

**RUSSIAN FEDERATION**  
**FEDERAL LAW**  
**ON CIRCULATION OF MEDICINES**

Adopted by  
the State Duma  
on March 24, 2010

Approved by  
the Federation Council  
on March 31, 2010

(as amended by Federal Laws of July, 27 2010, No. 192-FZ,  
of October 11, 2010, No. 271-FZ, of November 29, 2010 No. 313-FZ,  
of December 06, 2011 No. 409-FZ, of June 25, 2012 No. 93-FZ,  
of December 25, 2012 No. 262-FZ, of July 02, 2013 No. 185-FZ,  
of November 25, 2013 No. 317-FZ, of March 12, 2014 No. 33-FZ,  
of October 22, 2014 No. 313-FZ, of December 22, 2014 No. 429-FZ,  
of March 08, 2015 No. 34-FZ, of June 29, 2015 No. 160-FZ,  
of July 13, 2015 No. 233-FZ, of July 13, 2015 No. 241-FZ,  
of July 13, 2015 No. 262-FZ, of December 14, 2015 No. 374-FZ,  
of December 29, 2015 No. 389-FZ, of June 02, 2016 No. 163-FZ,  
of July 03, 2016 No. 261-FZ, of July 03, 2016 No. 305-FZ,  
of July 03, 2016 No. 350-FZ, of July 29, 2017 No. 242-FZ,  
of July 29, 2017 No. 278-FZ, of December 28, 2017 No. 425-FZ,  
of June 04, 2018 No.140-FZ, of November 28, 2018 No. 449-FZ,  
of December 27, 2018 No. 511-FZ, of June 06, 2019 No. 134-FZ,  
of July 26, 2019 No. 240-FZ, of August 02, 2019 No. 297-FZ,  
of December 27, 2019 No. 462-FZ, of December 27, 2019 No. 475-FZ)

**Chapter 1. GENERAL PROVISIONS**

Article 1. Subject of Regulation of This Federal Law

1. This Federal Law regulates relations arising in connection with circulation, i.e. development, preclinical trials, clinical trials, expert examination, state registration, standardization and quality control, production, manufacture, storage, transportation, import into the Russian Federation, export from the Russian Federation, advertising, dispensation, distribution, transfer, use and destruction of medicines.

(as amended by Federal Law of December 06, 2011 No. 409-FZ)

2. This Federal Law establishes the priority of the state regulation of safety, quality and efficacy of medicines in the process of their circulation.

(as amended by Federal Law of June 25, 2012 No. 93-FZ)

## Article 2. Scope of Application of this Federal Law

This Federal Law applies to relations arising in the process of circulation of medicines in the Russian Federation.

## Article 3. Legislation on Circulation of Medicines

1. Legislation on circulation of medicines comprises this Federal Law, other federal laws and other regulatory legal acts of the Russian Federation;

1.1. The legislation on the circulation of medicines applies to the legal entities and individual entrepreneurs who carry out the activity on the territory of the international medical cluster, considering special circumstances set forth by the Federal law "About the international medical cluster and amendments of certain legislative acts of the Russian Federation".

(clause 1.1 introduced by Federal Law of June 29, 2015 No. 160-FZ)

2. This Federal Law applies to circulation of narcotic and psychotropic medicines with account of the specifics established by the legislation of the Russian Federation on narcotic drugs, psychotropic substances and precursors thereof.

3. This Federal Law applies to circulation of radiopharmaceutical medicines with account of the specifics established by the legislation of the Russian Federation in the area of radiation safety.

4. If an international treaty of the Russian Federation establishes rules other than those stipulated by this Federal Law, the rules of the international treaty shall apply.

5. In the Russian Federation in accordance with the international treaties of the Russian Federation and (or) based on the principle of reciprocity, results of clinical trials of medicinal products for medical use conducted outside the Russian Federation shall be acknowledged.

## Article 4. Basic Concepts Used in this Federal Law

For the purpose of this Federal Law the following basic concepts are used:

1) medicines are substances or combinations thereof coming in contact with the human or animal body, penetrating into the organs and tissues of the human or animal body, used for prophylaxis, diagnostics (except for substances or combinations thereof not coming in contact with the human or animal body), treatment of disease, rehabilitation, as well as for maintenance, prevention or interruption of pregnancy, as may be made of blood, blood plasma, human or animal organs and tissues, plants and minerals by synthesis methods or using biological technologies. Medicines include pharmaceutical substances and medicinal products;

2) pharmaceutical substance is a medicine in the form of one or more active substances of any origin, being pharmacologically active, which is intended for production and formulation of medicinal products and determines the efficacy thereof;

(clause 2 as amended by Federal Law of December 22, 2014 No. 429-FZ)

3) excipients are substances of organic or non-organic origin used in the process of production and formulation of medicinal products in order to give the latter required physicochemical properties;

4) medicinal products are pharmaceutical forms of medicines used for prophylaxis, diagnostics, treatment of disease, rehabilitation, as well as for maintenance, prevention or interruption of pregnancy;

5) pharmaceutical form is a condition of a medicinal product corresponding to the modes of administration and use thereof, and ensuring the required therapeutic effect;

5.1) dosage is the content of one or more active substances in quantitative terms per dosage unit, or volume unit, or weight unit in accordance with the pharmaceutical form or, for certain types of pharmaceutical forms, amount of active substances released from pharmaceutical form per time unit;

(sub-clause 5.1 introduced by Federal Law of December 22, 2014 No. 429-FZ)

6) list of vital and essential medicinal products is the list of medicinal products for medical use annually approved by the Government of the Russian Federation, satisfying priority healthcare needs for prophylaxis and treatment of diseases, including, but not limited to, those prevailing in the morbidity structure of the Russian Federation;

6.1) orphan medicinal products are medicinal products designated solely for diagnostics or pathogenic treatment (treatment aimed at the mechanism of disease development) of rare (orphan) diseases ;

(sub-clause 6.1 introduced by Federal Law of December 22, 2014 No. 429-FZ)

6.2) biological medicinal products are medicinal products, whose active substance is produced or separated from a biological source and whose properties and quality can be determined using a combination of biological and physical-chemical methods. Biological medicinal products include immunobiological medicinal products, medicinal products made of blood, blood plasma of humans or animals (except for whole blood), biotechnological medicinal products, gene therapy medicinal products;

(sub-clause 6.2 introduced by Federal Law of December 22, 2014 No. 429-FZ)

7) immunobiological medicinal products are medicinal products designated for formation of active or passive immunity or immunity diagnostics or diagnostics of specific acquired modification of immune response to allergenic substances. Immunobiological medicinal products include vaccines, toxoids, toxins, serums, immunoglobulins and allergens;

(clause 7 introduced by Federal Law of December 22, 2014 No. 429-FZ)

7.1) biotechnological medicinal products are medicinal products produced using biotechnological processes and methods (including recombinant DNA technology, technology of controlled expression of genes encoding biologically active proteins in prokaryotes and eukaryotes, including modified mammalian cells), hybridoma technology and monoclonal antibody method;

(sub-clause 7.1 introduced by Federal Law of December 22, 2014 No. 429-FZ)

7.2) gene therapy medicinal products are medicinal products, whose pharmaceutical substance is a recombinant nucleic acid or includes recombinant nucleic acid allowing to carry out regulation, reparation, substitution, addition or removal of genetic sequence;

(sub-clause 7.2 introduced by Federal Law of December 22, 2014 No. 429-FZ)

8) narcotic medicines are medicinal products and pharmaceutical substances containing narcotic drugs and included into the list of Narcotic Drugs, Psychotropic Substances and Precursors Thereof, which are subject to control in the Russian Federation in accordance with the legislation of the Russian Federation and international treaties of the Russian Federation, including, but not limited to, the 1961 Single Convention on Narcotic Drugs;

9) psychotropic medicines are medicinal products and pharmaceutical substances containing psychotropic substances and included into the list of Narcotic Drugs, Psychotropic Substances and Precursors Thereof, which are subject to control in the Russian Federation in accordance with the legislation of the Russian Federation and international treaties of the Russian Federation, including, but not limited to, the 1971 Convention on Psychotropic Substances;

10) radiopharmaceutical medicines are medicines which contain one radionuclide or several radionuclides (radioactive isotopes) in ready-to-use form;

10.1) originator medicinal product - medicinal product containing new active substance first registered in the Russian Federation or foreign countries based on the results of preclinical trials of medicines and clinical trials of medicinal products which support its quality, efficacy and safety;

(sub-clause 10.1 introduced by Federal Law of December 27, 2019 No. 475-FZ)

11) reference medicinal product - medicinal product used for assessment of bioequivalence or therapeutic equivalence, quality, efficacy and safety of generic medicinal product or biosimilar (bioanalogical) medicinal product (bioanalogue). As reference medicinal product for medical use there is either originator medicinal product or, if originator medicinal product is not registered or utilized in the Russian Federation and is not utilized in foreign countries, generic medicinal product or biosimilar (bioanalogical) medicinal product (bioanalogue) first registered of the utilized number in the Russian Federation, which bioequivalence or therapeutic equivalence, quality, efficacy and safety were assessed regarding the originator medicinal product and also which quality, efficacy and safety are

proved by pharmacovigilance results and compliance testing of medicines under civil utilization, established quality requirements. As reference medicinal product for veterinary use there is a medicinal product for veterinary use registered in the Russian Federation based on the results of preclinical trials of medicines and clinical trials of medicinal products which support its quality, efficacy and safety;

(clause 11 as amended by Federal Law of December 27, 2019 No. 475-FZ)

12) generic medicinal product - medicinal product for medical use which has qualitative and quantitative composition of active substances equivalent to reference medicinal product and in equivalent dosage form or medicinal product for veterinary use which has the same qualitative and quantitative composition of active substances in similar dosage form with reference medicinal product, which bioequivalence or therapeutic equivalence for corresponding reference medicinal product is proved by respective studies;

(clause 12 as amended by Federal Law of December 27, 2019 No. 475-FZ)

12.1) therapeutic equivalence of medicinal products - achievement of clinically comparable therapeutic effect and parameters of efficacy and safety during application of medicinal products for medical use which have similar international nonproprietary (either chemical or group) name, in equivalent doses according to the same indications for use and within similar type of injection in similar group of patients;

(sub-clause 12.1 as amended by Federal Law of December 27, 2019 No. 475-FZ)

12.2) bioanalogue (biosimilar) medicinal product (biosimilar) is a biological medicinal product similar in terms of quality, efficacy and safety to a reference biological medicinal product in the same pharmaceutical form with identical mode of administration;

(sub-clause 12.2 introduced by Federal Law of December 22, 2014 No. 429-FZ)

12.3) substitutable medicinal product is a medicinal product with proved therapeutic equivalence or bioequivalence to a reference medicinal product, having equivalent qualitative composition and quantitative composition of active substances, composition of excipients, dosage form and mode of administration;

(sub-clause 12.3 introduced by Federal Law of December 22, 2014 No. 429-FZ)

12.4) bioequivalence of medicinal products - achievement of clinically comparable absorption rate, admission rate to the site of action and excretion rate of one or several active substances with pharmacological activity during application of medicinal products for medical use which have similar international nonproprietary (either chemical or group) name, in equivalent doses and within similar route of administration;

(sub-clause 12.4 introduced by Federal Law of December 27, 2019 No. 475-FZ)

13) herbal medicinal raw material is fresh or dried plants or parts thereof used for production of medicines by institutions producing medicines, or for manufacturing of medicinal products by pharmacy institutions, veterinary pharmacy institutions and sole traders holding pharmaceutical licenses;

14) herbal medicinal product is a medicinal product produced or manufactured of one type of herbal medicinal raw material or several types of such raw materials and being distributed as packed in the secondary (retail) packaging;

15) homeopathic medicinal product is a medicinal product produced or manufactured from pharmaceutical substance or pharmaceutical substances in accordance with the requirements of general pharmacopeia articles to homeopathic medicinal products or in accordance with the requirements of the pharmacopeia of the country of the manufacturer of this medicinal product;

(clause 15 as amended by Federal Law of December 22, 2014 No. 429-FZ)

16) international nonproprietary name of a medicine is a name assigned to active substance of pharmaceutical substance as recommended by the World Health Organization;

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

17) trade name of a medicine is a name assigned to the medicine by the developer thereof, holder or owner of the registration certificate for medicinal product;

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

17.1) modified name of a medicinal product is a name of a medicinal product, which does not

have an international nonproprietary name, or a combination of medicinal products used to join them into a group under a single name based on the equivalent composition of active substances;  
(sub-clause 17.1 introduced by Federal Law of December 22, 2014 No. 429-FZ)

18) general pharmacopoeia article is a document approved by the authorized federal executive body, containing a list of quality indicators and (or) quality control methods for a particular pharmaceutical form or herbal medicinal raw material, description of biological, biochemical, microbiological, physicochemical, physical, chemical and other methods of analysis of a medicine, as well as requirements for the reagents, titrated solutions and indicators used for the purpose of such analysis;

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

19) pharmacopoeia article is a document approved by the authorized federal executive body, containing a list of quality indicators and quality control methods for a medicine;

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

19.1) standard samples are substances with which studied medicines are compared for the quality control purposes by means of physical-chemical and biological methods in order to confirm the compliance of the medicines with requirements of normative documents established at state registration and which are applied to calibrate standard samples of the manufacturer of the medicines used for the quality control and other purposes in circulation of medicines;

(sub-clause 19.1 introduced by Federal Law of December 22, 2014 No. 429-FZ)

19.2) pharmacopoeia standard sample is a standard sample produced in accordance with a pharmacopoeia article;

(sub-clause 19.2 introduced by Federal Law of December 22, 2014 No. 429-FZ)

20) normative documentation is a document containing a list of quality indicators and quality control methods for a medicine for medical use as determined under the relevant expert examination results, established by the manufacturer;

21) normative document is a document containing a list of quality indicators and (or) quality control methods for a pharmaceutical form as determined under the relevant expert examination results, description of biological, biochemical, microbiological, physicochemical, physical, chemical and other methods of analysis of medicines for veterinary use and requirements to the reagents, titrated solutions and indicators used for the purpose of such analysis, established by the manufacturer;

21.1) general technical document is a set of documents and materials consisting of several sections: administrative documents, chemical, pharmaceutical and biological documents, pharmacological, toxicological documents, clinical documents, and submitted together with the application for state registration of the medicinal product for medical use in a format established by the authorized federal executive body;

(sub-clause 21.1 introduced by Federal Law of December 22, 2014 No. 429-FZ)

22) quality of a medicine is compliance of a medicine with the requirements of the pharmacopoeia article or, in case of non-availability of the latter, of the normative documentation or normative document;

23) safety of a medicine is a characteristic of a medicine based on comparative analysis of its efficacy and assessment of health hazard;

24) efficacy of a medicinal product is a characteristic of the degree of positive action of a medicinal product on the course, duration or prevention of a disease, or rehabilitation, as well as on maintenance, prevention or interruption of pregnancy;

25) batch of a medicine is certain quantity of a medicine produced in the course of one technological cycle by the manufacturer thereof;

26) registration certificate of a medicinal product is a document certifying the fact of state registration of a medicinal product;

26.1) holder or owner of the registration certificate for medicinal product is a developer of a medicine, manufacturer of medicines or another legal entity entitled to hold the registration certificate, that are responsible for quality, efficacy and safety of the medicinal product;

(sub-clause 26.1 introduced by Federal Law of December 22, 2014 No. 429-FZ)

27) registration number is a reference code assigned to a medicinal product in state registration;

28) circulation of medicines is development, preclinical trials, clinical trials, expert examination, state registration, standardization and quality control, production, formulation, storage, transportation, import into the Russian Federation, export from the Russian Federation, advertising, dispensation, distribution, transfer, use and destruction of medicines;  
(as amended by Federal Law of December 06, 2011 No. 409-FZ);

29) subjects of circulation of medicines are individuals, including, but not limited to, sole traders, and legal entities engaged in circulation of medicines;

30) developer of a medicine is an institution holding rights to the results of preclinical trials of a medicine, clinical trials of a medicinal product and (or) to production technology of a medicine;  
(as amended by Federal Law of December 22, 2014 No. 429-FZ)

31) production of medicines is activity in production of medicines carried out by institutions engaged in production of medicines at one, several or all stages of the technological process, as well as in storage and distribution of medicines manufactured;

31.1) production site is a territorially separated complex of a manufacturer of medicines designated to perform the entire process of production of medicines or its particular stage;  
(sub-clause 31.1 introduced by Federal Law of December 22, 2014 No. 429-FZ)

32) manufacturer of medicines is an institution producing medicines in compliance with the requirements of this Federal Law;

33) pharmaceutical activities are activities including wholesale of medicinal products, storage thereof, transportation and (or) retail of medicines, dispensation thereof, storage, transportation and (or) production of medicinal products;

34) wholesaler of medicines is an institution engaged in wholesale, storage and transportation of medicines in compliance with the requirements of this Federal Law;

35) pharmacy institution is an institution or a division of a medical institution engaged in retail of medicinal products, storage, transportation, formulation and dispensation of medicinal products for medical use in compliance with the requirements of this Federal Law;  
(as amended by Federal Law of November 25, 2013 No. 317-FZ)

36) veterinary pharmacy institution is an institution or division of a veterinary institution engaged in retailing, storage, formulation and dispensation of medicinal products for veterinary use in compliance with the requirements of this Federal Law;

37) counterfeited medicine is a medicine supplied with false information on the composition and (or) manufacturer thereof;

38) poor quality medicine is a medicine not complying with the requirements of the pharmacopoeia article or, in case of non-availability thereof, with the requirements of the normative documentation or normative document;

39) infringing medicine is a medicine being in circulation in violation of the civil law;

40) preclinical trial of a medicine is biological, microbiological, immunological, toxicological, pharmacological, physical, chemical and other trials of a medicine by means of scientific methods of assessment for the purpose of obtaining evidence of safety, proper quality and efficacy of the medicine;

41) clinical trial of a medicinal product is studying diagnostic, therapeutic, prophylactic and pharmacological properties of a medicinal product in the process of use thereof by a human being or animal, including, but not limited to, the processes of absorption, allocation, modification and excretion, by means of scientific methods of assessment for the purpose of obtaining evidence of safety, proper quality and efficacy of the medicinal product, data on anticipated side effects resulting from the use of the medicinal product by a human being or an animal, and the effect of interaction thereof with other medicinal products and (or) food substances, or animal food substances;

42) multicentre clinical trial of a medicinal product for medical use is a clinical trial of a medicinal product for medical use conducted by the developer of the medicinal product in two or more medical institutions under a uniform protocol of clinical trials of the medicinal product;

43) international multicentre clinical trial of a medicinal product for medical use is a clinical trial of a medicinal product for medical use conducted by the developer of the medicinal product in different countries under a uniform protocol of clinical trial of the medicinal product;

44) post-registration clinical trial of a medicinal product for medical use is a clinical trial of a medicinal product for medical use conducted by the manufacturer of the medicinal product which is put in civil circulation after the state registration, for the purpose of additional collection of data on its safety and efficacy, extension of indications of such medicinal product, as well as for the purpose of revealing adverse reactions of the medicinal product on the patients;

45) bioequivalence study of a medicinal product is a type of clinical trial conducted to determine the rate of absorption and excretion of one or more active substances, being pharmacologically active, the quantity of the medicinal product reaching the systemic blood flow, the results of which allow making a conclusion on bioequivalence of a certain pharmaceutical form and dosage of a generic medicinal product to the form and dosage of a reference medicinal product;  
(clause 45 as amended by Federal Law of December 22, 2014 No. 429-FZ)

46) therapeutic equivalence study of medicinal products is a type of clinical trials of medicinal products conducted to determine similar properties of medicinal products of a particular pharmaceutical form, as well as availability of similar indicators of safety and efficacy of medicinal products and similar clinical effects resulting from the use thereof;

47) protocol of a clinical trial of a medical product is a document determining the objectives, form and methodology of a clinical trial, statistical methods of processing the results of such trial and safety measures for the individuals involved in the clinical trial of the medicinal product;

48) investigator's brochure is a summary of the results of a preclinical trial of a medicine and a clinical trial of a medicinal product for medical use;

49) patient information sheet is a document containing information, in an intelligible form, about the clinical trial of the medicinal product to be conducted, and the patient's written voluntary consent to participate in the clinical trial of the medicinal product given after a prior acquaintance with the specifics of the clinical trial which are significant for giving such consent;

50) side effect is a reaction of the body to the use of a medicinal product in the dosage rate recommended in its Package Leaflet for prophylaxis, diagnostics, treatment of disease, or for rehabilitation;

50.1) adverse drug reaction is an undesirable adverse reaction of the body which may be associated with the use of the medicinal product;  
(sub-clause 50.1 introduced by Federal Law of December 22, 2014 No. 429-FZ)

51) serious adverse drug reaction is an undesirable reaction of the body to the use of a medicinal product which has caused death, congenital anomalies or malformation, or posing a threat to life, requiring hospitalization, or which has caused permanent incapacity to work and (or) disability;

52) unexpected adverse drug reaction is an undesirable reaction of the body associated with the use of a medicinal product in dosages recommended in its clinical trial protocol, investigator's brochure, or with the use of a medicinal product in dosages recommended in its Package Leaflet for prophylaxis, diagnostics, treatment of disease, or medical rehabilitation of the patient, and whose essence, seriousness or outcome does not conform to the information on the medicinal product contained in its clinical trial protocol, investigator's brochure or the Package Leaflet of the medicinal product;

(sub-clause 52 as amended by Federal Law of December 22, 2014 No. 429-FZ)

52.1) pharmacovigilance is activity for monitoring of efficacy and safety of medicinal products aimed to detect, assess and prevent undesirable consequences of the use of medicinal products;  
(sub-clause 52.1 introduced by Federal Law of December 22, 2014 No. 429-FZ)

52.2) risk management plan is a detailed description of pharmacovigilance measures aimed to detect, assess and prevent or mitigate risks relating to medicinal products, including assessment of effectiveness of such measures;

(sub-clause 52.2 introduced by Federal Law of December 22, 2014 No. 429-FZ)

53) medicinal product prescription is a medical document in a standard form containing prescription of a medicinal product for medical use issued in by a medical practitioner for the purposes of dispensation of the medicinal product or formulation and dispensation thereof in paper form or, with the consent of the patient or his or her authorized representative, in the form of an electronic document signed by an enhanced electronic signature of the medical practitioner or a document in a standard form containing prescription of the medicinal product for veterinary use issued by a veterinary practitioner for the purposes of dispensation of the medicinal product or formulation and dispensation thereof in paper form;

(sub-clause 53 as amended by Federal Law of July 29, 2017 No. 242-FZ, Federal Law of August, 02, 2019 No. 297-FZ)

54) medical institution or veterinary institution order is a standard form document issued by a medical or veterinary practitioner so entitled, which contains a written instruction addressed to a pharmacy institution or a veterinary pharmacy institution to dispense, or formulate and dispense a medicinal product or to formulate and dispense it in order to make provisions for treatment in the medical institution or veterinary institution;

(sub-clause 53 as amended by Federal Law of August, 02, 2019 No. 297-FZ)

55) comprehensive assessment of the medicinal product is an assessment of a registered medicinal product, which includes analysis of information on relative clinical efficacy and safety of the medicinal product, assessment of economic consequences of its use, studying additional consequences of the use of the medicinal product in order to make a decision on the possibility to include the medicinal product into the list of vital and essential medicinal products, normative legal acts and other documents determining the procedure for provision of medical aid, or removal thereof from the specified list, acts and documents;

(sub-clause 55 introduced by Federal Law of December 22, 2014 No. 429-FZ)

56) the system for monitoring the movement of medicinal products for medical use is a federal state information system for monitoring the movement of medicinal products for medical use from the manufacturer to the end consumer using means of identification in respect of medicinal products for medical use.

(sub-clause 56 introduced by Federal Law of December 28, 2017 No. 425-FZ)

## **Chapter 2. POWERS OF FEDERAL EXECUTIVE BODIES AND EXECUTIVE BODIES OF CONSTITUENT ENTITIES OF RUSSIAN FEDERATION WITH RESPECT TO CIRCULATION OF MEDICINES**

### Article 5. Powers of Federal Executive Bodies with Respect to Circulation of Medicines

The powers of federal executive bodies with respect to circulation of medicines include:

1) pursuing of a unified state policy in the area of supply of the citizens with medicinal products in the Russian Federation;

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

2) approval of general pharmacopeia articles and pharmacopeia articles and enactment of the state pharmacopeia, creating and keeping register of pharmacopeia standard samples;

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

3) provision of state control (supervision) over circulation of medicines;

(as amended by Federal Law of June 25, 2012 No. 93-FZ)

4) licensing of production of medicines and pharmaceutical activities in compliance with the legislation of the Russian Federation;

5) arrangement of medicines expert examination and ethical expert examination of the possibility to conduct a clinical trial of a medicinal product for medical use, expert examination of documents submitted to determine whether it is possible to consider the medicinal product for medical use at state registration as an orphan medicinal product;

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

5.1) organization of the conduct of a comprehensive assessment of a medicinal product in



order to make decisions on the possibility to include the medicinal product into the list of vital and essential medicinal products, normative legal acts and other documents determining the procedure for provision of medical aid, or removal thereof from the specified list, acts and documents;  
(sub-clause 5.1 introduced by Federal Law of December 22, 2014 No. 429-FZ)

6) issue of approvals for conducting clinical trials of medicinal products; maintenance of the register of issued approvals for conducting clinical trials of medicinal products;

7) state registration of medicinal products; maintenance of the state register of medicines;

8) organization and (or) conduct of inspections of subjects of circulation of medicines for compliance with the rules of good laboratory practice, good clinical practice, good storage and transportation practice for medicinal products, good distribution practice, good pharmacy practice;  
(clause 8 as amended by Federal Law of December 22, 2014 No. 429-FZ)

8.1) organization and (or) conduct of inspections of subjects of circulation of medicines for compliance with the rules of good manufacturing practice, issuing statements of conformity of the manufacturer of medicines to the requirements of good manufacturing practice;  
(sub-clause 8.1 introduced by Federal Law of December 22, 2014 No. 429-FZ)

8.2) establishment of a procedure for keeping and keeping a state register of statements of conformity of the manufacturer of medicines to the requirements of good manufacturing practice;  
(sub-clause 8.2 introduced by Federal Law of December 22, 2014 No. 429-FZ)

9) state registration of maximum ex-works prices for medicinal products included in the list of vital and essential medicinal products and maintenance of the state register of the manufacturers' maximum ex-works prices for the medicinal products included in the list of vital and essential medicinal products;

(clause 9 as amended by Federal Law of June 06, 2019 No. 134-FZ)

9.1) approval of draft resolutions of executive bodies of constituent entities of the Russian Federation on the establishment and (or) change of the maximum wholesale mark-ups and maximum retail mark-ups to actual ex-works prices established by manufacturers of medicinal products for medicinal products included in the list of vital and essential medicinal products;

10) issue, establishment of a procedure for the issue of a permit to import a particular batch of medicines into the Russian Federation;

(clause 10 as amended by Federal Law of August 02, 2019 No. 297-FZ)

10.1) issue, establishment of a procedure for the issue and a form of a document confirming that a medicinal product is manufactured in accordance with the requirements of good manufacturing practice rules or that the medicinal product for veterinary use is permitted for circulation in the Russian Federation and shall be submitted upon request of the authorized body of the country into which the medicinal product is imported;

(sub-clause 10.1 introduced by Federal Law of December 22, 2014 No. 429-FZ, as amended by the Federal Law of August 02, 2019 No. 297-FZ)

10.2) issue, establishment of a procedure for the issue and a form of a document containing information on stages of the technological process of production of a medicine for medical use performed in the territory of the Eurasian Economic Union;

(sub-clause 10.2 introduced by Federal Law of December 22, 2014 No. 429-FZ)

11) foundation of councils responsible for issues related to circulation of medicines;

12) attestation and certification of specialists;

13) ceased to be in force as of September 01, 2013 (Federal Law of July 02, 2013 No. 185-FZ);

14) pharmacovigilance;

(clause 14 as amended by Federal Law of December 22, 2014 No. 429-FZ)

15) participation in international cooperation;

16) obtaining information related to determination and use of prices for medicinal products and mark-ups to the prices from executive bodies of the constituent entities of the Russian Federation, as well as from the subjects of circulation of medicines for medical use, at the requests of the authorized federal executive body;

17) imposing of sanctions for violation of the legislation of the Russian Federation;

18) establishment of good laboratory practices, good clinical practices, good manufacturing

practices, good storage and transportation practices for medicinal products, good distribution practices, good pharmacy practices, good pharmacovigilance practices for medicinal products for medical use;

(sub-clause 18 introduced by Federal Law of December 22, 2014 No. 429-FZ)

19) establishment of a procedure for the formation of a registration dossier of a medicinal product and requirements for documents to be contained therein;

(sub-clause 19 introduced by Federal Law of December 22, 2014 No. 429-FZ)

20) approval of rules for reasonable choice of names for medicinal products for medical use;

(sub-clause 20 introduced by Federal Law of December 22, 2014 No. 429-FZ)

21) approval of a list of names of pharmaceutical forms;

(sub-clause 21 introduced by Federal Law of December 22, 2014 No. 429-FZ)

22) ceased to be in force as of March 01, 2020 (Federal Law of December 27, 2019 No. 475-FZ);

23) approval of requirements for an instruction for medical use of medicinal products and an instruction for veterinary use of medicinal products;

(sub-clause 23 introduced by Federal Law of December 22, 2014 No. 429-FZ)

24) pre-court closing of websites containing information on remote retail, offering to buy remotely, to deliver remotely and (or) to transfer to an individual remotely medicinal products, narcotic medicinal products and psychotropic medicinal products, unless otherwise set forth by the Government of the Russian Federation.

