Federation approved by Order of the Government of the Russian Federation of September 4, 2012 No.882 On Amending Certain Acts of the Government of the Russian Federation on the Matters Relating to Activities of the Ministry of Health of the Russian Federation (Collected Legislation of the Russian Federation, 2012, No.37, Article 5002).
5. Paragraph 28 of the amendments to be made to the acts of the Government of the Russian Federation approved by Order of the Government of the Russian Federation of October 15, 2014 No.1054 On Amending Certain Acts of the Government of the Russian Federation (Collected Legislation of the Russian Federation, 2014, No.43, Article 5892).
6. Order of the Government of the Russian Federation of December 28, 2016 No.1515 On Amending Paragraph 9 to the Rules on Importing Medicines for Medical Use into the Russian Federation (Collected Legislation of the Russian Federation, 2017, No.2, Article 346).