(sub-clause 24 introduced by Federal Law of December 22, 2014 No. 429-FZ)

25) issue of permits to put into circulation immunobiological medicinal products.

(From November 29, 2019, Article 5 shall be supplemented by sub-clause 25 introduced by Federal Law of November 28, 2018 No. 449-FZ)

ConsultantPlus: note

The provisions of clause 5.1 shall apply to the powers of federal executive bodies, which have not been transferred for exercise to executive bodies of constituent entities of the Russian Federation and local self-regulating authorities by relevant federal laws.

Article 5.1. Transfer of Powers of Federal Executive Bodies with Respect to Circulation of Medicines to Executive Bodies of Constituent Entities of the Russian Federation

(introduced by Federal Law of July 13, 2015 No. 233-FZ)

The powers of federal executive bodies with respect to circulation of medicines provided by this Federal Law may be transferred for exercise to executive bodies of constituent entities of the Russian Federation by regulations of the Government of the Russian Federation in the manner set forth in the Federal Law of October 6, 1999 No. 184-FZ "On General Principles of Organizing Legislative (Representative) and Executive Bodies of Constituent Entities of the Russian Federation."

Article 6. Powers of Executive Bodies of a Constituent Entity of the Russian Federation with Respect to Circulation of Medicines

Powers of the executive bodies of a constituent entity of the Russian Federation with respect to circulation of medicines include:

1) development and implementation of regional programs for supply of medicinal products to the population;

2) determination of maximum wholesale mark-ups and maximum retail mark-ups to the actual ex-works prices determined by the manufacturers of medicinal products for the medicinal products included into the list of vital and essential medicinal products;

3) implementation of local state monitoring over the price use for medicinal products included in the list of vital and essential medicinal products, by wholesaler of medicine organizations, pharmacy

institutions, sole proprietors who have pharmaceutical license, medical organizations who have pharmaceutical license, and their isolated units (dispensaries, feldsher and feldsher-midwife stations, centers (departments) of general (family) practice) located in rural areas where there are no pharmacy institutions;

(as amended by Federal Law of June 25, 2012 No. 93-FZ and Federal Law of December 27, 2019 No. 475-FZ)

4) making a decision to use prescriptions for medicinal products in the form of electronic documents along with prescriptions in paper form in the territory of the constituent entity of the Russian Federation.

(clause 4 introduced by Federal Law of July 29, 2017 No. 242-FZ)

### **Chapter 3. STATE PHARMACOPEIA**

#### **Article 7. Development and Enactment of State Pharmacopeia, Allocation of Data Thereof**

1. The state pharmacopeia means a set of general pharmacopeia articles and pharmacopeia articles.

2. General pharmacopeia articles and pharmacopeia articles, including pharmacopeia articles for pharmacopeia standard samples, are developed and included in the state pharmacopeia in the manner prescribed by the authorized federal executive body.

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

3. A pharmacopeia article for a reference medicinal product shall be developed and included in the state pharmacopeia within the period of validity of the exclusive right certified by the patent for the reference medicinal product with consent of its developer.

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

4. The state pharmacopeia is published by the authorized federal executive body using the federal budget funds, and is subject to republication at least every five years; during the period between the enactments addenda to the state pharmacopeia are published, comprising general pharmacopeia articles and (or) pharmacopeia articles approved after the state pharmacopeia has been enacted or reenacted.

5. The authorized federal executive body shall place the data of the state pharmacopeia and addenda thereto on its official website in the manner prescribed by this body.

### **Chapter 4. STATE CONTROL OVER CIRCULATION OF MEDICINES**

#### **Article 8. Licensing of Production of Medicines and Pharmaceutical Activities**

1. Production of medicines and pharmaceutical activities shall be licensed in compliance with the legislation of the Russian Federation.

2. A license for production of medicines shall be granted if a list of the pharmaceutical forms and (or) types of pharmaceutical substances which the manufacturer of medicines intends to produce is provided and necessarily attached to the application of the applicant.

3. If production of medicines needs to be expanded by introducing new pharmaceutical forms and types of pharmaceutical substances, the manufacturer of medicines shall reissue the license for production of medicines.

(clause 3 as amended by Federal Law of August 02, 2019 No. 297-FZ)

#### **Article 9. State Control (Supervision) over Circulation of Medicines**

(as amended by Federal Law of June 25, 2012 No. 93-FZ)

1. State control (supervision) in circulation of medicines includes:

1) licensing control in production of medicines and in pharmaceutical activities;

- 2) federal state supervision in circulation of medicines;
- 3) selective control of quality of medicines.

(sub-clause 3 introduced by Federal Law of December 22, 2014 No. 429-FZ)

2. Licensing control in production of medicines and in pharmaceutical activities shall be carried out by the authorized federal executive bodies and executive bodies of constituent entities of the Russian Federation within their competence in accordance with the procedure established by Federal Law of December 26, 2008 No. 294-FZ "On Protection of Rights of Legal Entities and Individual Entrepreneurs in State Control (Supervision) and Municipal Control", taking into account the specifics of organization and conduct of inspections as established by Federal Law of May 04, 2011 No. 99-FZ "On Licensing Certain Types of Activities";

3. Federal state supervision in circulation of medicines shall be carried out by the authorized federal executive bodies (hereinafter the "state supervision bodies") within their competence in the manner set forth by the Government of the Russian Federation.

- 4. Federal state supervision in circulation of medicines includes:

1) organization and compliance testing over subjects of circulation of medicines established by this Federal Law and accepted in accordance with it by other regulatory laws of the Russian Federation requirements for preclinical trials of medicinal products, clinical trial of medicinal products, storage, transport, import to the Russian Federation, release, utilization of medicines, application of medicinal products, disposal of medicines, manufacturers' suggested price on medicinal product included in the list of vital and essential medicinal products, and also executive authorities of constituent entities of the Russian Federation follow the methods on setting limitations of wholesale margins and limitations of retail premiums for effective price of medicinal products included in the list of vital and essential medicinal products (further - mandatory requirements) established by drug manufacturers; (as amended by Federal Law of December 27, 2019 No. 475-FZ)

2) organization and conduct of inspections of compliance of medicines in civil circulation with the established quality requirements;

2.1) performing controlled purchase to ensure that the subjects of circulation of medicines engaged in retail sale of medicinal products for medical use comply with the rules of sale of medicinal products for medical use and (or) the ban to sell counterfeited medicines, poor quality medicines and infringing medicines.

(sub-clause 2.1 introduced by Federal Law of December 27, 2018 No. 551-FZ)

2.2) performing controlled purchase to ensure that the subjects of circulation of medicines engaged in retail sale of medicinal products for veterinary use comply with the good pharmacy practice rules for medicinal products for veterinary use and (or) the ban to sell counterfeited medicines, poor quality medicines and infringing medicines;

(sub-clause 2.2 introduced by Federal Law of August 02, 2019 No. 297-FZ)

- 3) organization and conduct of pharmacovigilance;

4) taking measures, in the manner set forth in the laws of the Russian Federation, for restraint of detected violations of mandatory requirements and (or) elimination of consequences of such violations, including making a decision on keeping medicines in circulation, issue of orders for elimination of detected violations of mandatory requirements and holding liable those committed such violations.

(clause 4 as amended by Federal Law of December 22, 2014 No. 429-FZ)

5. Federal state supervision in circulation of medicines shall be carried out in accordance with the procedure established by Federal Law of December 26, 2008 No. 294-FZ "On Protection of Rights of Legal Entities and Individual Entrepreneurs in State Control (Supervision) and Municipal Control", taking into account the specifics set forth in this Article. No preliminary approval by prosecution authorities of timeframes of unscheduled inspections of subjects of circulation of medicines and no prior notice to legal entities, sole traders on the commencement of such an inspection shall be required. Prosecution authorities shall be notified of the conduct of an unscheduled inspection of subjects of circulation of medicines by sending relevant documents within three business days of the end of the unscheduled inspection.

(clause 5 as amended by Federal Law of December 22, 2014 No. 429-FZ)

6. Officers of state supervision bodies shall, in accordance with the legislation of the Russian Federation, have the right:

1) to obtain, based on substantiated written requests from subjects of circulation of medicines, executive bodies of constituent entities of the Russian Federation and self-regulating authorities, documents and information on matters relating to circulation of medicines;

2) to visit, without restriction, upon producing an official ID or a copy of the order (instruction) of the state supervision body for appointment of an inspection, territories, buildings, premises and facilities used by legal entities, sole traders being subjects of circulation of medicines in performance of their activities for the purpose of carrying out control activities;

3) to sample medicines designated for sale and sold by subjects of circulation of medicines in order to inspect quality thereof, conduct studies, tests in accordance with sampling rules established by the authorized federal executive body;

3.1) to perform controlled purchase of medicinal products for medical use to ensure that the subjects of circulation of medicines engaged in retail sale of medicinal products for medical use comply with the rules of sale of medicinal products for medical use and (or) the ban to sell counterfeited medicines, poor quality medicines and infringing medicines;

(sub-clause 3.1 introduced by Federal Law of December 27, 2018 No. 551-FZ)

3.2) to perform controlled purchase of medicinal products for veterinary use to ensure that the subjects of circulation of medicines engaged in retail sale of medicinal products for veterinary use comply with the good pharmacy practice rules for medicinal products for veterinary use and (or) the ban to sell counterfeited medicines, poor quality medicines and infringing medicines;

(sub-clause 3.2 introduced by Federal Law of August 02, 2019 No. 297-FZ)

4) to issue to subjects of circulation of medicines warnings to stop violations of mandatory requirements and orders for elimination of detected violations of mandatory requirements;

5) to send to authorized bodies materials relating to violations of mandatory requirements for making decisions on institution of criminal proceedings on the grounds of the offence.

7. Selective control of quality of medicines shall be carried out by the authorized federal executive body in the manner set forth by this body and shall include:

1) processing of information which must be provided by subjects participating in circulation of medicines on series, batches of medicines put in civil circulation in the Russian Federation;

2) sampling of medicines from subjects of circulation of medicines in order to test the same for compliance with the requirements of normative documentation or normative documents;

3) making a decision, based on the results of tests performed, on further civil circulation of the relevant medicine;

4) making a decision by the authorized federal executive body on transfer of the medicine to series-based selective control of the quality of medicines in the event of repeated incompliance of the medicine quality with the established requirements and (where necessary) on inspection of the subject participating in circulation of medicines. Expenses relating to series-based selective control of the quality of medicines shall be paid by the manufacturer of the medicine or the holder or owner of the registration certificate for the medicinal product.

(clause 7 as amended by Federal Law of December 22, 2014 No. 429-FZ)

## **Chapter 5. DEVELOPMENT, PRECLINICAL TRIALS OF MEDICINES AND CLINICAL TRIALS OF MEDICINAL PRODUCTS FOR VETERINARY USE**

### Article 10. Development of Medicines

1. Development of medicines involves the search for new pharmacologically active substances, subsequent investigation of their medicinal properties, preclinical trials, development of production technologies for pharmaceutical substances, development of compositions of and production technologies for medicinal products.

2. Financing of the development of medicines is provided using:

- 1) federal funds;
  - 2) funds of developers of medicines;
  - 3) funds of manufacturers of medicines within the framework of R&D projects implemented under a contract between the developer of the medicines and the manufacturer of the medicines;
  - 4) other sources not prohibited by the legislation of the Russian Federation.
3. The rights of a developer of a medicine are protected by the civil legislation.

#### Article 11. Preclinical Trial of a Medicine for Medical Use

1. A preclinical trial of a medicine for medical use is conducted using scientific assessment methods for the purpose of obtaining evidence of safety, proper quality and efficacy of the medicine.
2. A preclinical trial of a medicine for medical use is conducted in compliance with the rules of good laboratory practice approved by the authorized federal executive body.  
(as amended by Federal Law of December 22, 2014 No. 429-FZ)
3. Developers of medicines may involve research institutions and higher education organizations, which have a necessary material and technical base and qualified specialists in the relevant research area, to arrange and conduct a preclinical trial of a medicine for medical use.  
(as amended by Federal Law of July 02, 2013 No. 185-FZ)
4. A preclinical trial of a medicine for medical use shall be conducted in accordance with the plan approved by the developer of the medicine with the trial protocol keeping and generating a report which should contain the trial results and conclusion on the possibility of a clinical trial of the medicinal product for medical use.
5. Inspections for compliance with the rules of good laboratory practice and statutory regulations on the use of animals in preclinical trials of medicines for medical use shall be carried out by the authorized federal executive body.  
(as amended by Federal Law of December 22, 2014 No. 429-FZ)
6. The results of a preclinical trial of a medicine for medical use may be submitted to the authorized federal executive body in accordance with the standard procedure for the purpose of state registration of the medicinal product.

#### Article 12. Preclinical Trial of a Medicine and Clinical Trial of Medicinal Product for Veterinary Use

1. A preclinical trial of a medicine for veterinary use shall be conducted using scientific assessment methods for the purpose of obtaining evidence of safety, proper quality and efficacy of the medicine, including, but not limited to determination of the period of its excretion from the animal body, in order to ensure safety of animal products after the use of the relevant medicinal product.
2. A preclinical trial of a medicine, a clinical trial of a medicinal product for veterinary use and a bioequivalence study of such medicinal product shall be conducted in compliance with the regulations approved by the authorized federal executive body.
3. A preclinical trial of a medicine and a clinical trial of a medicinal product for veterinary use are conducted in accordance with the plan approved by the developer of the medicine with the trial record keeping and generating reports which should contain the trial results.
4. A developer of a medicine may engage institutions which have a necessary material and technical base and qualified specialists in the relevant research area, to arrange and conduct a preclinical trial of a medicine and a clinical trial of a medicinal product for veterinary use.
5. Clinical trials of medicinal products for veterinary use are conducted in veterinary institutions and institutions engaged in animal breeding, farming and keeping, for the purpose of:
  - 1) determination of tolerance for medicinal products with healthy animals;
  - 2) optimization of dosage rates of medicinal products and a course of treatment within a particular group of animals having a certain disease;
  - 3) determination of safety and efficacy of a medicinal product with animals having a certain disease, or prophylactic efficacy of a medicinal product with healthy animals;

4) study of possibilities to extend indications of a registered medicinal product and to reveal previously unknown side effects.

6. A clinical trial of a medicinal product for veterinary use is conducted at the expense of the developer of the medicine.

7. Reports on the results of a preclinical trial of a medicine and clinical trial of a medicinal product for veterinary use are generated by the developer of the medicine in consideration of the conclusions made by the institutions involved in the arrangement and conduct of the trials.

8. Control over the conduct of preclinical trials of medicines and clinical trials of medicinal products for veterinary use shall be carried out by the authorized federal executive body.

## **Chapter 6. PERFORMANCE OF STATE REGISTRATION OF MEDICINAL PRODUCTS**

### Article 13. State Registration of Medicinal Products

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

1. Production, manufacture, storage, transportation, import into the Russian Federation, export from the Russian Federation, advertising, delivery, sale, transfer, use, and destruction of medicinal products shall be allowed in the Russian Federation, if such medicinal products have been registered with the relevant authorized federal executive body.

(clause 1 as amended by Federal Law of July 13, 2015 No. 241-FZ)

2. State registration is required for:

1) all medicinal products which are put into circulation in the Russian Federation for the first time;

2) medicinal products which have been registered before but produced in other pharmaceutical forms in accordance with the list of names of pharmaceutical forms in new dosage when its clinical importance and efficacy have been proved;

3) new combinations of previously registered medical products.

3. State registration of medicinal products shall be carried out based on the results of expert examination of the medicines, and state registration of orphan medicinal products shall be carried out based on the results of expert examination of the documents submitted to determine whether it is possible to consider the medicinal product for medical use at state registration as an orphan medicinal product, and based on the results of expert examination of the medicines.

4. State registration of a medicinal product shall be carried out by the relevant authorized federal executive body within one hundred and sixty business days on filing the relevant application for state registration of the medical product. The period specified above includes the time necessary to carry out repeated expert examination of the medicine in accordance with Article 25 hereof. The period of state registration of a medicinal product is calculated from the date of filing by the relevant authorized federal executive body of the relevant application for state registration of the medical product together with required documents as enclosed to the date of issuance of the registration certificate for the medicinal product. Time required for sending by the authorized federal executive body a request for provision of necessary materials and the applicant's response to this request in accordance with Articles 16, 19 and 23 of this Federal Law shall not be taken into account in determining the period of the state registration of the medicinal product.

5. No state registration is required for:

1) medicinal products formulated by pharmacy institutions, veterinary pharmacy institutions and sole traders holding pharmaceutical licenses under medicinal product prescriptions and orders of medical institutions and veterinary institutions;

2) medicinal products acquired by individuals outside the Russian Federation and intended for personal use;

3) medicines imported into the Russian Federation for provision of life-saving medical aid to a particular patient on the basis of a permit issued by the authorized federal executive body;

4) medicines imported into the Russian Federation on the basis of a permit issued by the authorized federal executive body and intended for the conduct of clinical trials of medicinal products and (or) expert examination of medicines for carrying out state registration of the medicinal products;

5) pharmaceutical substances;

6) radiopharmaceutical medicinal products formulated directly in medical institutions in the manner prescribed by the authorized federal executive body;

7) medicinal products intended for export.

6. State registration is forbidden for:

1) medicinal products which are different in the qualitative composition of active substances under the same trade name;

2) one medicinal product submitted for state registration in respect of the same holder or owner of the registration dossier for the medicinal product in the form of two or more medicinal products under different trade names.

(sub-clause 2 as amended by Federal Law of June 04, 2018 No. 140-FZ)

7. At request (in electronic or paper form) of the subject participating in circulation of medicines, the relevant authorized federal executive body performing state registration of medicinal products shall, in the manner set forth by this body, provide scientific consultation on matters relating to the conduct of preclinical trials, clinical trials of medicinal products, expert examinations of quality, efficacy and safety of medicines, state registration of medicinal products. Such consultations shall be provided with involvement of federal state government-funded institutions subordinated to this federal executive body and not participating in organization of the expert examination of quality of medicines for the purpose of state registration thereof in accordance with Article 16 of this Federal Law, in the form of a written response of the authorized federal executive body to the request. A fee to be paid by the applicant shall be determined in accordance with the legislation of the Russian Federation on organization of provision of state and municipal services. Information on provision of scientific consultation, including papers, reviews, reference materials and other information on scientific consultation, shall be posted on the official website of the authorized federal executive body, subject to restrictions set forth in the laws on personal data, commercial and (or) state secret.

8. State registration of medicinal products not designated for the use in military actions, emergency situations, prophylaxis and treatment of diseases and injuries received due to exposure to adverse chemical, biological, radiation factors and developed on the assignment of federal executive bodies authorized in the area of the country defense and state security shall be carried out in the manner established by the Government of the Russian Federation.

#### Article 14. Principles of Expert Examination of Medicines

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

1. Expert examination of medicines is based on the principles of legality, observance of human and citizen rights and freedoms, legal entity rights, expert independence, objectiveness, comprehensiveness and completeness of the trials conducted using the latest achievements of science and technology, responsibility of the federal state-financed institution for carrying out expert examination of medicines and responsibility of experts for performance and quality of expert examination.

2. Expert examination of medicinal products for medical use includes:

1) expert examination of the documents submitted to determine whether it is possible to consider the medicinal product for medical use at state registration as an orphan medicinal product;

2) expert examination of proposed methods for control of quality of a medicine and quality of submitted samples of a medicine using this method (hereinafter the "expert examination of quality of a medicine");

3) expert examination of a correlation between the anticipated benefit and possible risk from



the use of the medicinal product;

4) expertise of registration profile in order to determine interchangeability of medicinal products for medical use.

(clause 4 introduced by Federal Law of December 27, 2019 No. 475-FZ)

3. Expert examination of medicinal products for veterinary use includes expert examination quality of a medicine and expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product.

#### Article 15. Federal State-Financed Institution Carrying Out Expert Examination of Medicines

Expert examination of medicines shall be carried out by a federal state-financed institution of the relevant authorized federal executive body founded for the purpose of exercising the powers of that federal body on issuance of approvals for the conduct of clinical trials of medicinal products and (or) on state registration of medicinal products (hereinafter "the expert institution").

#### Article 16. Organization of Expert Examination of Medicines

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

1. Expert examination of medicines is carried out by an expert commission under the expert institution appointed by the head thereof, under an assignment to conduct expert examination issued by the authorized federal executive body. The head of the expert institution provides for proper performance of expert examination of medicines in compliance with the assignment issued by the authorized federal executive body, and makes arrangements for preparation of the commission's summary conclusion. Under decision of the head of the expert institution persons not employed by that expert institution may be included on the commission as experts, if their special knowledge is necessary for performance of the expert examination, and if such experts are not available in that expert institution.

2. An expert appointed to carry out expert examination of medicines is a certified employee of an expert institution with higher medical, pharmaceutical, biological, veterinary or chemical education who carries out expert examination of medicines in the course of execution of his functions (hereinafter "the expert").

3. When carrying out expert examination of medicines, the expert shall in no way depend upon the person who ordered the expert examination, the developer of the medicine or other persons interested in the results of the expert examination.

4. When carrying out an expert examination of medicines, it is not allowed to demand any materials necessary to carry out the expert examination from the applicant or other persons. In case of insufficiency of the materials submitted to an expert for him to make a conclusion, such expert applies for submission of necessary documents to the head of the expert institution who shall make a relevant request to the authorized federal executive body that issued the assignment to carry out expert examination of the medicine. The above federal executive body shall, within five business days of receipt of the request from the head of the expert institution, send to the applicant a request for provision of necessary materials. This request may be delivered to an authorized representative of the applicant personally against signature, by registered mail or in electronic form via telecommunication channels. If the request is sent by registered mail, it shall be deemed received in six days of the dispatch.

(clause 4 as amended by Federal Law of November 25, 2013 No. 317-FZ)

4.1. The applicant shall respond to the request of the authorized federal executive body within ninety business days of its receipt. The authorized federal executive body that gave an assignment for the conduct of the expert examination of the medicine shall, within five business days of receipt of the response to the request from the applicant, refer this response to the expert institution. If the applicant fails to respond to the request within ninety business days, the authorized federal executive body that gave an assignment for the conduct of the expert examination of the medicine shall, within five business days, give the expert institution a notice of the applicant's failure to respond to the

request of the said federal body. The time from the date of sending the request by the expert institution to the authorized federal executive body to the date of receipt by the expert institution of the response to the request or notice of a failure to provide such a response shall not be taken into account when determining the period for the conduct of the expert examination of a medicine.

(clause 4.1 introduced by Federal Law of November 25, 2013 No. 317-FZ)

4.2. If the registration dossier for the medicinal product for medical use contains a copy of the decision of the authorized federal executive body to conduct an inspection of the manufacturer of medicines as provided by Article 18, part 1.1, of Article 30 and Article 34 of this Federal Law, a copy of the conclusion on the compliance of the manufacturer with the good manufacturing practice guidelines issued by the authorized federal executive body shall be provided to the expert prior to documenting the results of the medicines expert examination in the manner and on the conditions set forth in parts 4 and 4.3 of this Article.

(clause 4.2 introduced by Federal Law of June 04, 2018 No. 140-FZ)

4.3. The applicant shall provide to the authorized federal executive body a copy of the conclusion on compliance of the manufacturer of medicines with the good manufacturing practice guidelines within one hundred eighty business days of receipt of the request for its provision. The authorized federal executive body issuing the assignment to conduct the medicines expert examination shall, within five business days of receipt from the applicant of a copy of the conclusion on compliance of the manufacturer of medicines with the good manufacturing practice guidelines, send it to the expert institution. If the applicant fails to provide a copy of the conclusion on compliance of the manufacturer of medicines with the good manufacturing practice guidelines within the specified period, the authorized federal executive body issuing the assignment to conduct the medicines expert examination shall, within five business days, notify the institution of the applicant's failure to provide a copy of the conclusion on compliance of the manufacturer of medicines with the good manufacturing practice guidelines. The time elapsed from the date when the expert institution sends the request to the authorized federal executive body to the date when the expert institution receives the conclusion on compliance of the manufacturer of medicines with the good manufacturing practice guidelines or the notice of the applicant's failure to provide the same shall not be taken into account when determining the period for the conduct of the medicines expert examination.

(clause 4.3 introduced by Federal Law of June 04, 2018 No. 140-FZ)

5. When carrying out expert examination of a medicine assigned to an expert by the head of the expert institution, such expert shall:

1) carry out a complete examination of the objects and materials submitted to him, issue a reasonable and objective conclusion as to the questions put to him, or a reasoned conclusion on impossibility of performance of expert examination of the medicine, should the questions put to him be beyond the expert's competence, should the examination objects and the materials be inapplicable or not sufficient for carrying out the examination and making a conclusion, or should the state-of-the-art of the science not allow responding to such questions;

2) not disclose information made available to him in connection with expert examination of a medicine, as well as information that constitutes state, trade or other secret protected by the law;

3) ensure safe keeping of examination objects and materials submitted.

6. The expert may not:

1) carry out expert examination of a medicine on application of any institutions or individuals directly to him;

2) independently collect materials to carry out expert examination of a medicine;

3) carry out expert examination of a medicine as a non-state expert.

7. If necessary, an expert is entitled to petition the head of the expert institution to engage other experts to carry out expert examination of a medicine.

8. Each expert included in an expert commission which is assigned to carry out expert examination of a medicine shall carry out examination independently and solely, estimate the results obtained by him personally and by other experts, and draw inferences with respect to the questions put to the commission within his competence.

9. Results of expert examination of a medicine are documented in an opinion of the expert commission. An opinion of an expert commission shall include the list of examinations, the volume of examinations carried out by each expert, the facts determined by each expert and the inferences based on the examination results. An expert whose opinion does not meet the decision of the expert committee is entitled to express his opinion in writing, which opinion is enclosed with the opinion of the expert commission.

10. Experts included in an expert commission shall be forewarned of responsibility stipulated by the legislation of the Russian Federation for preparing opinions containing unreasonable or falsified inferences, which responsibility they acknowledge in writing.

11. Special expert and qualification commissions determine the professional level of the experts and certify the latter for carrying out expert examination in the manner prescribed by the authorized federal executive body. The professional level of experts is subject to review by such commissions at least every five years.

12. Rules for conduct of an expert examination of medicines and specifics of expert examinations for certain types of medicinal products (reference medicinal products, generic medicinal products, biological medicinal products, bioanalogue (biosimilar) medicinal products (biosimilars), homeopathic medicinal products, herbal medicinal products, combinations of medicinal products) and forms of opinions of the expert commission shall be established by the authorized federal executive body.

(clause 12 as amended by Federal Law of December 22, 2014 No. 429-FZ)

#### Article 17. Submission and Review of Applications for State Registration of a Medicinal Product for Veterinary Use

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

1. For the purpose of state registration of a medicinal product for veterinary use, the developer of the medicinal product or any other legal entity authorized by such developer (hereinafter "the applicant") submits to the authorized federal executive body carrying out state registration of medicinal products for veterinary use, in electronic or paper form, an application for state registration of the medicinal product for veterinary use, as well as necessary documents, in electronic or paper form, in the manner prescribed by the relevant authorized federal executive body, of which the registration dossier of the medicinal product for veterinary use is formed.

2. An application for state registration of a medicinal product for veterinary use shall contain:

1) name and address of the applicant, developer and manufacturer of the medicinal product for veterinary use and address of the place of production of the medicinal product for veterinary use (if there are more than one participant of the process each one of them shall be specified);

2) name of the medicinal product for veterinary use (international nonproprietary name or modified or chemical and trade names);

3) list of active substances and excipients composing the medicinal product for veterinary use specifying the quantity of each;

4) pharmaceutical form, dosage rate, modes of administration and use and validity period of the medicinal product for veterinary use;

5) pharmacotherapeutic group;

6) the necessity to apply an accelerated procedure for expert examination of medicines for the purpose of state registration of a medicinal product;

7) copies of documents confirming payment of state duty:

a) for the conduct of expert examination of medicine quality and expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product for veterinary use at its state registration;

b) for the issue of a registration certificate for medicinal product;

8) the consent as provided by clause 7 of this Article, if less than six years have passed since the registration of a reference medicinal product for veterinary use.

3. For the purpose of expert examination of a medicinal product for veterinary use a registration dossier shall be composed of the following documents:

1) a copy of the medicines manufacturing license issued to the manufacturer of the medicinal product for veterinary use being registered, for Russian manufacturers;  
(sub-clause 1 as amended by Federal Law of June 04, 2018 No. 140-FZ)

2) a copy of the medicines manufacturing license issued to the manufacturer of the pharmaceutical substance forming part of the medicinal product for veterinary use being registered, for Russian manufacturers;  
(sub-clause 2 as amended by Federal Law of June 04, 2018 No. 140-FZ)

2.1) a copy of the document issued by the competent authority of the manufacturer's country for each manufacturing site of the medicinal product for veterinary use being registered and evidencing compliance of the manufacturer of the medicinal product with the good manufacturing practice guidelines and its duly certified translation into Russian and a copy of the conclusion on compliance of the manufacturer of medicines with the good manufacturing practice guidelines issued by the authorized federal executive body for each manufacturing site of the medicinal product for veterinary use being registered, or a copy of the decision to conduct an inspection of the manufacturer of medicines made by the authorized federal executive body for each manufacturing site of the medicinal product for veterinary use being registered. The above documents shall be provided if the medicinal product is manufactured outside the Russian Federation;  
(sub-clause 2.1 introduced by Federal Law of November 25, 2013 No. 317-FZ)

2.2) a copy of the document issued by the competent authority of the pharmaceutical substance manufacturer's country and evidencing compliance of the manufacturer of the pharmaceutical substance forming part of the medicinal product for veterinary use being registered with the good manufacturing practice guidelines and its duly certified translation into Russian, if the pharmaceutical substance is manufactured outside the Russian Federation;  
(sub-clause 2.2 introduced by Federal Law of November 25, 2013 No. 317-FZ)

3) a draft normative document for the medicinal product for veterinary use;

4) a document containing the following information about pharmaceutical substance or pharmaceutical substances in the composition of the medicinal product for veterinary use:

a) name of the pharmaceutical substance, its structure, general properties (in the event of state registration of immunobiological medicinal products for veterinary use, information about the strain shall be provided, including its name, information on its origin, properties, characteristics and deposition place);  
(as amended by Federal Law of August 02, 2019 No. 297-FZ)

b) name and address of the manufacturer;

c) production technology with description of the production process stages and control methods at all production stages;

d) information on impurities (not provided in the event of state registration of immunobiological medicinal products for veterinary use);  
(as amended by Federal Law of August 02, 2019 No. 297-FZ)

e) specification for the pharmaceutical substance (not provided in the event of state registration of immunobiological medicinal products for veterinary use);  
(as amended by Federal Law of August 02, 2019 No. 297-FZ)

f) description of quality control methods;

g) results of analysis of the series of the pharmaceutical substance (not provided in the event of state registration of immunobiological medicinal products for veterinary use);  
(as amended by Federal Law of August 02, 2019 No. 297-FZ)

h) a list of standard samples or substances used in quality control;

i) description of characteristics and properties of packaging materials and closures;

j) data on stability (not provided in the event of state registration of immunobiological medicinal products for veterinary use);  
(as amended by Federal Law of August 02, 2019 No. 297-FZ)

k) expiration period, storage conditions;

5) report on the results of pre-clinical trial of the medicine for veterinary use, including description of methods for determining residual amounts of the active substance(s) reaching the systemic blood flow in products of animal origin after administration of this medicine, as well as documentary evidence (validation) of these methods;

(clause 5 as amended by Federal Law of August 02, 2019 No. 297-FZ)

6) a report on the results of clinical trials of the medicinal product for veterinary use in each kind of animals specified in the instruction for veterinary use;

7) a draft instruction for veterinary use of the medicinal product containing the following information:

a) name of the medicinal product for veterinary use (international nonproprietary name or modified or chemical and trade names);

b) pharmaceutical form specifying the names and quantitative composition of active substances and qualitative composition of excipients;

c) description of appearance of the medicinal product for veterinary use;

d) pharmacotherapeutic group of the medicinal product for veterinary use or the indication "homeopathic medicinal product";

e) pharmacodynamics and pharmacokinetics (except for pharmacokinetics of homeopathic medicinal products and herbal medicinal products) or description of immunobiological properties of the medicinal product;

f) indications for use;

g) contraindications for use;

h) safety precautions on use;

i) possibilities and specifics of use in pregnant animals, animals in period of lactation and in animal brood;

j) dosage regimen, mode of administration, time of administration, where necessary, and duration of treatment;

k) possible side effects, adverse drug reactions when using the medicinal product for veterinary use;

l) overdose symptoms, relief measures in case of overdose;

m) interaction with other medicinal products and (or) animal feeds;

n) presentation of the medicinal product for veterinary use;

o) references, if necessary, to specific effects of the medicinal product at first use or withdrawal thereof;

p) description, where necessary, of actions to be undertaken by a veterinary specialist, animal's owner in case of omission of one or more doses of the medicinal product for veterinary use;

(as amended by Federal Law of August 02, 2019 No. 297-FZ)

q) expiration period and a note about the prohibition to take the medicinal product for veterinary use after the expiration date;

r) storage conditions;

s) an indication to keep the medicinal product for veterinary use away from children;

t) a note (where necessary) of special precaution measures when destroying unused medicinal products for veterinary use;

u) a period for possible use of animal products after the animal has taken the medicinal product for veterinary use;

v) dispensation conditions;

w) names and addresses of production sites of the manufacturer of the medicinal product for veterinary use;

x) name and address of an organization authorized by the holder or owner of the registration certificate for medicinal product to receive claims from consumers;

8) draft design for primary and secondary package of the medicinal product for veterinary use;

9) the following information on the medicinal product for veterinary use:

a) description and composition of the medicinal product for veterinary use;

b) description of the pharmaceutical development;

c) description of the production process and its control signed in the manner established in accordance with part 1 of this Article;

(as amended by Federal Law of August 02, 2019 No. 297-FZ)

d) description of controls of critical production stages and intermediate products signed in the manner established in accordance with part 1 of this Article;

(as amended by Federal Law of August 02, 2019 No. 297-FZ)

e) names and addresses of the developer, the holder or owner of the registration certificate for the medicinal product, manufacturing sites of the manufacturer of the medicinal product for veterinary use specifying technological process stages performed at the manufacturing sites of the manufacturer of the medicinal product for veterinary use;

(as amended by Federal Law of July 13, 2015 No. 241-FZ, Federal Law of August 02, 2019 No. 297-FZ)

f) pharmaceutical compatibility;

g) microbiological characteristics;

h) material balance for production of a series of the finished product;

i) description of characteristics and properties of packaging materials and closures;

j) documentary confirmation (validation) of processes and (or) assessment thereof;

k) requirements for the quality of excipients (certificate, specification for excipients and substantiation thereof);

l) analytical methods used in quality control of excipients;

m) documentary confirmation (validation) of analytical methods used in quality control of excipients;

n) information on the use of excipients of human and animal origin;

o) ceased to be in force. — Federal Law of August 02, 2019 No.297-FZ;

p) requirements for the quality of the medicinal product for veterinary use (certificate, specification for the medicinal product and substantiation thereof);

q) analytical methods used in quality control of the medicinal product for veterinary use;

r) documentary confirmation (validation) of analytical methods used in quality control of the medicinal product for veterinary use;

s) a document confirming the quality of the medicinal product from three production series (analysis protocol or analysis certificate), of which one series shall correspond with the series of the sample of the medicinal product submitted for registration;

t) characteristics of impurities;

u) a list of standard samples used in quality control of the medicinal product for veterinary use;

v) data on stability of the medicinal product for veterinary use;

10) a copy of a document containing information on availability or non-availability of facts of registration of the medicinal product for veterinary use outside the Russian Federation;

11) written consent as provided by clause 7 of this Article, in case of registration of a generic medicinal product;

12) a copy of a document in Russian certified in accordance with the established procedure and confirming the validity of the application for state registration of the medicinal product for veterinary use (power of attorney);

13) information on state registration of genetically modified organisms designated for release in the environment (in the event of state registration of medicinal products for veterinary use manufactured with the use of genetically modified organisms or containing such organisms).

(clause 13 introduced by Federal Law of August 02, 2019 No. 297-FZ)

4. In the event of an accelerated procedure of expert examination of the medicinal product for veterinary use, for the purposes of its state registration, instead of the developer's report on the results of pre-clinical trial of the medicinal product for veterinary use, a review of scientific works on the results of pre-clinical trial of a reference medicinal product for veterinary use may be provided, and instead of the report on the results of a clinical trial of the medicinal product for veterinary use, a report on the results of a bioequivalence study of the generic medicinal product for veterinary use may be provided.

(clause 4 as amended by Federal Law of August 02, 2019 No. 297-FZ)

5. For expert examination of different pharmaceutical forms of the same medicinal product for veterinary use, the applicant shall provide separate applications and registration dossiers for each pharmaceutical form. If an applicant simultaneously submits for expert examination one pharmaceutical form with different dosage, concentration, volume, the applicant shall provide one application and registration dossier with attachment of primary and secondary package design. The primary and secondary package design shall specify all manufactured dosages, concentrations, volumes and number of dosage units in a package of the medicinal product for veterinary use.

(clause 5 as amended by Federal Law of August 02, 2019 No. 297-FZ)

6. The applicant may submit, on his own initiative, together with an application for state registration of the medicinal product for veterinary use, documents confirming payment of state duty specified in sub-clause 7 of clause 2 of this Article. In case such documents are not submitted, the relevant authorized federal executive body shall check the fact of payment by the applicant of state duty by using information on payment of state duties contained in the State Information System on state and municipal payments on the basis of copies of documents confirming the payment of state duty provided by the applicant.

7. It is not allowed to use for commercial purposes information on the results of preclinical trials of medicines and clinical trials of medicinal products for veterinary use submitted by the applicant for state registration of medicinal products without his consent within six years of the date of state registration of a reference medicinal product in the Russian Federation.

8. The holder or owner of the registration certificate for the medicinal product for veterinary use shall submit to the federal executive authority a report on the pharmacovigilance results once in six months during the first two years after state registration of the medicinal product in the Russian Federation; thereafter once a year during the next three years; and thereafter once in three years.

(clause 8 introduced by Federal Law of August 02, 2019 No. 297-FZ)

#### Article 18. Submission and Review of Applications for State Registration of a Medicinal Product for Medical Use

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

1. For the purpose of state registration of a medicinal product for medical use, a legal entity acting on its own behalf or authorized to act on behalf of another legal entity and submitting the medicinal product for state registration (hereinafter “the applicant”) submits to the authorized federal executive body carrying out state registration of medicinal products for medical use, in electronic and paper form, an application for state registration of the medicinal product for medical use, as well as necessary documents, in electronic and paper form, in the manner prescribed by the relevant authorized federal executive body, of which the registration dossier of the medicinal product for medical use is formed.

(clause 1 as amended by Federal Law of December 22, 2014 No. 429-FZ)

2. An application for state registration of a medicinal product for medical use shall contain:

1) name, address of the applicant and the manufacturer of the medicinal product for medical use, information on their registration as a taxpayer in the country of registration (for Russian legal entities — taxpayer identification number (INN), for foreign legal entities — country of registration, name of registering body, registration number, taxpayer’s code in the country of registration (incorporation) or its analogue) and the manufacturing site of the medicinal product (in case of more than one participant of the manufacturing process, each participant shall be specified in accordance with the relevant manufacturing stage);

(sub-clause 1 as amended by Federal Law of December 28, 2017 No. 425-FZ)

2) name of the medicinal product for medical use (international nonproprietary name or modified or chemical and trade names);

3) a list of active substances and excipients composing the medicinal product for medical use specifying the quantity of each;

4) pharmaceutical form, dosage rate, modes of administration and use and expiration period of the medicinal product for medical use;

5) pharmacotherapeutic group, code of the medicinal product in accordance with the Anatomical Therapeutic Chemical Classification System recommended by the World Health Organization, claimed indications for the use of the medicinal product for medical use;

6) the absence of the necessity to provide a report on the results of a clinical trial, bioequivalence study of the medicinal product permitted for medical use in the Russian Federation for more than twenty years, specifying normative legal acts confirming this period of use;

7) the necessity to obtain a permit to import into the Russian Federation a particular batch of registered and (or) unregistered medicines designated for the conduct of expert examination of medicines for the purpose of state registration;

8) the necessity to conduct expert examination of documents submitted to determine whether it is possible to consider the medicinal product for medical use at state registration as an orphan medicinal product;

9) the necessity to apply an accelerated procedure for expert examination of medicines for the purpose of state registration of the medicinal product;

10) copies of documents confirming payment of state duty:

a) for the conduct of expert examination of documents submitted to determine whether it is possible to consider the medicinal product for medical use at state registration as an orphan medicinal product;

b) for the conduct of expert examination of medicine quality and expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product permitted for medical use in the Russian Federation for more than twenty years, at state registration of the medicinal product;

c) for the conduct of expert examination of medicine quality and expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product for medical use at its state registration;

d) for the conduct of expert examination of quality of a medicine and expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product for medical use, in respect to which international multicentre clinical trials were held, a part of which was held in the Russian Federation, at state registration of the medicinal product;

11) consent of the manufacturer of the medicinal product produced outside the Russian Federation to the conduct of inspection of the manufacturer for compliance with the requirements of good manufacturing practice;

12) consent as provided by clause 18 of this Article;

13) indication of the type of the medicinal product submitted for registration (reference medicinal product, generic medicinal product, biological medicinal product, bioanalogue (biosimilar) medicinal product (biosimilar), homeopathic medicinal product, herbal medicinal product).

(clause 2 as amended by Federal Law of December 22, 2014 No. 429-FZ)

---

3. A registration dossier of the medicinal product for medical use shall be provided in the form of a general technical document.

(clause 3 as amended by Federal Law of December 22, 2014 No. 429-FZ)

---

4. Administration section of the documents shall include:

1) application for state registration of a medicinal product for medical use in the electronic form or in hard copies;

2) duly certified copy of the document in Russian confirming the applicant's authority to file an application for state registration of a medicinal product for medical use (Power of Attorney);

3) copy of license for production of medicines or copy of manufacturer's GMP compliance certificate issued by the authorized federal executive body in respect of the manufacturing site of the medicinal product being registered if the medicinal product is produced in the Russian Federation;

(sub-clause 3 as amended by Federal Law of June 04, 2018 No. 140-FZ)



4) duly certified copy of license for production of medicines issued by the authorized body of the manufacturer's country and translation thereof into Russian and copy of manufacturer's GMP compliance certificate issued by the authorized federal executive body in respect of the manufacturing site of the medicinal product being registered, or a copy of the decision of the authorized federal executive body to conduct an inspection of the manufacturer of medicines if the medicinal product is produced outside the Russian Federation;

(sub-clause 4 as amended by Federal Law of June 04, 2018 No. 140-FZ)

5) draft basic prescribing information of the medicinal product specifying the following data:

a) name of the medicinal product (international nonproprietary, or generic, or chemical, or trade name);

b) dosage form specifying the names and quantitative composition of active substances and qualitative composition of excipients (if necessary qualitative composition of excipients);

c) description of appearance of the medicinal product for medical use;

d) physical and chemical properties (for radiopharmaceutical medicines);

e) pharmacotherapeutic group, code of the medicinal product for medical use in accordance with Anatomical Therapeutic Chemical Classification System recommended by World Health Organization or designation "Homeopathic medicinal product";

f) pharmacodynamics and pharmacokinetics (excluding pharmacokinetics of homeopathic medicinal products and phytopharmaceutical products);

g) indications for use;

h) contraindications for use;

i) safety precautions on use;

j) possibilities and specifics of medical use of the medicinal product for medical use in pregnant women, women in period of lactation, children or adults with chronic diseases;

k) dosage regimen, mode of administration, time of administration of the medicinal product for medical use, if necessary, and duration of treatment (including those for children under and over one year old);

l) possible side effects of the medicinal product for medical use;

m) overdose symptoms; relief measures in case of overdose;

n) interaction with other medicinal products and (or) food products;

o) pharmaceutical forms of the medicinal product;

p) specification, if necessary, of peculiarities of action of the medicinal product for medical use when administered for the first time or withdrawal;

q) description, if necessary, of actions to be undertaken by a physician (physician's assistant) and/or patient in case of omission of one or several doses of the medicinal product for medical use;

r) information on possible effect of the medicinal product on the ability to drive and operate machinery;

s) shelf life and indication not to use the medicinal product after its expiry;

t) storage conditions;

u) indication to keep the medicinal product away from children;

v) special safety precautions to be used when destructing unused medicinal products for medical use, if necessary;

w) prescription status;

x) name and address of the manufacturer of the medicinal product and address of the place of production of the medical preparation;

y) name and address of the institution authorized by holder or owner of Registration Certificate of the medicinal product for medical use to accept the customers' claims;

6) Basic prescribing information or summary of product characteristics approved in the manufacturer's country;

7) draft primary and secondary package designs of the medicinal product for medical use;

8) draft regulatory and normative documents for medicinal product for medical use or reference to the correspondent pharmacopoeia article;

9) document containing information on presence or absence of the facts of registration of medicinal product for medical use outside the Russian Federation;

10) copies of duly certified documents confirming registration of the medicinal product in foreign countries as an orphan medicine;

11) risk management plan for biological medicinal products for medical use;

12) document on pharmacovigilance system of the holder or owner of the registration certificate of the medicinal product;

13) document confirming quality of three batches of the medicinal product (test report or certificate of analysis), one batch of which shall correspond to the batch of the sample of the medicinal product for medical use submitted for state registration.

(clause 4 as amended by Federal Law of December 22, 2014 No. 429-FZ)

---

5. Section of chemical, pharmaceutical and biological documents shall include the documents containing the information on pharmaceutical substance and medicinal product for medical use, process of manufacture thereof and quality control methods including:

1) document containing the following information on the pharmaceutical substance(s) composing the medicinal product with the exception of information about pharmaceutical substances included in the state registry of medicines in accordance with Article 34 of this Federal Law:

(as amended by Federal Law of December 27, 2019 No. 462-FZ)

a) name of pharmaceutical substance, structure and common properties thereof;

b) manufacturer's name and address;

c) production technology describing manufacturing steps and control procedures during all the manufacturing steps;

d) description of manufacturing process development;

e) description of control of critical steps and intermediates;

f) documented evidence (validation) of processes and (or) evaluation thereof;

g) properties and structure of active substances;

h) characteristics of impurities;

i) pharmaceutical substance specification and justification thereof;

j) analytical procedures used when controlling quality of pharmaceutical substances;

k) documented evidence (validation) of the analytical procedures used when controlling quality of pharmaceutical substances;

l) analysis results of series of pharmaceutical substances;

m) list of standard samples or the substances used when controlling quality of the products;

n) description of characteristics and properties of packaging materials and means of sealing;

o) stability data of the pharmaceutical substance;

p) shelf life;

1.1) regarding pharmaceutical substances comprising the medicinal product and included in the state registry of medicines in accordance with Article 34 of this Federal Law, - a copy of the document containing the following information:

a) name of the pharmaceutical substance, its structure, general properties;

b) name and address of the manufacturer;

c) results of batch analyses of the pharmaceutical substance;

d) shelf life;

(sub-clause 1.1 introduced by Federal Law of December 27, 2019 No. 462-FZ)

2) Document containing the following information on the medicinal product for medical use:

a) description and composition of the medicinal product for medical use;

b) description of pharmaceutical development (justification of the selected composition, primary packaging and other);

c) production technology describing manufacturing steps and control procedures during all the manufacturing steps;

d) description of control of critical steps and intermediates;

- e) name and address of the entity producing the medicinal product for medical use (if there are several parties to the manufacturing process it is necessary to list all of them);
- f) pharmaceutical compatibility;
- g) microbiological properties;
- h) material balance for production of batch of the finished product;
- i) description of characteristics and properties of packaging materials and means of sealing;
- j) documented evidence (validation) of manufacturing processes and (or) evaluation thereof;
- k) quality requirements applicable to excipients (certificate, specification on excipients and justification thereof);
- l) analytical procedures used when controlling quality of excipients;
- m) documented evidence (validation) of the analytical procedures used when controlling quality of excipients;
- n) information on use of excipients of human and animal origin;
- o) information on use of new excipients;
- p) quality requirements applicable to the medicinal product for medical use (certificate, specification on the medicinal product for medical use and justification thereof);
- q) analytical procedures used when controlling quality of the medicinal product for medical use;
- r) documented evidence (validation) of the analytical procedures used when controlling quality of the medicinal product for medical use;
- s) analysis results of series of the medicinal product for medical use;
- t) characteristics of impurities;
- u) list of standard samples or the substances used when controlling quality of the medicinal product for medical use;
- v) stability data of the medicinal product for medical use.

(clause 5 as amended by Federal Law of December 22, 2014 No. 429-FZ)

6. Section of pharmacological and toxicological documents shall include reports on results of pre-clinical trials of the medicinal product for medical use including:

- 1) pharmacodynamic study report;
- 2) pharmacokinetic study report;
- 3) toxicity study report.

(clause 6 as amended by Federal Law of December 22, 2014 No. 429-FZ)

7. Section of clinical documents shall include reports on clinical trials of the medicinal product for medical use including:

- 1) reports on bioavailability and bioequivalence studies, studies finding correlation between the in vitro and in vivo results;
- 2) pharmacokinetic study report;
- 3) pharmacodynamic study report;
- 4) reports on clinical trials of safety and efficacy;
- 5) report on post-registration experience (if any).

(clause 7 introduced by Federal Law of December 22, 2014 No. 429-FZ)

8. Requirements applicable to the scope of information provided as a part of the registration dossier for certain kinds of medicinal products for medical use shall be set up by the authorized federal executive body.

(clause 8 introduced by Federal Law of December 22, 2014 No. 429-FZ)

9. Regarding medicinal products authorized for medical use in the Russian Federation for more than twenty years and in respect of which it is impossible to perform trials about their bioequivalence (except biological medicinal products), the inclusion of pharmacological, toxicological documentation section and clinical documentation section in the content is allowed instead of developer report about

results of own preclinical trials of medicines and clinical trials of medicinal products for medical use, review of scientific works about results of preclinical trials of medicines and clinical trials of the medicinal products including their experience of post-marketing use.

(clause 9 introduced by Federal Law of December 22, 2014 No. 429-FZ, as amended by Federal Law of December 27, 2019 No. 475-FZ)

10. When carrying out state registration of generic medicinal products for medical use there shall be allowed to include into the section pharmacological and toxicological documents and the section of clinical documents instead of developer's report on results of its own preclinical trials of medicinal products, summary of scientific efforts on results of preclinical trials of reference medicinal products and to submit report on the results of bioequivalence of generic medicinal product for medical use instead of clinical trials to the fullest extent prescribed by the section of clinical documents if the medicinal products for medical use subject to registration are:

- 1) water solutions for parenteral (subcutaneous, intramuscular, intravenous, intraocular, intracavitary, intra-articular, intracoronary) administration;
- 2) oral solutions;
- 3) powders or lyophilisate for solutions;
- 4) gases;
- 5) aural or ophthalmic medicinal products in the form of water solutions;
- 6) topical water solutions;
- 7) water solutions for inhalations using nebulizer or nasal sprays applied using similar devices.

(clause 10 introduced by Federal Law of December 22, 2014 No. 429-FZ)

11. In the cases specified in clauses 1 – 3, 5 – 7 of part 10 of this article generic medicinal product for medical use shall also contain the excipients in the quantities identical to the reference medicinal product. If compositions of the excipients are different the applicant shall provide the evidences of that the excipients used in the said concentrations have no effect on safety and (or) efficacy of the medicinal product for medical use. If the applicant fails to provide those evidences and (or) has no access to the correspondent data it shall carry out the correspondent trials to prove absence of effect of different excipients or auxiliary units on safety and (or) efficacy of the medicinal product for medical use in accordance with the procedure set up by the authorized federal executive body.

(clause 11 introduced by Federal Law of December 22, 2014 No. 429-FZ)

12. In case of state registration of a combination of earlier registered medicinal products for medical use there shall be allowed to include into the section pharmacological and toxicological documents and the section of clinical documents instead of developer's report on results of its own preclinical trials of medicinal products, summary of scientific efforts on results of preclinical trials of reference medicinal products forming the combination of medicinal products and on absence of interaction thereof in one dosage form.

(clause 12 introduced by Federal Law of December 22, 2014 No. 429-FZ)

13. To carry out expert examination of different dosage forms of the same medicinal product for medical use the applicant shall file separate applications and registration dossiers for each dosage form. In case of concurrent provision for expert examination of one dosage form with different strength, concentration and volume the applicant shall file one application and registration dossier accompanied by package designs for each strength, concentration, volume and dose number per package.

(clause 13 introduced by Federal Law of December 22, 2014 No. 429-FZ)

14. When carrying out state registration of orphan medicinal product the applicant shall submit the information necessary to form the section of clinical documents to the extent determined by the authorized federal executive body.

(clause 14 introduced by Federal Law of December 22, 2014 No. 429-FZ)

15. When carrying out state registration of biological medicinal product made of human blood or plasma registration dossier for the medicinal product for medical use shall additionally include:

1) in the section of administrative documents the document containing the information on subjects of donated blood circulation and (or) components thereof, on the place of (blood and (or) plasma) donation as well as the data on the parenterally transmitted contagious diseases, the information on subjects of donated blood circulation and (or) components thereof subject to control of donated blood and (or) components thereof;

2) in the section of chemical, pharmaceutical and biological documents:

a) criteria and methods of withdrawal, transportation and storage of donated blood and (or) components thereof;

b) results of analysis of withdrawn blood and (or) blood plasma and contagious matter pools including the information of the used methodology and, in case of studying of blood plasma pools – documented evidence (validation) of the analytical procedures;

c) technical characteristics of package for withdrawal of blood and (or) blood plasma including the information on the used anticoagulants.

(clause 15 introduced by Federal Law of December 22, 2014 No. 429-FZ)

16. Clinical trials of the medicinal product for medical use for the purposes of state registration thereof shall be carried out in the Russian Federation in accordance with the procedure stipulated in articles 38 – 44 hereof. Clinical trial report shall be included into the section of clinical documents of the registration dossier for the medicinal product for medical use. For the medicinal products for medical use possibility of considering which as orphan medicinal products for medical use is confirmed on the basis of expert examination of the submitted documents and which has undergone clinical trials outside the Russian Federation in accordance with good laboratory practice and good clinical practice there shall be allowed to include into the section of clinical documents the report of results of the clinical trials carried out outside the Russian Federation instead of the report of results of the clinical trials of the medicinal product for medical use carried out in the Russian Federation.

(clause 16 introduced by Federal Law of December 22, 2014 No. 429-FZ)

17. The applicant shall be entitled to proactively submit the documents certifying payment of the state duty and the documents specified in clause 10 of part 2 of this article together with the application for state registration of the medicinal product for medical use. In case of failure to submit the above documents the authorized federal executive body shall verify the fact of the applicant's payment of the state duty using the information contained in the State Information System of State and Municipal Payments on the basis on a copies of the documents certifying payment of the state duty submitted by the applicant.

(clause 17 introduced by Federal Law of December 22, 2014 No. 429-FZ)

18. Commercial use of the information on results of preclinical trials of medicinal products and clinical trials of medicinal product for medical use submitted by the applicant for state registration thereof without the applicant's consent during six years from the date of state registration of the reference medicinal product in the Russian Federation shall be prohibited.

(clause 18 introduced by Federal Law of December 22, 2014 No. 429-FZ)

19. Holder or owner of the registration certificate of a biopharmaceutical or orphan medicinal product shall for a consideration provide the applicants with samples of the reference medicinal product to carry out clinical trials. Cost of a sample of the reference medicinal product included into the list of vital and essential medicines shall not exceed the registered maximum sale price for the reference medicinal product or price for the medicinal product in the manufacturer's country.

(clause 19 introduced by Federal Law of December 22, 2014 No. 429-FZ)

20. Application for state registration of a generic medicinal product for medical use may be filed to the authorized federal executive body accredited for state registration of the medicinal products upon expiration of four years from the date of state registration of the reference medicinal product in the Russian Federation.

(clause 20 introduced by Federal Law of December 22, 2014 No. 429-FZ)

21. Application for state registration of a biosimilar medicinal product may be filed to the authorized federal executive body accredited for state registration of the medicinal products upon expiration of three years from the date of state registration of the reference medicinal product in the Russian Federation.

(clause 21 introduced by Federal Law of December 22, 2014 No. 429-FZ)

22. Holder or owner of the registration certificate of a medicinal product shall submit to the authorized federal executive body maintaining control and supervision in the sphere of public health the report based on pharmacovigilance results every six month during two years after state registration of the medicinal product in the Russian Federation and annually during the following three years and once per five years hereafter.

(clause 22 introduced by Federal Law of December 22, 2014 No. 429-FZ)

---

#### Article 19. Procedure for Making Decision on Issuance of Assignment for Performance of Expert Examination of a Medicine for Expert Institution

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

1. Within ten business days from on receipt of an application for state registration of a medicinal product, the relevant authorized federal executive body shall review the documents contained in the registration dossier of the medicinal product submitted by the applicant for completeness, accuracy and correctness of execution and make a decision on issuance of an assignment to carry out:

1) expert examination of documents submitted to determine whether it is possible to consider the medicinal product for medical use at state registration as an orphan medicinal product;

2) expert examination of a medicine in the part of expert examination of quality of a medicine and expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product for medical use;

3) expert examination of a medicine in the part of expert examination of quality of a medicine and expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product for medical use using an accelerated procedure of expert examination of medicines in accordance with Article 26 of this Federal Law;

4) expert examination of a medicine in respect of a medicinal product for veterinary use.

2. The authorized federal executive body shall notify the applicant or expert institution, in electronic or paper form, of the decision made on giving assignments for the conduct of expert examinations provided by clause 1 of this Article and, where necessary, on issuing a permit to import into the Russian Federation a particular batch, series of registered and (or) unregistered medicines or on refusal to conduct relevant expert examinations, specifying the reasons for such a refusal.

3. If information contained in the documents provided by the applicant is found to be incomplete or inaccurate, the authorized federal executive body shall send to the applicant a request for clarification of this information (hereinafter the "request of the authorized federal executive body"), which may be delivered to an authorized representative of the applicant personally against signature, by registered mail or in electronic form via telecommunication channels. If the request is sent by registered mail, it shall be deemed received in six days of the dispatch.

4. The applicant shall respond to the request of the authorized federal executive body within

ninety business days of its receipt. The period specified in clause 1 of this Article shall be suspended from the date when the authorized federal executive body sends its request to the date when it receives the relevant response.

5. A failure to submit a complete set of the required documents, a failure to send a response to the request of the authorized federal executive body, or submission of the documents lacking comprehensive information shall be the grounds for refusal to carry out the expert examinations specified in clause 1 of this Article.

6. In the event of refusal to perform expert examination provided for by paragraph 4 of part 1 of this Article, documents included in the registration dossier for the medicinal product for veterinary use may be returned to the applicant based on its written request sent to the authorized federal executive body within thirty days after it makes a decision to refuse to perform this expert examination. The authorized federal executive body shall return to the applicant the above documents within ten business days of receipt of the relevant request from the applicant.

(clause 6 introduced by Federal Law of August 02, 2019 No. 297-FZ)

Article 20. Expert Examination of Documents Submitted in Order to Determine a Possibility to Consider a Medicinal Product for Medical Use as an Orphan Medicinal Product in the Process of State Registration

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

1. Expert examination of documents submitted to determine whether it is possible to consider a medicinal product for medical use at state registration as an orphan medicinal product shall be carried out and an opinion of the expert commission on the possibility or non-possibility to consider the medicinal product for medical use at state registration as an orphan medicinal product and shall be made and sent to the authorized federal executive body within thirty business days of receipt by the expert institution of the assignment of the authorized federal executive body and, in electronic or paper form, the required documents specified in sub-clauses 1, 2, 5, 6, 10 of clause 4 and in clause 7 of Article 18 of this Federal Law.

2. Documents contained in the registration dossier of the medicinal product and received to the expert institution in paper form for the purpose of their expert examination in order to determine whether it is possible to consider the medicinal product for medical use at state registration as an orphan medicinal product shall be returned to the authorized federal executive body together with opinions of relevant expert examinations.

Article 21. Decision on the Possibility to Consider the Medicinal Product for Medical Use at State Registration as an orphan medicinal Product

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

1. Within five business days of the date of receipt of the opinion specified in clause 1 of Article 20 of this Federal Law, the authorized federal executive body shall assess the received opinion in order to verify its compliance with the assignment for the conduct of the relevant examination and notify the applicant, in electronic or paper form, on the results of the expert examination conducted, with attachment of a copy of the expert opinion (keeping confidential the information on the composition of the expert commission) and on possibility or non-possibility to consider the medicinal product for medical use at state registration as an orphan medicinal product.

2. If the expert commission draws up an opinion on the possibility to consider the medicinal product for medical use at state registration as an orphan medicinal product, the authorized federal executive body shall, within five business days of receipt of this opinion, make a decision on giving an assignment for the conduct of expert examination of the medicine quality and expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product for medical use using an accelerated procedure for expert examination of the medicine in accordance

with Article 26 of this Federal Law.

3. If a decision is made on the non-possibility to consider the medicinal product for medical use at state registration as an orphan medicinal product, the authorized federal executive body shall terminate the procedure for state registration of the medicinal product. The applicant may submit to the registering body an application for state registration of the medicinal product in accordance with Article 18 of this Federal Law.

Article 22. Ceased to be in force as of July 1, 2015 (Federal Law of December 22, 2014 No. 429-FZ)

Article 23. Expert Examination of Quality of a Medicine and Expert Examination of a Correlation between the Anticipated Benefit and Possible Risk from the Use of the Medicinal Product for Medical Use

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

1. Expert examination of quality of a medicine and expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product for medical use shall be carried out and opinions by the expert commissions based on the results of the expert examination conducted shall be made and sent to the authorized federal executive body within one hundred and ten business days of receipt by the expert institution of the relevant assignment of the authorized federal executive body and required documents in electronic and paper form.

2. Within ninety business days from the date of receipt of the decision on performance of expert examinations specified in clause 1 of this Article, issued by the authorized federal executive body, the applicant shall submit, for the purpose of expert examination of the quality of the medicinal product, samples of the medicinal product for medical use produced in compliance with the requirements of the experimental industrial regulations and (or) industrial regulations approved by the head of the medicines manufacturing company and, if applicable, samples of pharmaceutical substance, test strains of microorganisms, cell cultures, samples of substances used for the purpose of quality control of a medicine by comparison of the studied medicine therewith, in quantities necessary to reproduce the quality control methods.

3. Upon receipt of samples of a medicinal product and pharmaceutical substance the expert institution shall provide the applicant with a document certifying the receipt of such samples, and notify the authorized executive body thereof in electronic or paper form within three business days.

4. The period specified in clauses 2 and 3 of this Article for submission of samples of a medicinal product and pharmaceutical substance by the applicant and the period of notifying the authorized federal executive body thereof in paper form by the expert institution shall not be included in the period of performance of expert examinations specified in clause 1 of this Article.

5. The documents received by the expert institution for the performance of expert examinations specified in clause 1 of this Article shall be returned to the authorized federal executive body concurrently with the opinions obtained based on the results of relevant examinations.

Article 24. Expert Examination of Quality of a Medicine and Expert Examination of Correlation between Anticipated Benefit and Possible Risk from Use of a Medicinal Product for Veterinary Use

1. Expert examination of the quality of a medicine and expert examination of a correlation between the anticipated benefit and possible risk from the use of a medicinal product for veterinary use, preparation of opinions based on the results of expert examinations by expert councils and forwarding of such opinions to the authorized federal executive body shall be exercised within one hundred and ten business days from the date of receipt by the expert institution of the relevant assignment issued by the authorized federal executive body together with the documents specified in clause 3 of Article 17 of this Federal Law.

(as amended by Federal Law of October 22, 2014 No. 313-FZ)



2. Within thirty business days from the date of receipt of the decision on performance of the expert examinations specified in part 1 of this Article issued by the authorized federal executive body, the applicant shall submit to the expert institution samples of the medicinal product for veterinary use produced in compliance with the requirements of the technological regulations approved by the head of the manufacturer of the medicines and, where applicable, test strains of microorganisms, cell cultures, samples of the pharmaceutical substance, samples of the substances used in quality control of the medicine, in the quantities necessary to reproduce the quality control methods, for the purposes of expert examination of the quality of the medicinal product.

(as amended by Federal Law of August 02, 2019 No. 297-FZ)

3. Upon receipt of samples of the medicinal product and pharmaceutical substance the expert institution shall provide the applicant with a document certifying the receipt of such samples, and notify the authorized executive body thereof in writing within three business days.

4. The period of submission of samples of the medicinal product and pharmaceutical substance by the applicant and the period of a written notification thereof of the authorized federal executive body by the expert institution specified in clauses 2 and 3 of this Article are not included in the period of performance of expert examinations specified in clause 1 of this Article.

5. The documents submitted to the expert institution for performance of expert examinations specified in clause 1 of this Article are subject to return to the authorized federal executive body concurrently with the opinions based on the results of such expert examinations.

#### Article 25. Repeated Expert Examination of Medicines

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

1. In case of insufficient feasibility or incompleteness of the opinion drawn up by the expert institution, presence of controversial data in such opinion, falsification of the inferences based on the results of expert examination of the medicine, concealment from the authorized federal executive body of any grounds for rejection of an expert due to his being interested in the results of the relevant expert examination, availability of data on direct or indirect interference in the expert examination procedure of any persons not participating in the performance thereof, however having influenced the procedure and the results thereof, the authorized federal executive body shall schedule repeated expert examination of the medicine and (or) repeated ethical examination.

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

2. Repeated expert examination of a medicine shall be carried out with regard to the results of previously conducted expert examination within the period prescribed by the authorized federal executive body, not exceeding thirty business days from the date of receipt by the expert institution of an assignment to carry out repeated expert examination of the medicine.

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

3. Financing of repeated expert examination of a medicine is not provided.

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

#### Article 26. Accelerated Procedure for Expert Examination of Medicines

1. Accelerated procedure for expert examination of medicines for the purpose of state registration of medicinal products shall apply to orphan medicinal products, first three medicinal products registered in the Russian Federation as generic medicinal products, the order of which shall be determined in accordance with the number and date of incoming applications for state registration of medicinal products under the same international nonproprietary name of the medicinal product or modified name of the medicinal product, and medicinal products designated solely for the use by minors.

(clause 1 as amended by Federal Law of December 22, 2014 No. 429-FZ).

2. Accelerated procedure for expert examination of medicines for the purposes of state registration of medicinal products shall not apply to:

- 1) bioanalogue (biosimilar) medicinal products (bioanalogues);
  - 2) reference medicinal products (except for orphan medicinal products);
  - 3) generic medicinal products (except for the first three medicinal products registered in the Russian Federation as generic medicinal products and medicinal products designated solely for the use by minors);
  - 4) new combinations of previously registered medicinal products;
  - 5) previously registered medicinal products produced in other pharmaceutical forms in accordance with a list of names of pharmaceutical forms and in new dosage.
- (clause 2 as amended by Federal Law of December 22, 2014 No. 429-FZ).

3. Accelerated procedure for expert examination of medicines shall be conducted under decision of the relevant authorized federal executive body, on the basis of the applicant's application, within eighty business days. In this case expert examination of the documents contained in the registration dossier of the medicinal product shall be conducted within ten business days, and expert examination of the quality of a medicine and expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product shall be conducted within sixty business days.

(clause 3 as amended by Federal Law of December 22, 2014 No. 429-FZ).

3.1. For orphan medicinal products the results of preclinical trials of medicines and clinical trials of medicinal products for medical use conducted outside the Russian Federation in accordance with the rules of good laboratory practice and good clinical practice may be provided.

(clause 3.1 introduced by Federal Law of December 22, 2014 No. 429-FZ)

4. Accelerated procedure for expert examination of medicines shall be performed in the manner prescribed in Articles 17-20, 23 and 24 hereof, and shall not mean downgrading of requirements for safety, quality and efficacy of medicinal products.

#### Article 27. Decision on State Registration of Medicinal Product

1. Within ten business days from the date of receipt of the opinions issued by the expert commission based on the results of expert examination of the quality of a medicine and expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product the relevant authorized federal executive body shall:

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

- 1) post on its official website relevant opinions of the expert commission and evaluate them in order to determine compliance thereof with the assignment for performance of these expert examinations;

(sub-clause 1 as amended by Federal Law of December 22, 2014 No. 429-FZ)

- 2) make a decision on whether to approve state registration of the medicinal product or to refuse approving state registration of the medicinal product;

- 3) in case of a positive decision on state registration of the medicinal product, enter the data on the registered medicinal product, including, but not limited to, the data on the pharmaceutical substance contained in the medicinal product, into the state register of medicines and issue to the applicant a registration certificate, the form of which is to be approved by the authorized federal executive body, approved normative documentation, the normative document, Package Leaflet for the medicinal product and designs of the primary and secondary (retail) packages bearing the number of the registration certificate for the medicinal product and the date of state registration thereof or, in case of refusal of state registration of the medicinal product, notify the applicant in writing of the grounds for such refusal. Issue of a registration dossier of a medicinal product shall be subject to payment of a state duty in accordance with the laws of the Russian Federation on taxes and duties.

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

2. Decision of the relevant authorized federal executive body stating that the data obtained do not confirm the quality and (or) efficacy of the medicinal product for medical use to be registered, or possible health hazard to human beings and animals taking the medicinal product for medical use exceeds the efficacy thereof is considered grounds for refusal of state registration of the medicinal

product for medical use.

(clause 2 as amended by Federal Law of June 04, 2018 No. 140-FZ)

3. Repeated submission to the relevant authorized federal executive body of a medicinal product, in respect to which a refusal to perform state registration has been received and whose composition was subsequently modified, shall be considered as submission of a new medicinal product for its state registration, regardless of whether its initial name is preserved.

(clause 3 as amended by Federal Law of December 22, 2014 No. 429-FZ)

4. When the applicant provides in the registration dossier for the medicinal product for veterinary use a copy of the decision of the authorized federal executive body to conduct an inspection of the manufacturer of medicines, the period for making a decision on state registration of the medicinal product for veterinary use shall be suspended from the date of receipt of the conclusions specified in part 1 of this Article to the date when the authorized federal executive body makes the decision to issue or to refuse to issue a conclusion on compliance of the manufacturer of medicines with the good manufacturing practice guidelines, but in any event by not more than one hundred eighty business days.

(clause 4 introduced by Federal Law of June 04, 2018 No. 140-FZ)

5. The basis for refusal to perform state registration of the medicinal product for veterinary use shall be the conclusion of the authorized federal executive body stating that the quality and (or) efficacy of the medicinal product for veterinary use being registered have not been evidenced or that the risk of causing harm to the animal taking the medicinal product for veterinary use exceeds the benefits from its use; the refusal of the authorized federal executive body to issue a conclusion on compliance of the manufacturer of medicines with the good manufacturing practice guidelines for each manufacturing site of the medicinal product for veterinary use being registered if the medicinal product for veterinary use is manufactured outside the Russian Federation, or the absence of such conclusion.

(clause 5 introduced by Federal Law of June 04, 2018 No. 140-FZ)

#### Article 27.1. Interchangeability of medicinal products for medical use

(as amended by Federal Law of December 27, 2019 No. 475-FZ)

1. Interchangeability of medicinal products for medical use is determined by federal authority implementing the state registration of medicinal products for medical use, within one international nonproprietary (either chemical or group) name based on the conclusion of the expert council of the expert institution either about the interchangeability of medicinal product for medical use or the medicinal product for medical use is not interchangeable. Procedure for determining the interchangeability of medicinal products for medical use and the form of conclusion of the expert council of the expert institution either about the interchangeability of medicinal products for medical use or the medicinal product for medical use is not interchangeable, are established by the Government of the Russian Federation.

2. Expert council of the expert institution gives the conclusion either about the interchangeability of medicinal product for medical use or the medicinal product for medical use is not interchangeable, based on the following criteria (characteristics):

1) equivalence (for biosimilar (bioanalogical) medicinal products (bioanalogue) - consistency) of qualitative and quantitative characteristics of pharmaceutical substances or consistency of antigenic composition used in vaccines. The use of different salts, ethers, complexes, isomers, crystalline forms and other derivatives of the same active substance is not an obstacle for determining the interchangeability of medicinal products if during the bioequivalence study of a medicinal product or therapeutic equivalence study of a medicinal product the absence of clinically significant differences between pharmacokinetics and (or) efficacy and safety of a medicinal product for medical use is proved;

2) equivalence of dosage form. Equivalent dosage forms are understood to be different dosage forms which have a similar route of administration and way of application possessing comparable

pharmacokinetic characteristics and pharmacological action and, also providing a necessary clinical effect. Differences of dosage forms are not the obstacle for determining the interchangeability of medicinal products if during the bioequivalence study of a medicinal product or therapeutic equivalence study of a medicinal product the absence of clinically significant differences between pharmacokinetics and (or) efficacy and safety of a medicinal product for medical use is proved;

3) equivalence or consistency of excipient composition of a medicinal product for medical use. Differences of excipient composition of a medicinal product are not the obstacle for determining the interchangeability of medicinal products if during the bioequivalence study of a medicinal product or therapeutic equivalence study of a medicinal product the absence of clinically significant differences between pharmacokinetics and (or) efficacy and safety of a medicinal product for medical use is proved. In case of presence of clinically significant differences between pharmacokinetics and (or) efficacy and safety of a medicinal product for medical use, interchangeability is determined by indicating the exclusion of isolated group of patients;

4) identity of the route of administration and way of application;

5) compliance of medicinal manufacturer to the requirements of good manufacturing practice.

3. Determination of the interchangeability of medicinal products for medical use stated in the part 10 of the Article 18 of this Federal Law is implemented without the need for bioequivalence evidence to be produced.

4. Determination features of the interchangeability of biological medicinal products, combined medicinal products (containing combination of two and more active substances), medicinal products for parenteral nutrition and non-dose medicinal products are established by the Government of the Russian Federation.

5. Determination of the interchangeability is not implemented regarding herbal medicinal products, homeopathic medicinal products.

6. Development of the list of interchangeable medicinal products for medical use is performed by the expert institution by bringing together medicinal products in to the separate groups in each of which medicinal products are interchangeable.

7. In case of inclusion the medicinal product to the instruction for medical use based on results of respective studies, indications for use other medicinal products from the interchangeable medicinal product group, in the list of interchangeable medicinal products for medical use there should be the following information to be stated.

8. The list of interchangeable medicinal products for medical use is hosted in official website "Internet" by the federal authorities implementing the state registration of medicinal products for medical use. The information in the list of interchangeable medicinal products for medical use is updated by the specified federal authority taking into account new registered medicinal products for medical use and amended documents which are contained in the registration profiles on registered medicinal products for medical use.

9. The use of information about interchangeable medicinal products for medical use and the procedure of explanations regarding issues of interchangeability medicinal products for medical use are established by the Government of the Russian Federation.

#### Article 28. Registration Certificate for Medicinal Product

1. A registration certificate for a medicinal product indicating pharmaceutical forms and dosage rates shall be issued for an unlimited period, except for registration certificates with a validity period of five years issued for the medicinal products to be registered in the Russian Federation for the first time.

2. Upon expiration of the period specified in clause 1 of this Article, a permanent registration certificate for the medicinal product shall be issued subject to confirmation of the state registration thereof.

3. In case any changes are made, in accordance with Articles 30 and 31 of this Federal Law, to documents contained in the registration dossier of a registered medicinal product, which affect information reflected in the registration certificate for the medicinal product, the authorized federal

executive body shall issue a new registration certificate for the medicinal product containing the changes made.

(clause 3 introduced by Federal Law of December 22, 2014 No. 429-FZ)

4. If the registration certificate for a medicinal product is lost or damaged, the authorized federal executive body shall, at written request of the holder or owner of the registration certificate for the medicinal product or other legal entity authorized by them for the issue of a copy of the registration certificate for the medicinal product, within ten business days of receipt of the request, issue a copy of the registration certificate for the medicinal product. A copy of a registration certificate for a medicinal product shall be issued against payment of state duty in accordance with the legislation of the Russian Federation on taxes and duties.

(clause 4 introduced by Federal Law of December 22, 2014 No. 429-FZ)

---

#### Article 29. Confirmation of State Registration of the Medicinal Product

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

1. Confirmation of state registration of a medicinal product shall be carried out when issuing a permanent registration certificate for the medicinal product in the case specified in Clause 2 of Article 28 hereof, within the period not exceeding sixty business days from the date of receipt of an application for confirmation of state registration of the medicinal product by the authorized federal executive body. Confirmation of state registration shall not be carried out for a medicinal product not circulating in the Russian Federation for three years or longer as well as for a medicinal product produced with violation of the requirement stipulated in part 37 of article 71 hereof.

2. Application for confirmation of state registration of the medicinal product for medical use shall be filed to the correspondent authorized federal executive body not earlier than one hundred and eighty days prior the expiration date of the registration certificate of the medicinal product.

(as amended by Federal Law of August 02, 2019 No. 297-FZ)

2.1) A statement of confirmation of state registration of the medicinal product for veterinary use shall be submitted to the relevant authorized federal executive body not earlier than one hundred eighty days prior to the expiration date of the registration certificate for the medicinal product for veterinary use and not later than its expiration date.

(sub-clause 2.1 as amended by Federal Law of August 02, 2019 No. 297-FZ)

3. Confirmation of state registration of a medicinal product is carried out based on the results of state examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product and the results of efficacy and safety monitoring of the medicinal product carried out by the holder or owner of the registration certificate of the medicinal product or authorized federal executive body in accordance with article 64 hereof.

4. Application for confirmation of state registration of a medicinal product for medical use shall be accompanied by:

1) the documents containing results of efficacy and safety monitoring of the medicinal product for medical use to be carried out by the holder or owner of the registration certificate of the medicinal product for medical use or a legal entity authorized thereby in the form approved by the correspondent authorized federal executive body;

2) a copy of manufacturing license or a copy of certificate of manufacturer's GMP compliance issued by the authorized federal executive body in respect of the manufacturing site of the medicinal product for medical use whose state registration is confirmed if the medicinal product is produced in the Russian Federation;

3) a duly certified copy of manufacturing license issued in the manufacturer's country and translation thereof into Russian and a copy of the conclusion on compliance of the manufacturer of medicines with the good manufacturing practice guidelines issued by the authorized federal executive body in respect of the manufacturing site of the medicinal product for medical use whose state

registration is confirmed, or a copy of the decision of the authorized federal executive body to conduct an inspection of the manufacturer of medicines if the medicinal product for medical use is manufactured outside the Russian Federation.

(clause 4 as amended by Federal Law of June 04, 2018 No. 140-FZ)

4.1. For biological medicinal products for medical use, the applicant shall additionally provide the results of actions envisaged by the risk management plan approved by the authorized federal executive body when performing state registration of the medicinal product for medical use.

(clause 4.1 introduced by Federal Law of June 04, 2018 No. 140-FZ)

4.2. The application for confirmation of state registration of the medicinal product for veterinary use shall be accompanied by documents containing the results of monitoring the efficacy and safety of the medicinal product for veterinary use conducted by the holder or owner of the registration dossier for the medicinal product for veterinary use or by a legal entity authorized by them, in the form approved by the authorized federal executive body, and the documents specified in clauses 1.2-2.2, sub-clauses "a", "b", "j", "k" of clause 4 of part 3 of Article 17 of this Federal Law. In respect of immunobiological medicinal products for veterinary use, information required by sub-paragraph 'j' of paragraph 4 of part 3 of Article 17 of this Federal Law shall not be provided. In respect of medicinal products for veterinary use manufactured with the use of genetically modified organisms or containing such organisms, additional information specified in paragraph 13 of part 3 of Article 17 of this Federal Law shall be provided.

(clause 4.2 introduced by Federal Law of June 04, 2018 No. 140-FZ, as amended by Federal Law of August 02, 2019 No. 297-FZ)

4.3. Together with the application for confirmation of state registration of the medicinal product, the applicant shall provide a copy of the document certifying payment of the state duty for confirmation of state registration of the medicinal product, or may provide the original document on its own initiative. In the case of failure to provide the above document, the authorized federal executive body shall verify the fact of payment of the state duty by the applicant using information on payment of state duty contained in the State Information System on State and Municipal Payments based on the copy of the document certifying payment of the state duty provided by the applicant.

(clause 4.3 introduced by Federal Law of June 04, 2018 No. 140-FZ)

5. Within ten business days from the date of receipt of an application for confirmation of state registration of a medicinal product and the documents containing the results of efficacy and safety monitoring of the medicinal product carried out by the holder or owner of the registration certificate of the medicinal product or a legal entity authorized thereby the authorized federal executive body shall:

- 1) examine the data contained in the materials submitted by the applicant for completeness;
- 2) take a decision on whether to carry out or refuse carrying out expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product based on the results of efficacy and safety monitoring of the medicinal product carried out by the holder or owner of the registration certificate of the medicinal product or a legal entity authorized thereby as well as the authorized federal executive body in accordance with article 64 hereof;
- 3) notify the applicant and the expert institution electronically or in writing of the decision made or, in case of refusal to carry out expert examination, of the grounds for such refusal.

6. If any unreliability and (or) incompleteness of the information contained in the documents submitted by the applicant is revealed the authorized federal executive body shall send to the applicant a request for clarification of the said information. Request of the authorized federal executive body may be personally transferred to the applicant's authorized representative against signed receipt, send by registered mail or e-mailed through the telecommunications channels. If the authorized federal executive body sends the request by registered mail it shall be deemed received upon expiration of six days from the date of sending the registered mail.

7. Applicant shall respond to request of the authorized federal executive body during the period not exceeding ninety business days after the date of receipt thereof. Period specified in part 5 of this article shall be suspended since the date of sending of request of the authorized federal

executive body to the applicant till the date of receipt of the corresponding response and shall not be accounted when calculating the period for confirmation of state registration of the medicinal product.

8. Reason for refusal to carry out expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product shall be submission of the documents containing results of efficacy and safety monitoring of the medicinal product and (or), for biological medicinal products, the results of implementation of tasks in accordance with the risk management plan approved by the authorized federal executive body when carrying out state registration of the medicinal product in part, lack of the information certifying payment of the state duty for confirmation of state registration of the medicinal product or the applicant's failure to respond to request of the authorized federal executive body specified in part 6 of this article within the stipulated period as well as absence of the information to be specified in the above documents.

9. Expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product for the purpose of confirmation of state registration of a medicinal product shall be carried out by the expert committee of the correspondent institution within the period not exceeding forty business days.

10. If the materials provided to the expert are insufficient for making a conclusion the expert shall ask the Head of the expert institution to provide him/her with the required materials. Head of the expert institution shall address the corresponding request to the authorized federal executive body issuing the assignment to carry out expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product on the basis of the documents containing results of efficacy and safety monitoring of the medicinal product. Within five business days from the date of the request of the Head of the expert institution the authorized federal executive body shall address to the applicant the request for provision with the required materials which may be personally transferred to the applicant's authorized representative against signed receipt, send by registered mail or e-mailed through the telecommunications channels. If the authorized federal executive body sends the request by registered mail it shall be deemed received upon expiration of six days from the date of sending the registered mail.

11. The applicant shall respond to request of the authorized federal executive body within the period not exceeding sixty business days from the date of receipt thereof. Within five business days from the date of receipt of the applicant's response to the above request the authorized federal executive body issuing the assignment to carry out expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product on the basis of the documents containing results of efficacy and safety monitoring of the medicinal product shall send this response to the expert institution. In case of the applicant's failure to respond within sixty business days the authorized federal executive body issuing the assignment to carry out expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product shall, within five business days, notify the expert institution of the applicant's failure to respond to the correspondent request. Period from the date of sending the request of the expert institution to the authorized federal executive body till the date when the expert institution receives the response or notice of the applicant's failure to respond shall not be accounted when calculating the period for carrying out of expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product on the basis of the documents containing results of efficacy and safety monitoring of the medicinal product.

12. Within ten business days from the date of receipt of conclusion of the expert committee based on the results of expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product the correspondent authorized federal executive body shall:

- 1) evaluate such a conclusion to determine compliance thereof with the assignment for carrying out of the above expert examination;
- 2) take a decision on whether to confirm state registration of the medicinal product or refuse to confirm state registration of the medicinal product;

3) enter the data into the state register of medicines when taking the decision on confirmation of state registration of the medicinal product and issue to the applicant an open-ended registration certificate of the medicinal product.

13. Reason for refusal to confirm state registration of the medicinal product shall be the conclusion of the correspondent authorized federal executive body that risk of infliction of harm to human or animal health due to use of the medicinal product exceeds efficacy of use thereof.  
(clause 13 as amended by Federal Law of June 04, 2018 No. 140-FZ)

14. When confirming state registration of the medicinal product circulation thereof in the Russian Federation shall not be suspended.

15. Circulation of the medicinal products produced within one hundred and eighty calendar days from the date of taking the decision on confirmation of state registration by the authorized federal executive body shall be allowed till the best before date in accordance with the information contained in the registration dossier for the medicinal product till the date of taking such a decision.  
(as amended by Federal Law of August 02, 2019 No. 297-FZ)

#### Article 30. Amendments to Documents Contained in Registration Dossier of Registered Medicinal Product for Medical Use

1. To enter amendments to the documents contained in the registration dossier for a registered medicinal product for medical use, the holder or owner of the registration certificate for the medicinal product or any other legal entity authorized by such holder or owner shall submit to the authorized federal executive body an application for such amendments in the form prescribed by the authorized federal executive body, together with the amendments to such documents as enclosed, as well as documents certifying the necessity of such amendments.

(clause 1 as amended by Federal Law of June 04, 2018 No. 140-FZ)

1.1. If the documents contained in the registration dossier for the registered medicinal product for medical use must be amended in accordance with clause 3 of part 2 of this Article, and such amendments require the conduct of an expert examination of the quality of medicines, the applicant shall additionally provide to the authorized federal executive body a copy of the medicines manufacturing license or a copy of the conclusion on compliance of the manufacturer of medicines with the good manufacturing practice guidelines issued by the authorized federal executive body in respect of the changed and (or) additional manufacturing site of the medicinal product, if the medicinal product is manufactured in the Russian Federation, or a copy of the license for manufacture medicinal product issued by the competent authority of the manufacturer's country and its duly certified translation into Russian, and a copy of the conclusion on compliance of the manufacturer of medicines with the good manufacturing practice guidelines issued by the authorized federal executive body in respect of the changed and (or) additional manufacturing site of the medicinal product, or a copy of the decision of the authorized federal executive body to conduct an inspection of the manufacturer of medicines if the medicinal product is manufactured outside the Russian Federation.

(sub-clause 1.1 introduced by Federal Law of June 04, 2018 No. 140-FZ)

1.2. If the documents contained in the registration dossier for the registered medicinal product for medical use must be amended in accordance with clause 4 of part 2 of this Article, and such amendments require the conduct of an expert examination of the quality of medicines, the applicant shall additionally provide to the authorized federal executive body a copy of the medicines manufacturing license or a copy of the conclusion on compliance of the manufacturer of medicines with the good manufacturing practice guidelines issued by the authorized federal executive body in respect of the manufacturing site of the medicinal product, if the medicinal product is manufactured in the Russian Federation, or a copy of the license for manufacture medicinal product issued by the competent authority of the manufacturer's country and its duly certified translation into Russian, and a copy of the conclusion on compliance of the manufacturer of medicines with the good manufacturing practice guidelines issued by the authorized federal executive body in respect of the manufacturing site of the medicinal product, or a copy of the decision of the authorized federal executive body to



conduct an inspection of the manufacturer of the medicine if the medicinal product is manufactured outside the Russian Federation.

(sub-clause 1.2 introduced by Federal Law of June 04, 2018 No. 140-FZ)

1.3. A decision to amend or to refuse to amend the documents contained in the registration dossier for the registered medicinal product for medical use shall be made, where necessary to conduct expert examination of the quality of medicines and (or) expert examination of the benefit to risk ratio of the use of the medicinal product for medical use, within ninety business days, and in all other cases, within thirty business days of acceptance of the application for making such amendments by the authorized federal executive body.

(sub-clause 1.3 introduced by Federal Law of June 04, 2018 No. 140-FZ)

1.4. The federal authority taking into account the results of pharmacovigilance and compliance testing of medicines under civil circulation, to established requirements to their quality during ten working days since the date of relevant information receipt posts the information about the need of changes regarding the indications and contraindications for use, revealed side effects, adverse reactions while medicinal product use to the instruction of medicinal product for medical use and notifies the marketing authorization holder or owner of medicinal products (or another legal authority), and also the marketing authorization holders or owners of interchangeable medicinal products (or another legal authorities) electronically or in writing (paper form).

(sub-clause 1.4 introduced by Federal Law of December 27, 2019 No. 475-FZ)

1.5. The marketing authorization holder or owner of medicinal product, and also the marketing authorization holders or owners of interchangeable medicinal products (or another legal authorities) must provide statements about amendments of documents to the federal authority which are contained in the registration profiles on registered medicinal product for medical use, regarding the information stated in the instruction for medical use, during forty working days since the date of information post specified in part 1.4 of this Article by the federal authority. This requirement is not distributed for cases of amendments of instruction for medical use regarding new indications for medicinal product use based on the results of corresponding studies.

(sub-clause 1.4 introduced by Federal Law of December 27, 2019 No. 475-FZ)

2. Expert examination of the quality of the medicine and (or) expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product for medical use shall be carried out in case of amendment of the documents contained in the registration dossier for the medicinal product as regards:

1) information specified in Basic prescribing Information of the medicinal product:

a) dosage form specifying the names and quantitative composition of active substances and qualitative composition of excipients (if necessary qualitative composition of excipients);

b) pharmacodynamics and pharmacokinetics (excluding pharmacokinetics of homeopathic medicinal products and phytopharmaceutical products);

c) indications for use;

d) counterindications for use;

e) safety precautions on use;

f) possibilities and specifics of medical use of the medicinal product for medical use in pregnant women, women in period of lactation, children or adults with chronic diseases;

g) dosage regimen, mode of administration, time of administration of the medicinal product for medical use, if necessary, and duration of treatment (including those for children under and over one year old);

h) possible adverse reactions and side effects on use of the medicinal product for;

i) overdose symptoms; relief measures in case of overdose;

j) interaction with other medicinal products and (or) food products;

k) pharmaceutical forms of the medicinal product;

l) specification, if necessary, of peculiarities of action of the medicinal product for medical use when administered for the first time or withdrawal;

m) information on possible effect of the medicinal product on the ability to drive and operate machinery;

- n) shelf life and indication not to use the medicinal product after its expiry;
- o) storage conditions;
- p) prescription status;
- 2) composition of the medicinal product for medical use;
- 3) change of the place of production of the medicinal product for medical use;
- 4) changes in quality indicators of the medicinal product for medical use and (or) quality control methods of the medicinal product for medical use;
- 5) changes in the shelf life of the medicinal product for medical use.

6) information on necessity of other amendments to basic prescribing information of the medicinal product as well as other documents contained in the registration dossier for the medicinal product. Thereat decision on carrying out of expert examination of the quality of the medicine and (or) expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product for medical use shall be made in accordance with the classification of changes entered into the documents contained in the registration dossier for the medicinal product approved by the authorized federal executive body.

(clause 2 as amended by Federal Law of December 22, 2014 No. 429-FZ)

3. In addition to the documents specified in clause 1 of this Article the applicant shall provide, together with the application for making amendments to the documents contained in the registration dossier of the registered medicinal product for medical use, copies of documents confirming payment of state duty for making to the documents contained in the registration dossier of the registered medicinal product for medical use amendments requiring expert examination of medicines in the part of expert examination of quality of a medicine and (or) expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product for medical use, state duty for making to the documents contained in the registration dossier of the registered medicinal product for medical use amendments not requiring expert examination of a medicine, or may submit, on his own initiative, the said documents. In case such documents are not submitted, the relevant authorized federal executive body shall check the fact of payment by the applicant of state duty by using information on payment of state duties contained in the State Information System on state and municipal payments on the basis of copies of documents confirming the payment of state duty provided by the applicant.

(clause 3 as amended by Federal Law of December 22, 2014 No. 429-FZ)

4. Within ten business days from the date of receipt of the application specified in clause 1 of this Article and necessary documents, the authorized federal executive body shall:

- 1) examine the data contained in the materials submitted by the applicant for completeness and reliability;
- 2) make a decision on whether to carry out or refuse carrying out expert examinations of the medicine specified in clause 2 of this Article;
- 3) notify the applicant in electronic or written form of the positive decision or, in case of refusal to carry out a relevant expert examination of the medicine, or the rounds for such refusal.

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

4.1. If any information contained in the materials submitted by the applicant is found to be inaccurate, the authorized federal executive body shall send to the applicant a request for clarification of the information. This request may be delivered to an authorized representative of the applicant personally against signature, by registered mail or in electronic form via telecommunication channels. If the request is sent by registered mail, it shall be deemed received in six days of the dispatch.

(sub-clause 4.1 introduced by Federal Law of November 25, 2013 No. 317-FZ)

4.2. The applicant shall respond to the request of the authorized federal executive body within ninety business days of its receipt. The period specified in clause 4 of this Article shall be suspended from the date when the authorized federal executive body sends its request to the date when it receives the relevant response and shall not be taken into account when determining a period for making a decision on amending the documents contained in the registration dossier of the registered medicinal product for medical use.

(sub-clause 4.2 introduced by Federal Law of November 25, 2013 No. 317-FZ)

5. A failure to submit a complete set of the documents listed in clauses 1 and 3 of this Article, a failure to send a response as specified in clause 4.1 of this Article to the request of the federal executive body, or submission of the documents lacking comprehensive information confirming the necessity to make the amendments or absence of information confirming the fact of payment of the state duties specified in clause 3 of this Article shall be the grounds for refusal to carry out the expert examinations specified in clause 2 of this Article.

(as amended by Federal Laws of November 25, 2013 No. 317-FZ, of December 22, 2014 No. 429-FZ)

6. Expert examinations specified in clause 2 of this Article shall be carried out in the manner prescribed in Article 23 hereof.

7. Within ten business days from the date of receipt of the opinions issued by the expert commission based on the results of expert examinations specified in clause 2 of this Article, the authorized federal executive body shall:

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

1) make a decision on whether to approve or refuse approving amendments to the documents contained in the registration dossier of the registered medicinal product for medical use;

2) make necessary changes in the state register of medicines based on the decision on amendments to the documents contained in the registration dossier of the registered medicinal product for medical use, and return them to the applicant;

3) issue to the applicant a new registration dossier of the medicinal product in case of changing the information contained therein.

(sub-clause 3 introduced by Federal Law of December 22, 2014 No. 429-FZ)

8. A conclusion of the authorized federal executive body on possible downgrading of safety, quality and efficacy of the medicine in case of such amendments is considered grounds for refusal to approve amendments to the documents contained in the registration dossier of the registered medicinal product for medical use.

9. Circulation of medicinal products for medical use before the expiry date produced within one hundred and eighty days after the date when the authorized federal executive body made a decision on making amendments to the documents contained in the registration dossier in accordance with the information which had been contained in the documents of the registration dossier of the medicinal product before the decision was made shall be allowed.

(clause 9 as amended by Federal Law of December 22, 2014 No. 429-FZ)

#### Article 31. Amendments to Documents Contained in Registration Dossier of a Registered Medicinal Product for Veterinary Use

1. To enter amendments to the documents contained in the registration dossier of a registered medicinal product for veterinary use, the holder or owner of the registration certificate for the medicinal product or any other legal entity authorized by such holder or owner (hereinafter the "applicant") shall submit to the authorized federal executive body an application for such amendments in the form prescribed by the authorized federal executive body, together with the amendments to such documents as enclosed, as well as documents certifying the necessity of such amendments. Approval of or refusal to approve such amendments shall be given within ninety business days from the date of receipt by the authorized federal executive body of an application for such amendments. If it is necessary to amend the documents contained in the registration dossier of a registered medicinal product for veterinary use, in cases of changing and (or) supplementing the production site of the medicinal product, as well as changing the quality indicators of the medicinal product for veterinary use and (or) methods of quality control of the medicinal product for veterinary use, the applicant shall additionally provide to the authorized federal executive body the following documents:

1) a copy of the medicines manufacturing license issued to the manufacturer of the medicinal product for veterinary use being registered, for Russian manufacturers;

2) a copy of the medicines manufacturing license issued to the manufacturer of the pharmaceutical substance forming part of the medicinal product for veterinary use being registered,

for Russian manufacturers;

3) a copy of the document issued by the competent authority of the manufacturer's country for each manufacturing site of the medicinal product for veterinary use being registered and evidencing compliance of the manufacturer of the medicinal product with the good manufacturing practice guidelines and its duly certified translation into Russian and a copy of the conclusion on compliance of the manufacturer of medicines with the good manufacturing practice guidelines issued by the authorized federal executive body for each manufacturing site of the medicinal product for veterinary use being registered, or a copy of the decision to conduct an inspection of the manufacturer of medicines made by the authorized federal executive body for each manufacturing site of the medicinal product for veterinary use being registered. The above documents shall be provided if the medicinal product is manufactured outside the Russian Federation;

4) a copy of the document issued by the competent authority of the pharmaceutical substance manufacturer's country and evidencing compliance of the manufacturer of the pharmaceutical substance forming part of the medicinal product for veterinary use being registered with the good manufacturing practice guidelines and its duly certified translation into Russian, if the pharmaceutical substance is manufactured outside the Russian Federation;

(clause 1 as amended by Federal Law of June 04, 2018 No. 140-FZ)

1.1. Where the manufacturing site of the medicine is changed and (or) added, the documents specified in part 1 of this Article shall be provided by the applicant in respect of the changed and (or) additional manufacturing site of the medicine. A decision to amend or to refuse to amend the documents contained in the registration dossier for the registered medicinal product for veterinary use shall be made, where necessary to conduct medicines expert examination, within ninety business days, and in all other cases, within thirty business days of acceptance of the application for making such amendments by the authorized federal executive body.

(clause 1.1 introduced by Federal Law of June 04, 2018 No. 140-FZ)

1.2. In the event of reorganization of the holder or owner of the registration certificate for the medicinal product for veterinary use, the developer or manufacturer of the medicinal product for veterinary use, the application for making amendments to the documents contained in the registration dossier for the registered medicinal product for veterinary use shall specify details of the document confirming the making of relevant amendments to the Unified State Register of Legal Entities (for organizations registered in the Russian Federation) or another document confirming reorganization of the legal entity (for organizations registered outside the Russian Federation). The application for making amendments to the documents contained in the registration dossier for the registered medicinal product for veterinary use and documents attached thereto shall be submitted to the authorized federal executive body not later than thirty business days after the relevant amendments are made to the Unified State Register of Legal Entities (for organizations registered in the Russian Federation) or the relevant document confirming reorganization of the legal entity (for organizations registered outside the Russian Federation) is adopted. In the event of reorganization of the holder or owner of the registration certificate for the medicinal product for veterinary use, the application for making amendments to the documents contained in the registration dossier for the registered medicinal product for veterinary use shall be submitted by the legal entity to which the right to hold this registration certificate has been transferred during reorganization.

(clause 1.2 introduced by Federal Law of August 02, 2019 No. 297-FZ)

2. In case of making amendments to the documents contained in the registration dossier of the registered medicinal product for veterinary use, in respect of information specified in items "f", "g", "j", "k", "m", "q", "u" of sub-clause 7 of clause 3 of Article 17 of this Federal Law, any changes and (or) supplements to the production site of the medicine and any changes in quality indicators of the medicinal product for veterinary use and (or) quality control methods for the medicinal product for veterinary use an expert examination of the medicine for veterinary use shall be conducted. If any other changes are to be made to the documents contained in the registration dossier of a registered medicinal product for veterinary use, expert examination of the medicine for veterinary use shall not be conducted.

(as amended by Federal Laws of October 22, 2014 No. 313-FZ, of December 22, 2014 No. 429-FZ)

3. In addition to the documents specified in part 1 of this Article, the applicant shall provide, together with the application for making amendments to the documents contained in the registration dossier for the registered medicinal product for veterinary use, documents certifying payment of the state duty for making to the documents contained in the registration dossier of the registered medicinal product for veterinary use amendments requiring expert examination of the medicine for veterinary use, or amendments not requiring expert examination of the medicine for veterinary use. Should it be necessary to amend the information contained in the registration certificate of the medicinal product for veterinary use, the applicant shall additionally provide, together with the application specified in part 1 of this Article, a copy of the document certifying payment of the state duty for issuing the registration certificate for the medicinal product. The applicant may, on its own initiative, submit original documents certifying payment of the state duties. If the applicant does not submit original documents certifying payment of the state duties, the authorized federal executive body shall verify the fact of payment by the applicant of the state duties by using information on payment of state duties contained in the State Information System on State and Municipal Payments based on copies of documents certifying payment of state duties provided by the applicant.

(as amended by Federal Law of October 22, 2014 No. 313-FZ and Federal Law of August 02, 2019 No. 297-FZ)

4. Within ten business days of the date of receipt of the application specified in clause 1 of this Article and necessary documents, the authorized federal executive body shall:

1) examine the data contained in the materials submitted by the applicant for completeness and reliability;

2) make a decision on whether to carry out or refuse carrying out expert examination of the medicine for veterinary use;

3) notify the applicant in writing of a positive decision or, in case of refusal to carry out expert examination of the medicine for veterinary use, of the grounds for such refusal.

4.1. Should it be discovered that any information contained in the documents provided by the applicant is inaccurate and (or) incomplete, the authorized federal executive body shall send to the applicant a request for clarification of the information. Such request may be hand delivered to the applicant's representative against signature, sent by registered mail or transmitted electronically using telecommunication channels. If the request for clarification of information is sent by registered mail, it shall be deemed to have been received upon expiration of a six-day period after the registered letter is sent.

(clause 4.1 introduced by Federal Law of June 04, 2018 No. 140-FZ)

4.2. The applicant shall respond to the request of the authorized federal executive body within ninety business days of receipt of the request. The periods specified in part 1.1 of this Article shall be suspended from the date when the authorized federal executive body sends the request to the applicant to the date of receipt of the response, which shall not be taken into account when determining a period for making a decision to amend the documents contained in the registration dossier for the registered medicinal product for veterinary use.

(clause 4.2 introduced by Federal Law of June 04, 2018 No. 140-FZ)

5. A failure to submit a complete set of the documents listed in clauses 1 and 3 of this Article, or submission of the documents lacking comprehensive data confirming the necessity of such amendments is considered grounds for refusal to carry out expert examination of the medicine for veterinary use or the applicant's failure to send in due time a response to the request of the authorized federal executive body specified in part 4.1 of this Article.

(clause 5 as amended by Federal Law of June 04, 2018 No. 140-FZ)

6. Expert examination of a medicine for veterinary use for the purpose of entering amendments to the documents contained in the registration dossier of the registered medicinal product for veterinary use shall be carried out in the manner prescribed in Article 24 hereof.

6.1. Within ten business days of the date of receipt of the expert commission's opinion based on the results of the expert examination specified in clause 2 of this Article, the authorized federal executive body shall:

(as amended by Federal Law of August 02, 2019 No. 297-FZ)

1) make a decision on making amendments to the documents contained in the registration dossier of the registered medicinal product for veterinary use, or on refusal to make such amendments;

2) based on the decision on making amendments to the documents contained in the registration dossier of the registered medicinal product for veterinary use, make relevant amendments to the state register of medicines and return the documents to the applicant;

3) issue to the applicant a new registration certificate for the medicinal product for veterinary use if it is necessary to change the information contained therein, preserving the number of the previously issued registration certificate for the medicinal product for veterinary use.

(sub-clause 3 introduced by Federal Law of August 02, 2019 No. 297-FZ)

(clause 6.1 introduced by Federal Law of 22.10.2014 N 313-FZ)

6.2. If documents contained in the registration dossier for the registered medicinal product for veterinary use are amended in respect of changing and (or) adding a manufacturing site of the medicinal product, then, when the applicant provides a copy of the decision of the authorized federal executive body to conduct an inspection of the manufacturer of medicines in accordance with clause 3 of part 1 of this Article, the period specified in part 6.1 of this Article shall be suspended from the date of receipt of the conclusion of the expert committee to the date when the authorized federal executive body makes a decision to issue or to refuse to issue a conclusion on compliance of the manufacturer of medicines with the good manufacturing practice guidelines, but in any event by not more than one hundred eighty business days.

(clause 6.2 introduced by Federal Law of June 04, 2018 No. 140-FZ)

7. Where expert examination of the medicine is not required, the basis for refusal to amend the documents contained in the registration dossier for the registered medicinal product for veterinary use shall be the provision of an incomplete set of documents specified in parts 1 and 3 of this Article, or the absence of necessary information in the provided documents, or the applicant's failure to send in due time a response to the request of the authorized federal executive body specified in part 4.1 of this Article.

(clause 7 as amended by Federal Law of June 04, 2018 No. 140-FZ)

7.1. Where expert examination of the medicine is required, the basis for refusal to amend the documents contained in the registration dossier for the registered medicinal product for veterinary use shall be the conclusion of the authorized federal executive body stating that such amendment may compromise the safety, quality, efficacy of the medicinal product, the refusal of the authorized federal executive body to issue a conclusion on compliance of the manufacturer of medicines with the good manufacturing practice guidelines in the case of changing and (or) adding a manufacturing site of the medicinal product if the medicinal product for veterinary use is manufactured outside the Russian Federation, or the absence of such conclusion.

(clause 7.1 introduced by Federal Law of June 04, 2018 No. 140-FZ)

8. Circulation of medicinal products for veterinary use before the expiry date produced within one hundred and eighty days after the date when the authorized federal executive body made a decision on making amendments to the documents contained in the registration dossier in accordance with the information which had been contained in the documents of the registration dossier of the medicinal product before the decision was made shall be allowed.

## Article 32. Cancellation of State Registration of Medicinal Product

Decision on cancellation of state registration of a medicinal product and removal of such medicinal product from the state register of medicines shall be made by the authorized federal executive body in the following cases:

1) the relevant authorized federal executive body advances an opinion on existence of a risk or threat to the health and life of people or animals taking that medicinal product, which risk or threat exceeds the efficacy thereof based on the results of safety monitoring of the medicinal product performed by said authorized federal executive body;

2) the holder or owner of the registration certificate for the medicinal product or any person authorized by the developer, or any other legal entity has filed an application for cancellation of the state registration of the medicinal product;

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

3) the state registration of the medicinal product failed to be confirmed upon expiration of the registration certificate issued for five years;

4) the applicant failed to provide information that can involve the need for amending the documents as part of the registration dossier of the registered medicinal product within 30 calendar days of the effective date of such amendments;

5) the medicinal product underwent state registration under the trade name of a medicinal product of different qualitative composition of active substances which was earlier registered under this trade name;

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

6) state registration of the same medicinal product in respect of the same holder or owner of the registration dossier for the medicinal product in the form of two or more medicinal products under different trade names;

(sub-clause 6 introduced by Federal Law of June 04, 2018 No. 140-FZ)

7) legal judgment was passed on violation of rights of a possessor of intellectual property rights in the area of medicines.

8) the medicinal product has not been in circulation in the Russian Federation for three and more years;

(sub-clause 8 introduced by Federal Law of December 22, 2014 No. 429-FZ)

9) the holder or owner of the registration certificate for the medicinal product or other legal entity authorized by its holder or owner fails to take measures ensuring safety of medicinal products established by the authorized federal executive body in accordance with clauses 3 and 4 of Article 64 of this Federal Law within the framework of pharmacovigilance;

(sub-clause 9 introduced by Federal Law of December 22, 2014 No. 429-FZ)

10) the holder or owner of the registration certificate for the medicinal product or other legal entity authorized by its holder or owner refuses to make amendments to the Package Leaflet for the medicinal product concerning new confirmed data that risk of causing harm to human or animal health through the use of the medicinal product is higher than the efficacy of its use.

(sub-clause 10 introduced by Federal Law of December 22, 2014 No. 429-FZ)

From January 01, 2023 article 32 will be supplemented by paragraph 11 (Federal Law from December 27, 2019 No. 475-FZ).

11) established by part 6 of the Article 65 of this Federal Law.

### Article 33. State Register of Medicines

1. The state register of medicines contains the list of medicinal products which passed state registration, the list of pharmaceutical substances included in the composition of medicinal products and the following information:

1) with respect to medicinal products:

a) name of the medicinal product (international nonproprietary name or modified or chemical and trade names);

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

b) pharmaceutical form with indication of dosage rate of the medicinal product and its quantity in consumer package;

c) the name of the holder or owner of the marketing authorisation for the medicinal product and information on registration of the holder or owner of the marketing authorisation for the medicinal product for medical use as a taxpayer in the country of registration (for Russian legal entities — taxpayer identification number (INN), for foreign legal entities — country of registration, name of

registering body, registration number, taxpayer's code in the country of registration (incorporation) or its analogue);

(item "c" as amended by Federal Law of December 28, 2017 No. 425-FZ)

d) the name and address of the manufacturer of the medicinal product and information on registration of the manufacturer of the medicinal product for medical use as a taxpayer in the country of registration (for Russian legal entities — taxpayer identification number (INN), for foreign legal entities — country of registration, name of registering body, registration number, taxpayer's code in the country of registration (incorporation) or its analogue);

(item "d" as amended by Federal Law of December 28, 2017 No. 425-FZ)

e) pharmacotherapeutic group, code of the medicinal product in accordance with the Anatomical Therapeutic Chemical Classification System recommended by the World Health Organization;

(item "d" as amended by Federal Law of December 22, 2014 No. 429-FZ)

f) indications and contraindications for use of the medicinal product;

g) side effects of the medicinal product;

h) shelf life of the medicinal product;

i) storage conditions for the medicinal product;

j) dispensing conditions for the medicinal product;

k) number of pharmacopoeia article and, failing the latter, of normative documentation or normative document;

l) date of state registration of the medicinal product and registration number thereof, date of replacement of the registration certificate for the medicinal product with a permanent registration certificate for the medicinal product, date of submission of an application or confirmation of state registration of the medicinal product, date of cancellation of state registration of the medicinal product;

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

m) qualitative and quantitative composition of active substances and qualitative composition of excipients of the medicinal product;

(item "m" introduced by Federal Law of December 22, 2014 No. 429-FZ)

n) information on all permitted types of secondary (consumer) packaging;

(item "n" introduced by Federal Law of December 22, 2014 No. 429-FZ)

o) date of making a decision on the possibility to consider the medicinal product at state registration as an orphan medicinal product (for the medicinal product for medical use);

(item "o" introduced by Federal Law of December 22, 2014 No. 429-FZ as amended by Federal Law of December 27, 2019 No. 475-FZ)

p) inclusion of the medicinal product in the list of vital and essential medicinal products (for the medicinal product for medical use);

(item "p" introduced by Federal Law of December 22, 2014 No. 429-FZ as amended by Federal Law of December 27, 2019 No. 475-FZ)

q) presence in the medicinal product of narcotic drugs, psychotropic substances and precursors thereof subject to control in the Russian Federation in accordance with the legislation of the Russian Federation and international treaties of the Russian Federation, including the 1961 Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances;

(item "q" introduced by Federal Law of December 22, 2014 No. 429-FZ)

r) information on whether the medicinal product is a reference medicinal product;

(item "r" introduced by Federal Law of December 22, 2014 No. 429-FZ)

s) information on submission of an application for making amendments to the documents contained in the registration dossier of the medicinal product;

(item "s" introduced by Federal Law of December 22, 2014 No. 429-FZ)

t) ceased to be in force as of March 01, 2020 (Federal Law of December 27, 2019 No. 475-FZ);

u) date when the medicinal product is put in civil circulation;

(item "u" introduced by Federal Law of December 22, 2014 No. 429-FZ)



2) with respect to pharmaceutical substances:

a) name of the pharmaceutical substance (international nonproprietary name or modified or chemical and trade names);

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

b) name and address of the manufacturer of the pharmaceutical substance;

c) shelf life of the pharmaceutical substance;

d) storage conditions for the pharmaceutical substance;

e) number of the pharmacopoeia article and, failing the latter, of normative documentation or normative document;

f) inclusion of the pharmaceutical substance in the list of narcotic drugs, psychotropic substances and precursors thereof subject to control in the Russian Federation in accordance with the legislation of the Russian Federation and international treaties of the Russian Federation, including the 1961 Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances.

(item "f" introduced by Federal Law of December 22, 2014 No. 429-FZ)

2. A pharmaceutical substance produced for sale may be included in the state register of medicines on the basis of an application of the developer or manufacturer of the medicine, or a legal entity authorized by any of them, provided that the pharmaceutical substance was duly evaluated for quality as prescribed in Article 34 of this Federal Law. In respect of pharmaceutical substances produced for sale the following information shall be contained in the state register of medicines:

1) name of the pharmaceutical substance (international non-proprietary, or modified, or chemical and trade names);

2) the name and address of the manufacturer of the pharmaceutical substance and, in respect of medicines for medical use, information on registration of the manufacturer of the pharmaceutical substance as a taxpayer in the country of registration (for Russian legal entities — taxpayer identification number (INN), for foreign legal entities — country of registration, name of registering body, registration number, taxpayer's code in the country of registration (incorporation) or its analogue);

(as amended by Federal Law of December 28, 2017 No. 425-FZ)

3) expiration period of the pharmaceutical substance;

4) storage conditions of the pharmaceutical substance;

5) number of the pharmacopoeia article or, in case of the absence thereof, number of normative documentation or normative document;

6) inclusion of the pharmaceutical substance in the list of narcotic drugs, psychotropic substances and precursors thereof subject to control in the Russian Federation in accordance with the legislation of the Russian Federation and international treaties of the Russian Federation, including the 1961 Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances;

7) date of inclusion of the pharmaceutical substance into the state register of medicines, date of making amendments to the documents of the pharmaceutical substance, date of removal of the pharmaceutical substance from the state register of medicines.

(clause 2 as amended by Federal Law of December 22, 2014 No. 429-FZ)

3. The procedure for maintenance of the state register of medicines intended for medical use and the procedure for maintenance of the state register of medicines intended for veterinary use shall be approved by the relevant authorized federal executive body.

Article 34. Inclusion into the State Register and Removal of the State Register of Pharmaceutical Substance Produced for Sale

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

1. Any pharmaceutical substance produced for sale requires quality evaluation before it is included in the state register of medicines.

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

2. Expert examination of quality specified in part 1 of this pharmaceutical substance article, drawing up of expert conclusions following the results of such expert examination and submission

thereof to the authorized federal executive body shall be carried out within sixty business days since the date of receipt of the correspondent assignment of the authorized federal executive body by the expert institution and the following documents:

1) copy of manufacturing license or a copy of certificate of manufacturer's GMP compliance issued by the authorized federal executive body if the medicinal product is produced in the Russian Federation;

2) duly certified copy of manufacturing license issued in the manufacturer's country and translation thereof into Russian and a copy of certificate of manufacturer's GMP compliance issued by the authorized federal executive body or a copy of the decision of the authorized federal executive body to conduct an inspection of the manufacturer of medicine. The above documents shall be provided if the medicinal product is produced outside the Russian Federation:

(sub-clause 2 as amended by Federal Law of June 04, 2018 No. 140-FZ)

3) document containing the following information on the pharmaceutical substance:

- a) name of pharmaceutical substance, structure and common properties thereof;
- b) manufacturer's name and address;
- c) production technology describing manufacturing steps and control procedures during all the manufacturing steps;
- d) description of manufacturing process development;
- e) description of control of critical steps and intermediates;
- f) documented evidence (validation) of processes and (or) evaluation thereof;
- g) properties and structure of active substances;
- h) characteristics of impurities;
- i) pharmaceutical substance specification and justification thereof;
- j) analytical procedures used when controlling quality of pharmaceutical substances;
- k) documented evidence (validation) of the analytical procedures used when controlling quality of pharmaceutical substances;
- l) analysis results of series of pharmaceutical substances;
- m) list of standard samples or the substances used when controlling quality of the products;
- n) description of characteristics and properties of packaging materials and means of sealing;
- o) stability data of the pharmaceutical substance;
- p) shelf life;

4) a document containing information on registration of the manufacturer of the medicines for medical use as a taxpayer in the country of registration (for Russian legal entities — taxpayer identification number (INN), for foreign legal entities — country of registration, name of registering body, registration number, taxpayer's code in the country of registration (incorporation) or its analogue).

(sub-clause 4 introduced by Federal Law of December 28, 2017 No. 425-FZ)

(clause 2 as amended by Federal Law of December 22, 2014 No. 429-FZ (amend. July 13, 2015))

3. For the purpose of quality evaluation of the pharmaceutical substance referred to in clause 1 of this Article, the applicant shall submit to the authorized federal executive body:

1) an application for including medicines of this pharmaceutical substance into the state register;

2) a copy of a document to confirm payment of state duty for the inclusion of the pharmaceutical substance produced for sale into the state register of medicines, or, on the initiative of the applicant, the original document. In case this document is not submitted, the relevant authorized federal executive body shall check the fact of payment by the applicant of state duty by using information on payment of state duties contained in the State Information System on state and municipal payments on the basis of copies of documents confirming the payment of state duty provided by the applicant;

(sub-clause 2 as amended by Federal Law of December 22, 2014 No. 429-FZ)

3) documents specified in clause 2 of this Article;

4) application for issuing a permit for import into the Russian Federation of a particular batch of an unregistered medicine designated for the conduct of the said expert examination.

(sub-clause 4 introduced by Federal Law of December 22, 2014 No. 429-FZ)

4. Within ten business days on filing the application for including the pharmaceutical substance referred to in clause 1 of this Article in the state register of medicines and documents enlisted in clause 1 and sub-clause 2 of clause 3 of this Article, the authorized federal executive body shall:

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

1) make sure that the data contained in the documents submitted by the applicant are complete and accurate;

(as amended by Federal Law of November 25, 2013 No. 317-FZ)

2) decide to assign a task to the expert institution to carry out quality evaluation of the pharmaceutical substance referred to in clause 1 of this Article or reject such assignment;

3) notify the applicant in electronic or written form of a decision made or, in the event of a rejection, give the reasons of such rejection;

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

4.1. If any information contained in the materials submitted by the applicant is found to be inaccurate, the authorized federal executive body shall send to the applicant a request for clarification of the information. This request may be delivered to an authorized representative of the applicant personally against signature, by registered mail or in electronic form via telecommunication channels. If the request is sent by registered mail, it shall be deemed received in six days of the dispatch.

(clause 4.1 introduced by Federal Law of November 25, 2013 No. 317-FZ)

4.2. The applicant shall respond to the request of the authorized federal executive body within ninety business days of its receipt. The period specified in clause 4 of this Article shall be suspended from the date when the authorized federal executive body sends its request to the date when it receives the relevant response and shall not be taken into account when determining a period of the expert examination of quality of the pharmaceutical substance not used in the production of medicinal products.

(clause 4.2 introduced by Federal Law of November 25, 2013 No. 317-FZ)

5. A failure to provide any of the documents listed in clause 2 of this Article, absence of information confirming the payment of state duty for inclusion of the pharmaceutical substance produced for sale into the state register of medicines, the applicant's failure to provide in due time a response to a request of the authorized executive body specified in clause 4.1 of this Article or submission of the documents lacking comprehensive information shall be the grounds for rejection of quality evaluation of the pharmaceutical substance specified in clause 1 of this Article by the expert institution.

6. Within fifteen business days of receipt of the decision made by the authorized federal executive body to assign quality evaluation of the pharmaceutical substance specified in clause 1 of this Article to the expert institution, the applicant shall provide the expert institution with samples of the pharmaceutical substance in the quantity as may be necessary for realization of quality control methods. Upon receipt of samples of the pharmaceutical substance referred to in clause 1 of this Article, the expert institution shall issue to the applicant a documentary proof of receipt of the samples and notify the authorized federal executive body in electronic or written form within three business days. This term is not included in the term for the quality evaluation.

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

7. The documents submitted to the expert institution for quality evaluation of the pharmaceutical substance referred to in clause 1 of this Article shall be returned to the authorized federal executive body together with the expert opinion.

8. Within five business days of receipt of the expert opinion on the pharmaceutical substance referred to in clause 1 of this Article, the authorized federal executive body shall:

1) study this expert opinion to make sure that it complies with the expert assignment;

2) decide on including the pharmaceutical substance referred to in clause 1 of this Article in the state register of medicines or reject such inclusion;

3) if it is decided to include the pharmaceutical substance referred to in clause 1 of this Article in the state register of medicines as specified in clause 2 of Article 33 hereof, add the necessary information and notify the applicant in electronic or written form.

(as amended by Federal Law of December 22, 2014 No. 429-FZ and Federal Law of December 27, 2019 No. 462-FZ)

9. A conclusion of the relevant authorized federal executive body stating that the quality of the pharmaceutical substance has not been confirmed by the data obtained shall be the grounds for refusal to include the pharmaceutical substance specified in clause 1 of this Article into the state register of medicines.

(clause 9 introduced by Federal Law of December 22, 2014 No. 429-FZ, as amended by Federal Law of June 04, 2018 No. 140-FZ)

10. It is not allowed to include into the state register of medicines the same pharmaceutical substance produced for sale by one manufacturer in two or more register records.

(clause 10 introduced by Federal Law of December 22, 2014 No. 429-FZ)

11. Any amendments to the documents for pharmaceutical substance produced for sale and included into the state register of medicines shall be made in the manner established in Articles 30 and 31 of this Federal Law, subject to payment of state duty in accordance with the legislation of the Russian Federation on taxes and duties.

(clause 11 introduced by Federal Law of December 22, 2014 No. 429-FZ)

12. Circulation of pharmaceutical substances produced for sale shall be allowed within one hundred and eighty days before and after the decision of the authorized federal executive body on making amendments to the documents for the pharmaceutical substance produced for sale and included into the state register of medicines.

(clause 12 introduced by Federal Law of December 22, 2014 No. 429-FZ)

13. A decision on removal of pharmaceutical substance produced for sale from the state register of medicines shall be made by the authorized federal executive body in the following cases:

1) the relevant authorized federal executive body submits a conclusion that the use of the medicine poses a risk and threat to life or health of a human or animal;

2) the developer of the medicine or manufacturer of the medicine or any other legal entity authorized by them submits an application for removal of pharmaceutical substance produced for sale from the state register of medicines;

3) pharmaceutical substance produced for sale has not been in circulation in the Russian Federation for three and more years.

(clause 13 introduced by Federal Law of December 22, 2014 No. 429-FZ)

Article 35. Ceased to be in force as of July 1, 2015 (Federal Law of December 22, 2014 No. 429-FZ)

Article 36. Appeal of a Decision on Refusal to Issue Approval for a Clinical Trial of a Medicinal Product, Refusal to Perform State Registration of a Medicinal Product, Opinion of the Expert Commission of the Expert Institution or Opinion of the Ethical Council

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

A decision of the relevant authorized federal executive body on refusal to issue approval for a clinical trial of a medicinal product, decision of the said federal executive body on refusal to perform state registration of the medicinal product, opinion of the expert commission of the expert institution or conclusion of the ethical council may be appealed in the manner established by the legislation of the Russian Federation. An opinion of the expert commission of the expert institution either about interchangeability of medicinal products for medical use or a medicinal product for medical use is not interchangeable may be appealed by the marketing authorization holder or owner of medicinal product to the federal authority which involves subordinate scientific organizations and educational organizations of higher education carrying out activities in the circulation of medicines for revising the specified claim. An opinion of the expert commission of the expert institution executed based on the results of review of the appealed expert opinion may be contested by the holder or owner of the registration certificate for medicinal product or by a person authorized by them in the manner

established by the legislation of the Russian Federation. When appealing a decision of the authorized federal executive body, opinion of an expert or the expert commission of the expert institution, opinion of the ethical council, the holder or owner of the registration certificate for medicinal product or a person authorized by them may submit results of the expert examination of the medicinal product, protocols of results of trials and tests accredited by testing laboratories (centers).

(as amended by Federal Law of December 27, 2019 No. 475-FZ)

**Article 37. Information Relating to State Registration of Medicinal Products, Information about Registered Medicinal Products, and Medicinal Products Removed from the State Register of Medicines**

1. The relevant authorized federal executive body shall post on its official website in the Internet information relating to the performance of state registration of medicinal products, including by performing expert examination of medicines (including its results), information on registered medicinal products and medicinal products excluded from the state register of medicines within five business days of receipt of the relevant information by the authorized federal executive body.

(as amended by Federal Law of December 22, 2014 No. 429-FZ and Federal Law of August 02, 2019 No. 297-FZ)

2. The term and procedure of placing information referred to clause 1 of this Article shall be established by the authorized federal executive body. Information referred to clause 1 of this Article is open and publicly available and shall be provided to concerned parties in accordance with the legislation of the Russian Federation.

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

#### **Chapter 7. CLINICAL TRIALS OF MEDICINAL PRODUCTS FOR MEDICAL USE, CLINICAL TRIAL CONTRACT, RIGHTS OF PATIENTS INVOLVED IN CLINICAL TRIALS**

**Article 38. Clinical Trials of Medicinal Products for Medical Use**

1. Clinical trials of medicinal products for medical use, including international multicentre, multicentre, post-registration trial shall be conducted in one or more medical institutions as required by good clinical practices approved by the authorized federal executive body for the following purposes:

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

1) to establish safety and (or) tolerance of medicinal products for healthy volunteers, except for the trials of medicinal products manufactured outside the Russian Federation;

2) to select optimal dosages of medicinal product and course of treatment for patients with specific disease, optimal dosages and vaccination schemes of immunobiological medicinal products for healthy volunteers;

3) to establish safety and efficacy of a medicinal product for patients with specific disease, prophylactic efficacy for immunobiological medicinal products for healthy volunteers;

4) to study the possibility to widen the indication for medical use and identify earlier unknown side effects of registered medicinal products.

2. Generic medicinal products intended for medical use are subject to trials for bioequivalence and (or) therapeutic equivalence in the procedure established by the authorized federal executive body.

3. Clinical trials of a medicinal product for medical use may be organized by:

1) developer of the medicinal product or a person authorized by the developer;

2) educational organizations of higher education, educational organizations of additional professional education;

(sub-clause 2 as amended by Federal Law of July 2, 2013 No. 185-FZ)

3) scientific and research organizations.

4. Clinical trials of a medicinal product for medical use shall be conducted under an approval to conduct the clinical trial of the medicinal product issued by the authorized federal executive body. The authorized federal executive body shall maintain a register of issued approvals to conduct clinical trials of a medicinal product indicating the purpose or purposes thereof in the procedure established by this body.

(clause 4 as amended by Federal Law of December 22, 2014 No. 429-FZ)

5. Ceased to be in force as of July 1, 2015 (Federal Law of December 22, 2014 No. 429-FZ)

6. The developer of a medicinal product may involve legal entities of any form of incorporation to organization of clinical trials of a medicinal product for medical use provided that these trials comply with the requirements of this Federal Law.

7. Clinical trials of medicinal products for medical use shall be carried out in medical institutions accredited by the authorized federal executive body in the manner prescribed by the Government of the Russian Federation.

8. A list of medical institutions entitled to conduct clinical trials of medicinal products for medical use and the register of issued approvals to conduct clinical trials of medicinal products shall duly be published and placed on the official website by the authorized federal executive body.

#### Article 39. Decision on the Conduct of a Clinical Trial of a Medicinal Product for Medical Use

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

1. A clinical trial of a medicinal product for medical use is conducted under an approval to conduct a clinical trial of a medicinal product issued by the authorized federal executive body based on the results of expert examination of documents required to obtain an approval to conduct a clinical trial of a medicinal product and ethical expert examination.

2. To obtain an approval to conduct a clinical trial of a medicinal product for medical use the applicant shall submit to the authorized federal executive body:

1) application for issuing an approval to conduct a clinical trial of a medicinal product for medical use;

2) copies of documents confirming payment of state duty for the conduct of ethical expert examination, expert examination of documents for medicinal product in order to obtain an approval to conduct a clinical trial of the medicinal product for medical use, for the issue of approval to conduct the clinical trial of the medicinal product for medical use, for the conduct of expert examination of documents for the medicinal product in order to obtain approval for the conduct of international multicenter clinical trial of the medicinal product for medical use, for the issue of approval to conduct international multicenter clinical trial of the medicinal product for medical use, for the conduct of ethical expert examination, expert examination of documents for the medicinal product in order to obtain approval for the conduct of post-registration clinical trial of a medicinal product for medical use, for the issue of approval for the conduct of post-registration clinical trial of a medicinal product for medical use, or, upon the applicant's own initiative, the original documents. In case such documents are not submitted by the applicant, the relevant authorized federal executive body shall check the fact of payment by the applicant of state duty by using information on payment of state duties contained in the State Information System on state and municipal payments on the basis of copies of documents confirming the payment of state duty provided by the applicant.

3) clinical trial protocol for a medicinal product for medical use;

4) investigator's brochure;

5) patient information sheet;

6) information on experience of investigators in relevant special fields and their experience in the conduct of clinical trials;

7) information on medical organizations which are scheduled to conduct the clinical trial of the medicinal product for medical use (full and brief names, legal form of medical organization, the seat and business location, telephone, fax, email address of each medical organization);

8) information on estimated dates of the clinical trial of the medicinal product for medical use;

9) a copy of the compulsory insurance agreement made in accordance with standard compulsory insurance rules, specifying the maximum number of patients participating in the clinical trial of the medicinal product for medical use;

10) information on the composition of the medicinal product for medical use;

11) a document composed by the manufacturer of the medicinal product for medical use containing data on parameters (characteristics) as well as information on the medicinal product for medical use manufactured to conduct clinical trials;

12) a copy of license for manufacture of medicines if production of medicinal product is performed in the Russian Federation, or a copy of a statement of compliance of the manufacturer of the medicinal product with requirements of good manufacturing practice issued by the authorized body of the country of the manufacturer of the medicinal product.

(sub-clause 12 as amended by Federal Law of June 04, 2018 No. 140-FZ)

3. In the period not longer than five business days on receipt of the application and required documents specified in sub-clause 1 of clause 2 of this Article, the authorized federal executive body shall:

1) verify completeness and accuracy of data contained in the documents submitted by the applicant;

2) make a decision on the conduct of expert examination of documents submitted to obtain approval to conduct the clinical trial of the medicinal product for medical use and ethical expert examination or on refusal to conduct such expert examinations;

3) notify the applicant, in electronic or paper form, on the decision made and, in case of refusal, also specify the reasons for such refusal;

4) prepare and send to the expert institution and ethical council an assignment for the conduct of relevant expert examinations.

4. If any information contained in the documents submitted by the applicant is found to be incomplete and (or) inaccurate, the authorized federal executive body shall send to the applicant a request for clarification of the information. This request may be delivered to an authorized representative of the applicant personally against signature, by registered mail or in electronic form via telecommunication channels. If the request is sent by registered mail, it shall be deemed received in six days of the dispatch. The applicant shall respond to the request of the authorized federal executive body within ninety business days of its receipt. The period specified in clause 3 of this Article shall be suspended from the date when the authorized federal executive body sends its request to the applicant to the date when it receives the relevant response and shall not be taken into account when determining a period for making by the authorized federal executive body a decision on the conduct of expert examination of the documents submitted to obtain approval to conduct a clinical trial of a medicinal product for medical use.

5. A failure to submit a complete set of the documents listed in clause 2 of this Article, a failure to send a response as specified in clause 4 of this Article to the request of the federal executive body, or submission of the documents lacking comprehensive information which must be reflected therein, or a failure to submit information confirming payment of state duty for the conduct of ethical expert examination, expert examination of documents for the medicinal product in order to obtain approval to conduct a clinical trial of the medicinal product for medical use, for the issue of approval to conduct the clinical trial of the medicinal product for medical use, for the conduct of expert examination of documents for the medicinal product in order to obtain approval for the conduct of international multicenter clinical trial of the medicinal product for medical use, for the issue of approval to conduct international multicenter clinical trial of the medicinal product for medical use, for the conduct of ethical expert examination, expert examination of documents for the medicinal product in order to obtain approval for the conduct of post-registration clinical trial of a medicinal product for medical use, for the issue of approval for the conduct of post-registration clinical trial of a medicinal product for medical use shall be the grounds for refusal to conduct expert examination of documents submitted to obtain approval to conduct the clinical trial of the medicinal product for medical use and ethical expert examination.

6. Expert examination of the documents submitted to obtain approval to conduct a clinical trial

of a medicinal product for medical use and ethical expert examination shall be conducted, and awards of the expert commission and ethical council on the possibility or impossibility to conduct such clinical trial shall be issued and sent to the authorized federal executive body, within thirty business days of the date of receipt by the expert institution of the assignment of the authorized federal executive body with attachment of the documents specified in sub-clauses 3, 4, 10 and 11 of clause 2 of this Article, and by the ethical council of the assignment of the authorized federal executive body with attachment of the documents specified in sub-clauses 3-6, 8 and 9 of clause 2 of this Article.

7. Within five business days of the receipt of the awards specified in clause 6 of this Article, the authorized federal executive body shall:

1) evaluate the received awards in order to verify their compliance with the assignments for the conduct of relevant expert examinations;

2) make a decision on the issue of an approval to conduct the clinical trial of the medicinal product for medical use or on refusal to issue such approval;

3) issue an approval to conduct the clinical trial of the medicinal product for medical use or a decision on refusal to issue such approval specifying the reasons for such refusal.

8. An award of the expert commission or award of the ethical council on impossibility to conduct a clinical trial of a medicinal product for medical use based on the results of expert examinations provided by clause 6 of this Article shall be the grounds for refusal to issue an approval to conduct the clinical trial of the medicinal product for medical use.

9. A decision on refusal to conduct expert examination of documents submitted to obtain an approval to conduct a clinical trial of a medicinal product for medical use and ethical expert examination and to issue an approval to conduct a clinical trial of a medicinal product for medical use may be appealed in the manner established by the legislation of the Russian Federation.

#### Article 39.1. Ethical Expert Examination

(introduced by Federal Law of December 22, 2014 No. 429-FZ)

1. Ethical expert examination shall be conducted by the ethical council founded in the manner prescribed by the authorized federal executive body for the purpose of issuing an award on ethical justification of the possibility to conduct a clinical trial of a medicinal product for medical use.

2. Experts of the ethical council may include representatives of medical organizations, scientific organizations, and higher education organizations as well as representatives of public organizations and mass media. These experts shall not be dependent, in any manner whatsoever, on the developers of medicinal products and other persons interested in the results of the ethical expert examination.

3. Remuneration to ethical council experts shall be paid under a contract concluded between the authorized federal executive body that founded the ethical council and the expert of the ethical council at the cost of budget allocations stipulated to authorized federal executive body, founded ethical council, in the federal budget for corresponding year to ensure its activities in extent prescribed by the Government of the Russian Federation.

4. Experts of the ethical council shall be liable in accordance with the legislation of the Russian Federation.

5. The composition of the ethical council, regulations on the council, procedure for the conduct of its activities, requirements for qualification and work experience of experts of the ethical council in the field of expert evaluation of scientific, medical and ethical aspects of clinical trials of medicinal products for medical use, procedure for the organization and conduct of ethical expert examinations, form of a award of the ethical council shall be established by the authorized federal executive body. The number of representatives of medical organizations shall not exceed one half of the total number of experts of the ethical council.

6. Information on the composition of the ethical council, plan of operation and current activities shall be placed on the official website of the authorized federal executive body in accordance with the procedure established thereby.



#### Article 40. Conduct of a Clinical Trial of a Medicinal Product for Medical Use

1. The head of the medical organization conducting a clinical trial of a medicinal product shall appoint an investigator responsible for the clinical trial of the medicinal product for medical use, which investigator shall have a medical qualification corresponding to the clinical trial of the medicinal product to be conducted, with at least three-year experience on programs of clinical trials of medicinal products, and at his/her suggestion appoint subinvestigators from among of the physicians of this medical institution.

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

2. The investigator shall select patients who may be enrolled in the clinical trials of that medicinal product for medical use based on the medical indications.

3. The investigator and subinvestigators shall be familiarized with the results of the non-clinical trial of the medicine contained in the investigator's brochure, a clinical trial draft protocol prepared by the developer of the medicinal product or any other legal entity engaged in organization of the clinical trial of the medicinal product for medical use, and with other materials of the clinical trial.

3.1. The head of the medical institution shall, within three business days of the start of the clinical trial of a medicinal product for medical use, notify thereof the authorized federal executive body, which issued approval for this clinical trial in the form established by this body.

(clause 3.1 introduced by Federal Law of November 29, 2010 No. 313-FZ)

4. The institutions that organize a clinical trial of the medicinal product for medical use and referred to in clause 3 of Article 38 of this Federal Law, shall, if the protocol of the clinical trial of the medicinal product for medical use needs to be amended, notify the authorized federal executive body, which issued the approval to conduct such clinical trial.

4.1. A form of notice of on amending the protocol of the clinical trial of a medicinal product for medical use shall contain the following data:

- 1) name, identification number and date of the protocol of the clinical trial;
- 2) date of amendments to the protocol of the clinical trial;
- 3) name and location of the applicant;
- 4) name of the organization engaged by the developer of the medicinal product to arrange the conducting of the clinical trial (if any);
- 5) names locations of medical organizations in which the clinical trial is conducted;
- 6) date of issue of approval to conduct the clinical trial and the number of the approval;
- 7) amendments to the protocol of the clinical trial.

(clause 4.1 introduced by Federal Law of October 11, 2010 No. 271-FZ)

5. Within thirty business days of receipt of the notice referred to in clause 4 of this Article, the authorized federal executive body shall review this notice in accordance with the procedure established by this federal executive body and make a decision on amending the protocol of the clinical trial of the medicinal product for medical use or on rejection of such amendment. When considering a notification on the necessity to make amendments to the protocol of the clinical trial of the medicinal product for medical use, in order to evaluate the feasibility of making such amendments and determine the degree of risk for patients participating in the clinical trials, the authorized federal executive body may engage experts of the ethical council.

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

6. A clinical trial of a medicinal product for medical use may be suspended or terminated if proving a danger to the patients' health and life while in progress. In the event of a danger to the life or health of the patient involved in the clinical trial of a medicinal product for medical use, the investigators shall notify the head of the medical organization and (or) the organization, which obtained an approval from the authorized federal executive body to organize a clinical trial of the medicinal product. A decision to suspend a clinical trial of a medicinal product for medical use shall be made by the head of the medical organization and (or) the organization, which obtained an approval from the authorized federal executive body to organize a clinical trial of the medicinal product. A decision to terminate such trial shall be made by the authorized federal executive body on the basis of a written notice received from the head of the medical organization or organization which obtained

an approval from the authorized federal executive body to organize the clinical trial of the medicinal product for medical use.

7. Within not later than five business days on completion, suspension or termination of the clinical trial of the medicinal product for medical use, the notice of the same shall be forwarded to the organizations referred to in clause 3 of Article 38 of this Federal Law, and to the authorized federal executive body according to the prescribed form.

8. The form of notice of completion, suspension or termination of the clinical trial of the medicinal product for medical use shall include:

- 1) information about the medical organization(s) which has/have conducted this trial;
- 2) trial description;
- 3) investigator's details (full name, place or employment, position, qualification, experience in the conduct of clinical trial programs for medicinal products and list of clinical trials of medicinal products in which he/she participated (when) as an investigator or a subinvestigator);  
(as amended by Federal Law of October 11, 2010 No. 271-FZ)

- 4) trial results (trial completion/suspension/termination indicating their reasons and the effect on the reasons on the results assessment, risk assessment and anticipated benefit from the use of the medicinal product under investigation, as well as further supposed actions).

8.1. If the federal executive body performing control and supervision functions in the field of healthcare detects any violations of the rules of good clinical practice in the conduct of the clinical trial of the medicinal product, which affect the completeness and (or) accuracy of the clinical trial, this federal executive body shall suspend the conduct of this clinical trial and issue an order requiring that the medical organization conducting the clinical trial remedies these violations. If the medical organization fails to remedy the detected violations within the period specified in the order, this federal executive body shall make a decision on the termination of the clinical trial of the medicinal product and refer to the federal executive body performing functions of development and implementation of state policy and legal regulation in the field of healthcare a conclusion of the detection of violations of the rules of good clinical practice in the conduct of this clinical trial for the purpose of making a decision on the cancellation of the permit for the conduct of this clinical trial starting from the date of suspension of the clinical trial of the medicinal product.”

(clause 8.1 introduced by Federal Law of December 22, 2014 No. 429-FZ)

9. The authorized federal executive body shall publish and place on its official website a notice of completion, suspension or termination of the clinical trial of the medicinal product for medical use within five business days on its duly receipt.

10. The authorized federal executive body shall maintain a register of investigators who are conducting or conducted clinical trials of medicinal products for medical use in accordance with the rules approved by such body and duly place the register on its official website. Such register shall contain data as provided for in sub-clause 3 of clause 8 of this Article.

11. The organization mentioned in clause 3 of Article 38 of this Federal Law shall prepare a report on the findings of clinical trial of a medicinal product for medical use on the basis of conclusions of the medical organizations involved in this trial, and submit it to the authorized federal executive body, which issued an approval to conduct the trial, within three months on the trial completion, suspension or termination in accordance with the procedure established by the authorized federal executive body.

12. A failure to follow the rules of good clinical practice, falsification of clinical trial results of a medicinal product for medical use shall entail liability as prescribed by the laws of the Russian Federation.

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

13. When conducting a clinical trial of a medicinal product for medical use, biological sampling in patients is permitted (biologic fluids, tissues, secretion and waste products, physiologic and pathologic discharge, smears, scrapes, washouts, microorganisms, biopsy materials) for study of the samples inside and (or) outside the Russian Federation

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

14. The procedure for import into the Russian Federation and export from the Russian Federation of biological materials obtained in a clinical trial of a medicinal product for medical use shall be established by the Government of the Russian Federation.  
(as amended by Federal Law of December 22, 2014 No. 429-FZ)

#### Article 41. Contract for Clinical Trial of Medicinal Product for Medical Use

1. A clinical trial of a medicinal product for medical use shall be conducted in accordance with the contract for the clinical trial of the medicinal product for medical use to be concluded between the organization which obtained an approval from the authorized executive body for organization of such trial and medical organization conducting the clinical trial of the medicinal product.

2. A contract for a clinical trial of a medicinal product for medical use shall:

- 1) prescribe trial terms and conditions,
- 2) determine the total cost of the trial program indicating the amount to be paid to the investigators and subinvestigators; and
- 3) determine the form in which the trial results are to be presented to the authorized federal executive body.

#### Article 42. Finance Support of Clinical Trial of Medicinal Product for Medical Use

A clinical trial of a medicinal product shall financially be supported from:

- 1) federal funds,
- 2) funds of the organizations which have obtained an approval to conduct this trial, in accordance with the terms and conditions of the trial contract; and
- 3) other sources not prohibited by the laws of the Russian Federation.

#### Article 43. Rights of Patients Involved in Clinical Trial of Medicinal Product for Medical Use

1. Participation of patients in a clinical trial of a medicinal product for medical use shall be voluntary.

2. The patient or his/her legal representative shall be informed in writing of the following:

- 1) medicinal product for medical use and the nature of the clinical trial of this medicinal product;
- 2) safety, anticipated efficacy of the medicinal product for medical use, and the degree of risk for the patient;
- 3) conditions of the patient's participation in the clinical trial of the medicinal product for medical use;
- 4) objective(s) and duration of the clinical trial of the medicinal product for medical use;
- 5) patient's actions in the event of unforeseen effects of the medicinal product for medical use on the patient's health;
- 6) terms and conditions of compulsory life and health insurance for the patient;
- 7) guarantees of confidentiality for the patient's participation in the clinical trial of the medicinal product for medical use.

3. The patient's voluntary consent to participate in the clinical trial of a medicinal product for medical use shall be confirmed by his/her signature or signature of his/her legal representative on the patient information sheet.

4. The patient, or his legal representative, may withdraw from the clinical trial of a medicinal product for medical use at any stage of such trial.

5. A clinical trial of medicinal product for medical use with participation of children as patients shall only be permitted with written consent of their parents/adoptive parents. Children may only be considered as potential patients of such trial if the trial is required for promotion of children's health or prophylaxis of infectious diseases in childhood, or where the objective of a clinical trial is to obtain data on the best dosage of medicinal product for treatment of children. In such cases the trial shall be

preceded by a clinical trial of the medicinal product for medical use in adults, unless the medicinal product for medical use is designed solely for the use by minors.

(as amended by Federal Law of October 22, 2014 No. 313-FZ)

6. It shall be prohibited to conduct a clinical trial of medicinal product for medical use in the following patients:

- 1) orphaned children/children without parental care;
- 2) pregnant and nursing women, except for clinical trials conducted on a medicinal product designed for said women where the information sought may only be obtained in respective clinical trials of medicinal products and when all the appropriate measures have been taken in order to exclude any risk of harm to the pregnant or nursing woman, the foetus or the baby;
- 3) military personnel, except where a clinical trial of a medicinal product specially designed for use in military operations, emergency situations, prophylaxis and treatment of diseases and damages resulting from the exposure to unfavorable chemical, biological or radiation factors. A clinical trial of such medicinal products may be conducted with participation of military personnel as patients, except for military personnel doing call-up military service, in accordance with the requirements established by this Federal Law with respect to civilians;
- 4) law enforcement personnel; and
- 5) individuals serving sentences at places of confinement, or individuals in custody at detention facilities.

7. It is allowed to conduct a clinical trial of a medicinal product for medical use designed for treatment of mental disorders in individuals with mental disorders recognized as disabled in accordance with the laws of the Russian Federation. A clinical trial of a medicinal product in this case shall be conducted subject to consent in writing having been given by legal representatives of said individuals.

Article 44. Compulsory Insurance of Life and Health of a Patient Involved in a Clinical Trial of a Medicinal Product for Medical use

(as amended by Federal Law of November 29, 2010 No. 313-FZ)

1. The organization which has obtained an approval for organization of a clinical trial of a medicinal product for medical use must insure risk of causing any harm to the patient's life or health as a result of the clinical trial of the medicinal product for medical use at its own expense by making a compulsory insurance contract.

2. The object of compulsory insurance shall be the patient's property interest connected with harm caused to the patient's life or health as a result of a clinical trial of a medicinal product for medical use.

3. An insurance event under a compulsory insurance contract shall be the patient's death or health impairment, including health impairment entailing disability in case there is a cause-and-effect relationship between the occurrence of this event and the patient's participation in the clinical trial of the medicinal product.

4. Claims for compensation of harm caused to the patient's life or health shall be made within the limitation period established by the civil legislation.

5. The extent of benefits under a compulsory insurance contract shall be as follows:

- 1) in case of patient's death — two million rubles for each patient who participated in the clinical trial of the medicinal product;
- 2) in case of patient's health impairment:
  - a) which caused first class disability — one million five hundred thousand rubles for each patient participated in the clinical trial of the medicinal product;
  - b) which caused second class disability — one million rubles for each patient participated in the clinical trial of the medicinal product;
  - c) which caused third class disability — five hundred thousand rubles for each patient participated in the clinical trial of the medicinal product;

d) which did not cause disability — not more than three hundred thousand rubles for each patient participated in the clinical trial of the medicinal product, based on the standard rates reflecting the nature and degree of harm caused to health and expenses actually incurred by the patient due to the harm caused to his/her health for medical aid and purchase of medicinal products.

(clause “d” as amended by Federal Law of December 22, 2014 No. 429-FZ)

6. Ceased to be in force as of July 1, 2015 (Federal Law of December 22, 2014 No. 429-FZ)

7. The term of a compulsory insurance contract shall not be less than the term of the clinical trial of the medicinal product.

8. Terms and conditions of a compulsory insurance contract, including compulsory insurance rates, list of necessary documents for making insurance payment, procedure for assignment by the insuring party of an individual identification code to a patient, procedure for notification of the insurer by the insuring party about patients involved in the clinical trial of the medicinal product for medical use, procedure for payment of insurance premium, procedure for exercise of rights and performance of obligations under the compulsory insurance contract as determined by this Federal Law and other federal laws and standard rates reflecting the nature and degree of harm caused to health shall be established by the standard compulsory insurance rules.

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

9. If harm is caused to the life of a patient involved in a clinical trial of a medicinal product, the beneficiary under the compulsory insurance contract shall be people entitled to compensation for harm in the event of death of the breadwinner in accordance with the civil legislation; if there are no such people, the beneficiary will be the parents, spouse, children of the deceased patient involved in the clinical trial of the medicinal product; if the deceased patient involved in clinical trials of a medicinal product had been dependent, the beneficiary will be people on whom he/she depended; compensation for funeral expenses on the patient involved in the clinical trial of the medicinal product will be paid to the person who has incurred such expenses.

10. Insurance payout for compensation of harm caused to the life of a patient involved in a clinical trial of a medicinal product shall be distributed among the beneficiaries in proportion to their number in equal shares.

11. In case of an insurance event with the patient involved in a clinical trial of a medicinal product, the beneficiary shall have the right to claim immediately to the insurer for compensation of the harm caused. The insurer shall pay benefits within thirty days on receipt of the appropriate documents. A patient involved in a clinical trial of a medicinal product, or the beneficiary shall be obliged to provide the insurer, for the purpose of insurance payout, with his/her individual patient identification code prescribed by the standard rules for compulsory insurance.

12. Until the extent of harm to be indemnified is determined in full, the insurer may, on request of the patient involved in a clinical trial of a medicinal product, or on request of the beneficiary, pay part of the insurance benefits corresponding to the actually determined part of the harm caused.

13. Insurance payout under the compulsory insurance contract shall be paid irrespective of any benefits payable on any other type of insurance.

14. The participation of a patient in a clinical trial of medicinal product without the contract of compulsory insurance shall be prohibited.

15. The federal executive body which issued an approval to conduct a clinical trial of a medicinal product for medical use shall ensure that the organization, which has obtained the approval to conduct the clinical trial of the medicinal product for medical use, fulfils its obligation on compulsory life and health insurance of a patient participating (participated) in the clinical trial of the medicinal product as stated in this Article.

## **Chapter 8. MANUFACTURE AND MARKING OF MEDICINES**

### **Article 45. Production of Medicines**

1. Production of medicines shall comply with the requirements of good manufacturing practice approved by the authorized federal executive body. The specifics of transferring production of certain

medicines to the production in accordance with good manufacturing practice requirements shall be established by the Government of the Russian Federation. Statements of compliance of the manufacturer with good manufacturing practice requirements shall be issued based on the results of inspections of manufacturers of medicines in the manner established by the Government of the Russian Federation. The amount of fee for the issue of a statement of compliance of the manufacturer of medicines with the requirements of good manufacturing practice shall be established by the Government of the Russian Federation. The procedure for the organization and conduct of inspections of manufacturers of medicines to verify their compliance with good manufacturing practice requirements shall be established by the Government of the Russian Federation.

(as amended by Federal Laws of June 25, 2012 No. 93-FZ, of October 22, 2014 No. 313-FZ, of December 22, 2014 No. 429-FZ)

2. Production of medicines in the Russian Federation shall be performed by manufacturers of medicines that possess a license to manufacture medicines. Compliance of the licensee with good manufacturing practice requirements shall be confirmed within the framework of license control in accordance with the legislation of the Russian Federation taking into account the specifics specified in clause 1 of this Article.

(as amended by Federal Laws of October 22, 2014 No. 313-FZ, of December 22, 2014 No. 429-FZ)

3. Manufacture of medicines shall conform to the production regulations approved by the medicines manufacturer's head and include a list of pharmaceutical substances and excipients indicating the quantity of each of them, information on the equipment, description of the technological processes and the control methods used at all production stages of the medicines.

4. During the manufacture of medicines there are pharmaceutical substances used as detailed in the state registry of medicines except the pharmaceutical substances manufactured for clinical trials and export. The process of production of pharmaceutical substance includes any stages of technological process allowing to obtain finished product which complies with the requirements of the pharmacopeia article, including fermentation, extraction, purification, separation, re-crystallization, drying, grinding.

(as amended by Federal Law of December 22, 2014 No. 429-FZ and Federal Law of December 27, 2019 No. 462-FZ)

4.1. A list of medicinal products for medical use, for which the requirements for the volume of containers, packaging, and completeness are established, a list of medicinal products for veterinary use, for which the requirements for the volume of containers are established, as well as requirements for the volume of containers, packaging, and completeness of medicinal products for medical use, and requirements for the volume of containers of medicinal products for veterinary use shall be determined by relevant federal executive bodies in the manner established by the Government of the Russian Federation.

(clause 4.1 as amended by Federal Law of December 14, 2015 No. 374-FZ)

4.2 Organizations manufacturing a pharmaceutical substance of ethyl alcohol (ethanol) to produce alcohol-containing medicinal products shall perform registration and declaration in the manner set forth in Articles 8 and 14 of Federal Law of 22 November 1995 No.171-FZ "On State Regulation of the Production and Circulation of Ethyl Alcohol, Alcoholic and Alcohol-Containing Products and Limitation of Consuming (Drinking) Alcoholic Products;"

(clause 4.2 introduced by Federal Law of July 3, 2016 No. 261-FZ)

4.3. Individual entrepreneurs and legal entities engaged in the purchase and use of the pharmaceutical substance of ethyl alcohol (ethanol) and manufacture, production and (or) circulation (except for retail) of alcohol-containing medicines shall perform registration and declaration in the manner prescribed by Articles 8 and 14 of Federal Law of 22 November 1995 No. 171-FZ "On State Regulation of the Production and Circulation of Ethyl Alcohol, Alcoholic and Alcohol-Containing Products and Limitation of Consuming (Drinking) Alcoholic Products"

(clause 4.3 introduced by Federal Law of July 29, 2017 No. 278-FZ)

4.4. When producing medicinal products for veterinary use, it shall be allowed to use pharmaceutical substances produced for sale and included in the state register of medicines by the authorized federal executive body that maintains the state register of medicines for medical use.

(clause 4.4 introduced by Federal Law of August 02, 2019 No. 297-FZ)

5. It is prohibited to produce:

- 1) medicines not included in the state register of medicines except for medicines manufactured for clinical trials and for export;
- 2) counterfeit medicines;
- 3) medicines with no license for production of medicines;
- 4) medicines with violation of good manufacturing practices
- 5) the pharmaceutical substance of ethyl alcohol (ethanol) using technological equipment that has not been registered or conserved in accordance with Federal Law of 22 November 1995 No. 171-FZ "On State Regulation of the Production and Circulation of Ethyl Alcohol, Alcoholic and Alcohol-Containing Products and Limitation of Consuming (Drinking) Alcoholic Products".

(sub-clause 5 introduced by Federal Law of July 29, 2017 No. 278-FZ)

6. When medicines are introduced into the civil circulation, an authorized representative of the manufacturer of medicines shall confirm the compliance of the medicines with the requirements established during their state registration and shall guarantee that the medicines have been manufactured in accordance with good manufacturing practices.

(as amended by Federal Law of December 22, 2014 No. 429-FZ).

7. An authorized representative of a manufacturer of medicines is its employee attested in accordance with the procedure established by the authorized federal executive body who has work experience of at least five years in the field of manufacture and (or) quality control of medicines, higher education in one of the following relevant specialties and (or) training programs: biology, biotechnology, veterinary medicine, veterinary and sanitary expert examination, clinical medicine, radiation, chemical and biological protection, pharmacy, basic medicine, chemical engineering, chemistry.

(clause 7 as amended by Federal Law of October 22, 2014 No. 313-FZ and Federal Law of August 02, 2019 No. 297-FZ)

8. Manufacturers of medicines with the exception of the pharmaceutical substance of ethyl alcohol (ethanol) may sell or transfer medicines in the procedure established by the laws of the Russian Federation to:

(as amended by Federal Law of July 29, 2017 No. 278-FZ)

- 1) other manufacturers of medicines for manufacturing of medicines;
- 2) wholesalers of medicines;
- 3) pharmacy institutions, veterinary pharmacy institutions, sole traders licensed for pharmaceutical activity or for a medical activity;
- 4) research and development organizations for research work;
- 5) medical institutions and veterinary institutions;
- 6) organizations and sole traders that deal with animals breeding, rearing and keeping (other than sale or transfer of pharmaceutical substances to such organizations).

(sub-clause 6 as amended by Federal Law of August 02, 2019 No. 297-FZ)

9. Manufacturers of the pharmaceutical substance of ethyl alcohol (ethanol) shall sell (transfer in the manner prescribed by the laws of the Russian Federation) the pharmaceutical substance of ethyl alcohol (ethanol) to manufacturers of medicines for the purpose of manufacturing medicines in containers of not more than 1 litre and (or) not less than 1,000 liters and to organisations specified of clauses 2-6 of Part 8 of this Article, in transport containers of not more than 1 litre.

(clause 9 introduced by Federal Law of July 29, 2017 No. 278-FZ)

#### Article 46. Marking of Medicines

1. Medicinal products, except for medicinal products manufactured by the pharmacy institutions, veterinary pharmacy institutions, sole traders licensed for pharmaceutical activity, shall come into circulation if:

- 1) their primary packaging (with the exception for primary packaging of herbal medicinal products) contains the name of the medicinal product (international nonproprietary, or modified, or

chemical, or trade name), batch number, date of issue (for immunobiological medicinal products), shelf-life, dosage or concentration, volume, activity in activity units or number of doses printed well readable in Russian;

(as amended by Federal Laws of October 11, 2010 No. 271-FZ, of December 22, 2014 No. 429-FZ)

2) their secondary (consumer) packaging contains printed, well readable Russian name of the medicinal product (international nonproprietary, or modified, or chemical name and a trade name), name of the manufacturer of the medicinal product, batch number, date of issue (for immunobiological medicinal products), registration certificate number, shelf-life, mode of administration, dosage or concentration, volume, activity in activity units or number of doses, pharmaceutical form, dispensation conditions, storage conditions, caution notices.

(as amended by Federal Laws of October 11, 2010 No. 271-FZ, of December 22, 2014 No. 429-FZ)

2. Pharmaceutical substances shall come into circulation if their primary packaging states in well readable print in Russian the name of the pharmaceutical substance (international nonproprietary, or modified, or chemical and trade names), name of the manufacturer of the pharmaceutical substance, batch number and date of manufacture, quantity in a package, and units of measure, shelf-life and storage conditions.

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

3. Medicines as serums shall come into circulation having the indication of the animal, whose blood, blood plasma, organs or tissues were used for production of these medicinal products.

4. The secondary (consumer) packaging of medicines produced from the blood, blood plasma, human organs and tissues shall have the following notice applied on to it: "No HIV-1, HIV-2, HCV virus antibodies and no surface antigen of hepatitis B virus".

5. A radiation danger symbol shall be applied on to the primary and secondary (consumer) packaging of radiopharmaceutical medicines.

6. The word "Homeopathic" shall be applied on to the secondary (consumer) packaging of homeopathic medicinal products.

7. The secondary (consumer) packaging of the herbal medicinal products shall contain the inscription "The product has passed radiation control".

8. The primary (if technically possible) and secondary (consumer) packaging of the medicinal products intended for clinical trials shall contain the inscription "For clinical trials".

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

9. The packaging of the medicines designated exclusively for export shall be marked in compliance with the importing country requirements.

10. The shipping container, which is not intended for the consumers and in which the medicine is placed, shall be marked with the name and batch of the medicine, date of manufacture, quantity of the secondary (consumer) packages of the medicine, manufacturer of the medicine indicating his name and location (address, including country and (or) place of the medicine manufacture), as well as the shelf-life of the medicine and the conditions of its storage and transportation, necessary caution notices and handling symbols.

11. The words "For veterinary use" shall be applied on to the primary packaging and the secondary (consumer) packaging of the medicines for veterinary use.

12. A bar code shall be applied to the secondary (consumer) packaging of the medicine.

**Chapter 9. IMPORT OF MEDICINES  
INTO THE RUSSIAN FEDERATION AND EXPORT OF MEDICINES  
FROM THE RUSSIAN FEDERATION**

(as amended by Federal Law of December 06, 2011 No. 409-FZ)

Article 47. Procedure for Import of Medicines to the Russian Federation and Export of Medicines from the Russian Federation

(as amended by Federal Law of December 06, 2011 No. 409-FZ)



1. Import of medicines into the Russian Federation shall be performed in the procedure established by the Government of the Russian Federation and in compliance with the customs legislation of the Customs Union within Eurasian Economic Union (hereinafter the Customs Union) and (or) the customs legislation of the Russian Federation.

(as amended by Federal Law of December 06, 2011 No. 409-FZ)

2. Medicines imported into the Russian Federation must be contained in the state registry of medicines.

(as amended by Federal Law of December 06, 2011 No. 409-FZ and Federal Law of December 27, 2019 No. 462-FZ)

3. It is allowed to import into the Russian Federation a specific consignment of registered and (or) unregistered medicines to be used in clinical trials of medicinal products, for state expert examination of medicines for the purpose of state registration of medicinal products, or for delivery of health care in accordance with individual vital indications for the patient, on the basis of the permit granted by an authorized federal executive body due to applications of the parties mentioned in Article 48 hereof. This application shall be reviewed and the decision on the issue of the import permit of the specific consignment of registered and (or) unregistered medicines to be used in clinical trials of medicinal products, for state expert examination of medicines for the purpose of state registration of medicinal products or for delivery of health care in accordance with individual vital indications for the patient, or on the rejection of the above mentioned permit shall be taken within the time not exceeding five (5) business days. This permit shall be granted at no charge.

(as amended by Federal Law of December 06, 2011 No. 409-FZ)

3.1. There is permitted import of particular batch of unregistered medicinal products containing narcotic drugs or psychotropic substances in order established by the Government of the Russian Federation for life-saving medical aid to a certain patient or group of patients in case if there is a decision of medical board of a medical organization about inefficiency or inability to take other registered medicinal products in a certain patient and also containing other active substances, and about need of particular unregistered medicinal product import specifying its international nonproprietary (either chemical or group) name, release form and quantity. The list of diseases and conditions and corresponding medicinal products containing narcotic drugs or psychotropic substances is established by the federal authority in order to implement their import according to the requirements of this part.

(sub-clause 3.1 introduced by Federal Law of December 27, 2019 No. 475-FZ)

4. The medicines, the quality of which can be proved with the certificate of the manufacturer of medicines stating that the imported medicines is in compliance with the pharmacopeia monograph or, failing the latter, with the normative documentation or normative document, may be imported into the Russian Federation.

(as amended by Federal Law of December 06, 2011 No. 409-FZ)

5. It is prohibited to import to the Russian Federation counterfeit medicines, poor quality medicines, or infringing medicines.

(as amended by Federal Law of December 06, 2011 No. 409-FZ)

6. Counterfeit medicines and poor quality medicines are subject to confiscation and subsequent destruction or exportation from the territory of the Russian Federation, and infringing medicines are subject to confiscation and subsequent destruction. Destruction or exportation from the territory of the Russian Federation of counterfeit medicines, poor quality medicines, or infringing medicines shall be performed at the expense of the person that imported such medicines. The procedure for destruction of counterfeit medicines, poor quality medicines, or infringing medicines shall be determined by the Government of the Russian Federation.

(as amended by Federal Law of December 06, 2011 No. 409-FZ)

7. The persons importing counterfeit medicines, poor quality medicines, or infringing medicines to the Russian Federation shall be liable in accordance with the customs legislation of the Customs Union and (or) the customs legislation of the Russian Federation.

(as amended by Federal Law of December 06, 2011 No. 409-FZ)

8. The export of medicines from the Russian Federation shall be performed without application of any restrictions imposed thereon in accordance with the customs legislation of the Customs Union and (or) the Laws of the Russian Federation on state regulation of the foreign trade activity.  
(as amended by Federal Laws of December 06, 2011 No. 409-FZ, of November 25, 2013 No. 317-FZ, of December 22, 2014 No. 429-FZ)

9. Medicinal products for medical use imported into the Russian Federation shall be put into circulation subject to the requirements set forth in Article 52.1 of this Federal Law.  
(From November 29, 2019, Article 47 shall be supplemented by clause 9 introduced by Federal Law of November 28, 2018 No. 449-FZ)

Article 48. Legal Entities Authorized to Import Medicines into the Russian Federation  
(as amended by Federal Law of December 06, 2011 No. 409-FZ)

Medicines may be imported to the Russian Federation by:  
(as amended by Federal Law of December 06, 2011 No. 409-FZ)

1) manufacturers of medicines for the purpose of in-house manufacture of medicines;  
2) foreign developers of medicines and foreign manufacturers of medicines or other legal entities on the instructions of the developer of a medicines for the purpose of carrying out clinical trials of the medicinal product, state registration of the medicinal product, inclusion of the pharmaceutical substance in to the state register of medicines, quality control of medicines, subject to a permit from an authorized federal executive body to import a specific consignment of medicines;

3) wholesalers of medicines;

4) research and development organizations, higher education organizations, manufacturers of medicines for the development, study and control of the safety, quality and efficacy of medicines subject to a permit from an authorized federal executive body;  
(as amended by Federal Law of July 02, 2013 No. 185-FZ)

5) medical institutions and other institutions mentioned in clauses 1-4 of this Article for delivery of health care in accordance with individual vital indications for a patient subject to a permit from an authorized federal executive body to import a specific consignment of medicinal products issued in the established order in the form of the electronic document signed using enhanced qualified electronic signature;

(as amended by Federal Law of March 12, 2014 No. 33-FZ)

6) state unitary enterprises, whose property is federally owned, determined by the Government of the Russian Federation, in part of the Russian Federation import of unregistered medicinal product containing narcotic drugs or psychotropic substances for life-saving medical aid to a certain patient or group of patients according to the part 3.1 of the Article 47 of this Federal Law.  
(clause 6 introduced by Federal Law of December 27, 2019 No. 475-FZ)

Article 49. Documents Submitted to Customs Authorities of the Russian Federation when Importing Medicines into the Russian Federation  
(as amended by Federal Law of December 06, 2011 No. 409-FZ)

1. When medicines are imported into the Russian Federation, the following documents shall be submitted to the customs authorities of the Russian Federation, in addition to the documentation provided for by the customs legislation of the Customs Union and (or) the customs legislation of the Russian Federation:

(as amended by Federal Law of December 06, 2011 No. 409-FZ)

1) certificate of manufacturer of a medicine stating that the imported medicine is in compliance with the pharmacopeia article or, failing the latter, with the normative documentation or normative document;

2) permit from an authorized federal executive body to import a specific consignment of medicine under the circumstances provided for in clause 3 of Article 47 hereof.

2. The documents specified in clause 1 sub-clauses 1 and 2 of this Article shall be submitted to the customs authorities of the Russian Federation on arrival of the medicines in the Russian Federation. (as amended by Federal Law of December 06, 2011 No. 409-FZ)

Article 50. Bringing Medicinal Products into the Russian Federation for Personal Use and Other Non-Commercial Purposes, and also for the use on the territory of the international medical cluster (as amended by Federal Law of December 06, 2011 No. 409-FZ, of June 29, 2015 No. 160-FZ)

1. Medicinal products may be brought to the Russian Federation without regard to the requirements provided for by clauses 1-4 of Article 47, Articles 48 and 49 hereof, if they are designated for:

1) for personal use by individuals arriving in the Russian Federation. In such a case, medicinal products containing potent substances and (or) toxic agents included respectively in the list of potent substances for the purposes of the criminal legislation of the Russian Federation and in the list of toxic agents for the purposes of the criminal legislation of the Russian Federation approved by the Government of the Russian Federation, may be imported into the Russian Federation subject to the documents (certified copies of the documents or certified extracts from the documents) evidencing that these medicinal products have been administered to the individual (unless such medicinal products are registered in the Russian Federation and dispensed in the Russian Federation without prescription). Such evidencing documents (certified copies thereof or certified extracts therefrom) shall contain information on the name and quantity of the prescribed medicinal product. If such evidencing documents (certified copies thereof or certified extracts therefrom) are executed in a foreign language, they shall be accompanied by a notarized translation into the Russian language; (clause 1 as amended by Federal Law of June 2, 2016 No. 163-FZ)

2) members of diplomatic corps or representatives of international organizations accredited in the Russian Federation;

3) treatment of passengers and crewmen of transport vehicles, train crews and transport vehicles drivers arrived in the Russian Federation; (as amended by Federal Law of December 06, 2011 No. 409-FZ)

4) treatment of participants of international cultural and sport events and of international expeditions;

5) treatment of particular zoo animals, animals used in circuses, oceanariums, dolphinariums, treatment of wild animals that permanently or temporarily inhabit the territory of the Russian Federation, are in a state of natural freedom and attributed to species listed in the Red Book of the Russian Federation and (or) Red Books of constituent entities of the Russian Federation, as well as animals brought into the Russian Federation to take part in sport and entertainment events; (as amended by Federal Law of December 06, 2011 No. 409-FZ and Federal Law of August 02, 2019 No. 297-FZ)

6) the use on the territory of the international medical cluster (sub-clause 6 introduced by Federal Law of June 29, 2015 No. 160-FZ)

2. In the circumstances provided for in clause 1 of this Article, it is allowed to import into the Russian Federation medicinal products that are not registered in the Russian Federation. (as amended by Federal Law of December 06, 2011 No. 409-FZ)

3. Medicinal products meant for humanitarian aid (assistance) or help under emergency situations are imported into the Russian Federation in the order established by the Government of the Russian Federation. It is forbidden to import into the Russian Federation unregistered medicinal products meant for humanitarian aid (assistance) or help in emergency situations. (as amended by Federal Law of December 06, 2011 No. 409-FZ)

Article 51. Cooperation between the Federal Executive Body Authorized in the Area of Customs and Other Authorized Federal Executive Bodies

1. The authorized federal executive bodies make available to the federal executive body authorized in the area of customs a state register of medicines, as well as the information on issued

permits to import a specific consignment of medicines in the cases provided for by clause 3 of Article 47 hereof.

2. The federal executive body authorized in the area of customs shall inform the authorized federal executive bodies mentioned in clause 1 of this Article on the import of medicines into the Russian Federation and export of the medicines from the Russian Federation in the form and in the order established by the Government of the Russian Federation.  
(as amended by Federal Law of December 06, 2011 No. 409-FZ)

## **Chapter 10. PHARMACEUTICAL ACTIVITY**

### **Article 52. Realization of Pharmaceutical Activity**

1. Pharmaceutical activity is carried out by wholesalers of medicines, pharmacy institutions, veterinary pharmacy institutions, sole traders licensed to carry out pharmaceutical activity, medical organizations having a license for pharmaceutical activity and their separate subdivisions (ambulance stations, paramedic's and paramedical-obstetric centers, centers (departments) of general (family) practice) located in rural settlements which have no pharmacy offices, and veterinary organizations licensed to carry out pharmaceutical activity.

(as amended by Federal Law of November 25, 2013 No. 317-FZ)

2. Individuals may be engaged in pharmaceutical activities provided that they have higher or secondary pharmaceutical education or a certificate of a specialist, higher or secondary veterinary education and a certificate of a specialist, and also higher or secondary medical education, certificate of a specialist and additional professional education in retailing of the medicinal products, if they work in detached divisions at medical organizations specified in clause 1 of this Article.

(clause 2 as amended by Federal Law of July 27, 2010 No. 192-FZ)

### **Article 52.1. Putting into circulation of medicinal products for medical use**

(Article 52.1 (except sub-clause 6) comes into force on November 29, 2019 (introduced by Federal Law dated November 28, 2018 No.449-FZ).

1. Before putting into circulation each batch or each lot of a medicinal product for medical use manufactured in the Russian Federation other than immunobiological medicinal products, the manufacturer of this medicinal product shall provide to the federal executive authority carrying out control and supervision functions in healthcare a document of the manufacturer of the medicine confirming the quality of the medicinal product and confirmation of compliance of the medicinal product with the requirements established at its state registration issued by an authorized person of the manufacturer of medicines.

2. Before putting into circulation each batch or each lot of a medicinal product for medical use manufactured in the Russian Federation other than immunobiological medicinal products, the entity importing the medicinal product into the Russian Federation shall provide to the federal executive authority carrying out control and supervision functions in healthcare a certificate of the manufacturer of medicines evidencing the compliance of the imported medicinal product with the requirements of the pharmacopeial monograph and, in the absence of a pharmacopeial monograph, the requirements of normative documents and confirmation of compliance of the medicinal product with the requirements established at its state registration issued by a representative of the entity importing the medicinal product into the Russian Federation and authorized by the foreign manufacturer of medicines.

3. The procedure for the provision of documents and information on medicinal products to be put into circulation as required by parts 1 and 2 of this Article shall be established by the Government of the Russian Federation.

4. In respect of the first three batches or lots of the medicinal product for the first time manufactured in the Russian Federation or for the first time imported into the Russian Federation, a

testing protocol confirming the conformity of the batch or lot of the medicinal product for medical use to the quality criteria set forth in the normative documents (hereinafter the “testing protocol”) shall be provided to the federal executive authority carrying out control and supervision functions in healthcare, such testing to be performed by state budgetary institutions subordinate to the federal executive authority carrying out the functions of development and implementation of state policy and state regulation in healthcare and to the federal executive authority carrying out control and supervision functions in healthcare and accredited in accordance with the laws of the Russian Federation on the accreditation in the national system of accreditation. The procedure for issuing the protocol by the above-mentioned state budgetary institutions and the fee for its issue shall be established by the Government of the Russian Federation.

5. Annually, not later than February 1, manufacturers of medicines or entities importing medicinal products into the Russian Federation shall provide to the federal executive authority carrying out control and supervision functions in healthcare a testing protocol for the medicinal product of a particular manufacture that was put into circulation during the year (for one batch of each trade name taking into account the dosage form and strength), such testing to be carried out by testing labs (centres) accredited in accordance with the laws of the Russian Federation on the accreditation in the national system of accreditation.

6. Manufacturers of medicines or entities importing medicinal products into the Russian Federation shall, at least one year prior to the intended suspension or termination of manufacture of the medicinal products or their importation into the Russian Federation, give relevant notice to the federal executive authority carrying out control and supervision functions in healthcare and the federal executive authority carrying out the functions of licensing manufacture of medicines.

(Clause 6 of Article 52.1 comes into force on November 28, 2018 (introduced by Federal Law dated November 28, 2018 No.449-FZ)).

7. Each batch or each lot of an immunobiological medicinal product manufactured in the Russian Federation or imported into the Russian Federation shall be put into circulation on the basis of a permit issued by the federal executive authority carrying out control and supervision functions in healthcare and on the basis of an opinion issued by federal state budgetary institutions specified in part 4 of this Article confirming that the batch or lot of the immunobiological medicinal product complies with the requirements established at its state registration. The procedure for issuing a permit to put into circulation a batch or lot of an immunobiological medicinal product and the procedure for issuing the above opinion and the fee for its issue shall be established by the Government of the Russian Federation.

8. For failure to provide or untimely provision of the documents and information required by parts 1, 2, 4, 5 and 6 of this Article, manufacturers of medicines and entities importing medicinal products into the Russian Federation shall be liable in accordance with the laws of the Russian Federation.

9. Provision of documents and information required by parts 1, 2 and 4 of this Article and obtaining a permit to put into circulation of immunobiological medicinal product under part 7 of this Article is not required for medicinal products designated for clinical trials of medicinal products, expert examinations of medicines for the purposes of state registration of medicinal products and for unregistered medicinal products used to provide life-saving medical aid to a particular patient or group of patients imported into the Russian Federation in accordance with parts 3 and 3.1 of the Article 47 of this Federal Law.

(as amended by Federal Law of December 27, 2019 No. 475-FZ)

10. If a batch or lot of a medicinal product is found in the circulation, for which no documents or information required by parts 1, 2 and 4 of this Article have been provided to the federal executive authority carrying out control and supervision functions in healthcare, or if a batch or lot of an immunobiological medicinal product is found in the circulation, which does not have a permit for its being put into circulation required by part 7 of this Article, the federal executive authority carrying out control and supervision functions in healthcare shall, in the manner prescribed by the Government of the Russian Federation, make a decision to terminate the circulation of this batch or lot until the above documents and information are provided or the above permit is obtained.

### Article 53. Sale, Transfer of Medicines by Wholesalers of Medicines

1. Wholesalers of medicinal products may sell medicines or transfer the latter in the manner established by the legislation of the Russian Federation to:

- 1) other wholesalers of medicines;
- 2) manufacturers of medicines for production purposes;
- 3) pharmacy institutions and veterinary pharmacy organizations;
- 4) scientific-and-research and development organizations for research activities;
- 5) sole traders licensed to carry out pharmaceutical activity or having a license to carry out medical activities;

6) medical organizations, including foreign legal entities, sole traders created and registered in accordance with the laws of a foreign state that is a member of the Organization for Economic Cooperation and Development and participating in the project in accordance with the Federal Law on the International Medical Cluster and Amendment of Certain Legal Acts of the Russian Federation, and to veterinary institutions.

(as amended by Federal Law of July 26, 2019 No. 240-FZ)

7) organizations and sole traders that deal with animals breeding, rearing and keeping (other than sale or transfer of pharmaceutical substances to such organizations).

(sub-clause 7 as amended by Federal Law of August 02, 2019 No. 297-FZ)

2. Wholesalers of medicines shall store purchased pharmaceutical substance of ethyl alcohol (ethanol), and sell and transfer it in the manner prescribed by the laws of the Russian Federation to organisations specified in clauses 1-7 of Part 1 of this Article, in transport containers of not more than 1 litre.

(clause 2 introduced by Federal Law of July 29, 2017 No. 2278-FZ)

### Article 54. Regulations on Medicines Wholesale

Manufacturers and wholesalers of medicines shall wholesale medicines subject to the rules of good distributor practice, good storage and transportation practice for medicinal products approved by the relevant authorized federal executive bodies.

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

### Article 55. Procedure for Medicinal Products Retail

1. Retailing of medicinal products in such quantities as necessary to fulfill physician's (physician assistant's) prescriptions or the prescription of a veterinarian is carried out by pharmacy institutions, veterinary pharmacy institutions, sole traders licensed to carry out pharmaceutical activity, medical organizations having a license for pharmaceutical activity and their separate subdivisions (ambulance stations, paramedic's and paramedical-obstetric centers, centers (departments) of general (family) practice) located in rural settlements which have no pharmacy offices, and veterinary organizations licensed to carry out pharmaceutical activity. Only medicinal products registered in the Russian Federation or manufactured by pharmacy institutions, veterinary pharmacy institutions, sole traders licensed to carry out pharmaceutical activity are allowed to be retailed. Retailing of medicinal products shall be carried out in accordance with the rules of good pharmacy practice approved by the authorized federal executive body.

(as amended by Federal Laws of November 25, 2013 No. 317-FZ, of December 22, 2014 No. 429-FZ)

2. The types of pharmacy institutions and the rules of dispensation of medicinal products for medical use by pharmacy institutions, sole traders licensed to carry out pharmaceutical activity, as well as the rules of dispensation of medicinal products for through medical organizations having a license for pharmaceutical activity and their separate subdivisions (ambulance stations, paramedic's and paramedical-obstetric centers, centers (departments) of general (family) practice) located in rural

settlements which have no pharmacy offices shall be approved by the authorized federal executive body.

(as amended by Federal Law of November 25, 2013 No. 317-FZ)

3. The rules of dispensation of narcotic drugs and psychotropic substances registered as medicinal products, and of medicinal products containing narcotic drugs and psychotropic substances shall be approved by the authorized federal executive body by agreement with the federal executive internal affairs body.

(as amended by Federal Law of July 3, 2016 No. 305-FZ)

4. Medicinal products for veterinary use are subject to be dispensed through veterinary pharmacy institutions, veterinary organizations and sole traders licensed to carry out pharmaceutical activity. Medicinal products for veterinary use shall be dispensed in accordance with the good pharmacy practice rules for medicinal products for veterinary use approved by the authorized federal executive body.

(as amended by Federal Law of August 02, 2019 No. 297-FZ)

5. The list of medical organizations having a license for pharmaceutical activity and their separate subdivisions (ambulance stations, paramedic's and paramedical-obstetric centers, centers (departments) of general (family) practice) located in rural settlements which have no pharmacy offices, as well as the list of medicinal products (except for narcotic medicinal products and psychotropic medicinal products), which can be sold by the organizations mentioned above and by their separate subdivisions shall be specified by executive bodies of the Russian Federation constituent entities.

(as amended by Federal Law of November 25, 2013 No. 317-FZ)

6. Pharmacy institutions, sole traders licensed to carry out pharmaceutical activity are obliged to provide a minimum range of medicinal products necessary to deliver health care, as approved and composed in the manner established by the Government of the Russian Federation.

(clause 6 as amended by Federal Law of November 25, 2013 No. 317-FZ)

7. In addition to medicinal products, pharmacy institutions, sole traders licensed for a pharmaceutical activity are entitled to acquire and sell medical accessories, disinfectants, personal hygiene means and items, vessels for health care purposes, means and items designed for taking care of patients, newborns and children under three years of age, eyewear and means of taking care thereof, mineral water, health food, baby food and invalid food, biologically active additives to food, perfumes and cosmetics, medical and sanitary educative printed publications for healthy lifestyle promotion.

(as amended by Federal Laws of July 27, 2010 No. 192-FZ, of November 25, 2013 No. 317-FZ)

8. The activities of pharmacy institutions of the Armed Forces of the Russian Federation, other corps and military units and bodies, wherein military and law enforcement service is provided for by the legislation, are regulated by the present Federal Law and the regulations approved by the competent federal executive bodies. The control over the said pharmacy institutions being in compliance with the provisions hereof is exercised by the appropriate federal executive bodies.

#### Article 56. Manufacture and Dispensation of Medicinal Products

1. Manufacture of medicinal products by pharmacy institutions, veterinary pharmacy institutions, sole traders licensed to carry out pharmaceutical activity shall be performed based on the medicinal products prescriptions, requirements of medical organizations and veterinary institutions according to the rules for manufacture and dispensation of medicinal products, as approved by the authorized federal executive body.

2. When they manufacture medicinal products, pharmacy institutions, veterinary pharmacy institutions, sole traders licensed to carry out pharmaceutical activity shall use the pharmaceutical substances included into the state register of medicines for and the state register of medicines for veterinary use respectively in the appropriate way. The pharmacy institutions, veterinary pharmacy institutions, sole traders with a pharmaceutical license are not allowed to manufacture the medicinal products registered in the Russian Federation.

3. Marking and labeling of medicinal products manufactured by a pharmacy institution, a veterinary pharmacy institution and a sole trader with a pharmaceutical license shall be consistent with the rules specified in clause 1 of this Article.

4. A pharmacy institution, a veterinary pharmacy institution and a sole trader with a pharmaceutical license shall bear responsibility for failure to comply with the rules for manufacture and dispensation of medicinal products in accordance with the legislation of the Russian Federation.

#### Article 57. Ban on Sale of Counterfeit Medicines, Poor Quality Medicines or Infringing Medicines

It is forbidden to sell counterfeit medicines, poor quality medicines, infringing medicines.

#### Article 58. Storage of Medicines

1. Storage of medicines shall be exercised by manufacturers of medicines, wholesalers of medicines, pharmacy institutions, veterinary pharmacy institutions, sole traders with a pharmaceutical license or a medical license, medical organizations, veterinary institutions and other organizations involved in the circulation of medicines. Organizations and legal entities may store medicines for veterinary use without obtaining a license for performance of pharmaceutical activities, if such medicines are used solely in breeding, nurturing, managing and treating animals.

(as amended by Federal Law of October 22, 2014 No. 313-FZ)

2. The regulations for storage of medicines shall be approved by the appropriate authorized federal executive body.

3. The storage of the narcotic medicines, psychotropic medicines and radiopharmaceutical medicines shall be performed in compliance with the legislation of the Russian Federation.

#### Article 58.1. Strict Record Keeping

(introduced by Federal Law of December 25, 2012 No. 262-FZ)

1. A list of medicines for medical use subject to strict record keeping shall be approved by the authorized federal executive body.

2. The procedure for inclusion of medicines for medical use into the list of medicines for medical use subject to strict record keeping shall be established by the authorized federal executive body in agreement with the federal executive internal affairs body.

(as amended by Federal Law of July 3, 2016 No. 305-FZ)

3. Strict records of medicines for medical use shall be kept by manufacturers of the medicines, wholesalers of medicines, pharmacy organizations, sole traders licensed to perform pharmaceutical activities or medical activities and medical organizations carrying out circulation of medicines for medical use by registration of any transactions relating to the circulation thereof which result in any change in the quantity and (or) conditions of such substances in special registers of transactions relating to the circulation of medicines for medical use (hereinafter "special registers").

4. Rules for registration of transactions relating to the circulation of medicines for medical use included into the list of medicines for medical use subject to strict record keeping in special registers and rules for keeping and storing special registers shall be approved by the authorized federal executive body.

5. Compliance with the rules for registration of transactions relating to the circulation of medicines for medical use included into the list of medicines for medical use subject to strict record keeping in special registers and rules for keeping and storing special registers shall be controlled by authorized federal executive bodies and executive bodies of constituent entities of the Russian Federation performing licensing of production of medicines and pharmaceutical activities within the framework of licensing control.



## **Chapter 11. DESTRUCTION OF MEDICINES**

### Article 59. Reasons and Procedure for Destruction of Medicines

1. Poor quality medicines and counterfeit medicines are subject to be withdrawn from circulation and to be destroyed in the order established by the Government of the Russian Federation. The basis for the destruction of the medicines shall be the decision of the owner of the medicines, the decision of the competent authorized federal executive body or the court decision.

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

2. Infringing medicines are subject to be withdrawn from circulation and to be destroyed by the court decision. The procedure of the medicines destruction shall be specified by the Government of the Russian Federation.

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

3. Infringing medicines, poor-quality medicines and counterfeit medicines destruction expenses shall be reimbursed by the owner of the mentioned medicines.

4. The owner of the medicines shall submit a document or its duly authenticated copy that testifies to the destruction of the medicines to the authorized federal executive body.

5. The respective authorized federal executive body, which has taken decision on the destruction of the medicines, shall supervise the destruction thereof.

6. Destruction of the medicines shall be performed by organizations licensed to carry out such activities at specially equipped sites, special grounds and in specially equipped rooms and meeting the requirements in the field of the environment protection in accordance with the Laws of the Russian Federation.

7. Narcotic medicines, psychotropic medicines and radiopharmaceutical medicines shall be destroyed in compliance with the legislation of the Russian Federation.

## **Chapter 12. STATE REGULATION OF PRICES FOR MEDICINAL PRODUCTS FOR MEDICAL USE**

### Article 60. State Regulation of Prices for Medicinal Products for Medical Use

The state regulation of prices for medicinal products for medical use shall be exercised by means of:

1) approval by the Government of the Russian Federation of a list of vital and essential medicinal products created in accordance with the established procedure on the basis of the complex assessment of medicinal products, including analysis of information on comparative clinical efficacy and safety of the medicine, evaluation of economic implications of the use of the medicine and studying additional consequences of the use of the medicine;

(sub-clause 1 as amended by Federal Law of December 22, 2014 No. 429-FZ)

2) approval of the methodology for determining the manufacturers' maximum ex-works prices for the medicinal products included in the list of vital and the essential medicinal products and introduction of mechanisms for creating a system of reference prices;

(as amended by Federal Law of December 22, 2014 No. 429-FZ and Federal Law of June 06, 2019 No. 134-FZ)

3) state registration of the manufacturers' maximum ex-works prices for the medicinal products included in the list of vital and essential medicinal products;

(as amended by Federal Law of June 06, 2019 No. 134-FZ)

4) maintaining of the state register of the manufacturers' maximum ex-works prices for the medicinal products included into the list of vital and essential medicinal products;

5) approval of the methodology for determination by executive bodies of the Russian Federation constituent entities of maximum wholesale and maximum retail mark-ups to the actual ex-

works prices of manufacturers of medicinal products for the medicinal products included into the list of vital and essential medicinal products;

6) determination of maximum wholesale and maximum retail mark-ups to the actual ex-works prices of manufacturers of medicinal products for the medicinal products included into the list of vital and essential medicinal products;

7) approval of the procedure for giving mandatory instructions to the executive bodies of the Russian Federation constituent entities to bring their decisions on determination of maximum wholesale and maximum retail mark-ups to the actual ex-works prices of manufacturers of medicinal products for the medicinal products included into the list of vital and essential medicinal products into compliance with the legislation of the Russian Federation in the order established by the Government of the Russian Federation, if such decisions were taken in violation of the legislation of the Russian Federation;

8) addressing executive bodies of the Russian Federation constituent entities by an authorized federal executive body with mandatory instructions to bring the decisions on determination of maximum wholesale and maximum retail mark-ups to the actual ex-works prices for the medicinal products included into the list of vital and essential medicinal products taken in violation of the laws of the Russian Federation into compliance with the legislation of the Russian Federation;

9) federal government supervision in the sphere of circulation of medicines and regional government supervision over fixing the prices for the medicines shall be carried out by the authorized federal executive bodies and executive bodies of constituent entities of the Russian Federation in accordance with their competence and under the procedure stipulated by the Government of the Russian Federation;

(sub-clause 9 as amended by Federal Law of June 25, 2012 No. 93-FZ)

10) application of sanctions for violation of the pricing procedure for the medicinal products included in the list of vital and the essential medicinal products as provided for by the legislation of the Russian Federation.

(as amended by Federal Law of December 27, 2019 No.475-FZ)

Article 61. State Registration and Reregistration of Manufacturers' Maximum Ex-Works Prices for Medicinal Products Included in the List of Vital and Essential Medicinal Products

(as amended by Federal Law of June 06, 2019 No.134-FZ)

1. Maximum ex-works prices for medicinal products included in the list of vital and essential medicinal products shall be subject to state registration in the manner established by the Government of the Russian Federation, based on an application submitted to the authorized federal executive body by the holder or owner of the registration certificate for the medicinal product (a person authorized by it).

2. The registered manufacturer's ex-works price for a medicinal product included in the list of vital and essential medicinal products may be re-registered upwards once in a calendar year based on an application submitted to the authorized federal executive body before October 1 of each year by the holder or owner of the registration certificate for the medicinal product (a person authorized by it).

3. The registered manufacturer's ex-works price for a medicinal product included in the list of vital and essential medicinal products may be re-registered downwards based on an application submitted to the authorized federal executive body by the holder or owner of the registration certificate for the medicinal product (a person authorized by it).

4. The holder or owner of the registration certificate for the medicinal product (a person authorized by it) shall submit to the authorized federal executive body an application for the downwards reregistration of the manufacturer's maximum ex-works price for the medicinal product included in the list of vital and essential medicinal products in the following cases:

1) the price for the medicinal product in the foreign currency has been reduced in the manufacturer's country and (or) in countries where the medicinal product is registered and (or) to which it is supplied by the manufacturer;

2) prices for the reference medicinal products have been reduced in accordance with paragraph 1 of this part (for relevant generic, bio-analog (biosimilar) medicinal products);

3) the maximum ex-works price for the first foreign-made generic, bio-analog (biosimilar) medicinal product exceeds the manufacturer's maximum ex-works price for the second generic, bio-analog (biosimilar) medicinal product calculated in accordance with the methodology approved by the Government of the Russian Federation;

4) the maximum ex-works price for the first generic, bio-analog (biosimilar) medicinal product of the manufacturer who is a member of the Eurasian Economic Union exceeds the maximum ex-works price for the second generic, bio-analog (biosimilar) medicinal product of the manufacturer who is a member of the Eurasian Economic Union calculated in accordance with the methodology approved by the Government of the Russian Federation.

5. The procedure for re-registering registered ex-works prices for medicinal products included into the list of vital and essential medicinal products in the cases provided by parts 2-4 of this Article shall be established by the Government of the Russian Federation.

6. The economic analysis of the manufacturer's maximum ex-works price for the medicinal product included in the list of vital and essential medicinal products, at its state registration or reregistration, shall be performed by the authorized federal executive body performing the functions of adopting normative legal acts and controlling compliance of the laws governing state regulation of prices (tariffs) for goods (services).

7. Maximum ex-works prices specified in parts 1 and 2 of this Article, at its state registration or reregistration, shall be calculated in accordance with the methodology approved by the Government of the Russian Federation, which takes into account, in particular:

1) maintenance of the balance of interests of consumers of the medicinal products included in the list of vital and essential medicinal products and manufacturers of the medicinal products included in list of vital and essential medicinal products;

2) the actual ex-works price for the medicinal products in the Russian Federation, the price of import of the medicinal products into the Russian Federation and prices for similar medicinal products being in circulation in the Russian Federation;

3) expenses of the manufacturer of the medicinal product relating to the production and sale of the medicinal product;

4) the price for the medicinal product, its price in the manufacturer's country and in countries in which the medicinal product is registered and (or) to which it is supplied by the manufacturer.

8. It is not allowed to sell and dispense medicinal products included in list of vital and essential medicinal products for which manufacturers of medicinal products have not registered a maximum ex-works price, and manufacturers are not permitted to sell medicinal products at prices exceeding registered or re-registered maximum ex-works prices for medicinal products including value-added tax.

9. The peculiarities of state regulation of maximum ex-works prices for medicinal products included in the list of vital and essential medicinal products, depending on economic and (or) social criteria (changes in the conditions, procedure and cost of production of medicinal products, use of new forms, methods and means of state regulation of prices for medicinal products, including on the basis of a reference pricing mechanism, changes in the procedure for provision of medical aid and other changes), shall be established by the Government of the Russian Federation.

#### Article 62. State Register of Manufacturers' Maximum Ex-Works Prices for Medicinal Products Included into the list of Vital and Essential Medicinal Products

1. The registered or re-registered manufacturers' maximum ex-works prices for the medicinal products included into the list of vital and essential medicinal products are subject to inclusion into the

state register of manufacturers' maximum ex-works prices for the medicinal products included into the list of vital and essential medicinal products.

(as amended by Federal Law of June 06, 2019 No.134-FZ)

2. The state register of manufacturers' maximum ex-works prices for the medicinal products included into the list of vital and essential medicinal products shall contain the following information:

1) the name of the holder or owner of the marketing authorisation for the medicinal product, the name of the manufacturer of the medicinal product, information on registration of the holder or owner of the marketing authorisation for the medicinal product, information on registration of the manufacturer of the medicinal product for medical use as a taxpayer in the country of registration (for Russian legal entities — taxpayer identification number (INN), for foreign legal entities — country of registration, name of registering body, registration number, taxpayer's code in the country of registration (incorporation) or its analogue), location of manufacturing sites used in the manufacture of the medicinal product specifying the manufacturing stage;

(sub-clause 1 as amended by Federal Law of December 28, 2017 No. 425-FZ)

2) name of the medicinal product (international nonproprietary, or modified, or chemical and trade names);

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

3) number of the registration certificate for the medicinal product;

4) pharmaceutical form with indication of the dosage rate of the medicinal product and its quantity in the secondary (consumer) package and completeness;

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

5) registered maximum ex-works medicinal product price in rubles;

(as amended by Federal Law of December 27, 2019 No. 475-FZ)

6) date and number of the order of the authorized federal executive body for state registration or re-registration of the maximum ex-works price for the medicinal product included into the list of vital and essential medicinal products;

(as amended by Federal Law of December 22, 2014 No. 429-FZ and Federal Law of June 06, 2019 No. 134-FZ)

6.1) the effective date of the order of the authorized federal executive body on state registration or reregistration of the manufacturer's maximum ex-works price for a medicinal product included in the list of vital and essential medicinal products;

(sub-clause 6.1 introduced by Federal Law of June 06, 2019 No. 134-FZ)

7) bar code applied to the secondary (consumer) packaging of the medicinal product;

(sub-clause 7 introduced by Federal Law of December 22, 2014 No. 429-FZ)

8) code of the medicinal product in accordance with the Anatomical Therapeutic Chemical Classification System recommended by the World Health Organization.

(sub-clause 8 introduced by Federal Law of December 22, 2014 No. 429-FZ)

3. The state registration or re-registration of the maximum ex-works prices for the medicinal products included into the list of vital and essential medicinal products, as well as the maintenance of the state register of the manufacturers' maximum ex-works prices for the medicinal products included into the list of vital and essential medicinal products shall be exercised in the order prescribed by the Government of the Russian Federation.

(as amended by Federal Law of June 06, 2019 No.134-FZ)

Article 63. Determination by Executive Bodies of Constituent Entities of the Russian Federation of Maximum Wholesale and Maximum Retail Mark-Ups to Actual Ex-Works Prices of Manufacturers of Medicinal Products for Medicinal Products Included in the List of Vital and the Essential Medicinal Products

(as amended by Federal Law of December 27, 2019 No. 475-FZ)

1) Authorities of members of the Russian Federation establish limitations of wholesale margins and limitations of retail premiums for effective price of medicinal products (excluding value added tax) set by medicinal product manufacturers, included in the list of vital and essential medicinal products

according to the federal authority method of setting limitations of wholesale margins and limitations of retail premiums for effective price of medicinal products set by medicinal product manufacturers, included in the list of vital and essential medicinal products under the procedure established by the Government of the Russian Federation. Projects of decisions by authorities of members of the Russian Federation about setting and (or) changing limitations of wholesale margins and limitations of retail premiums for effective price of medicinal products set by medicinal product manufacturers, included in the list of vital and essential medicinal products are subject to agreement with the federal authority implementing acceptance of regulatory laws and legislation monitoring in government regulation of price (fare) of goods (services) in order established by the Government of the Russian Federation. (as amended by Federal Law of July 13, 2015 No. 241-FZ and Federal Law of December 27, 2019 No. 475-FZ)

2) Wholesaler of medicine organizations, pharmacy institutions, sole proprietors who have pharmaceutical license, medical organizations who have pharmaceutical license, and their isolated units (dispensaries, feldsher and feldsher-midwife stations, centers (departments) of general (family) practice) located in rural areas, where there are no pharmacy institutions, provide the implementation of medicinal products included in the list of vital and essential medicinal products using the price which is formed in accordance with order established by the Government of the Russian Federation, and which limit (excluding value added tax) should not be higher than effective price set by medicinal product manufacturers, not exceeding unregistered or reregistered limit price of manufacturer (at the date of medicinal product implementation by manufacturer), and amount of wholesale margin and (or) amount of retail premium not exceeding limitations of wholesale margins and (or) limitations of retail premiums respectively established in constituent entity of the Russian Federation. (as amended by Federal Law of December 27, 2019 No. 475-FZ)

3) Authorities of members of the Russian Federation post the information in the website "Internet" about registered limit price on medicinal products of manufacturers included in the list of vital and essential medicinal products, about established in the constituent entity of the Russian Federation limitations of wholesale margins and (or) limitations of retail premiums for effective price of medicinal products set by medicinal product manufacturers, included in the list of vital and essential medicinal products, and also about the sum of the registered limit price on medicinal products of manufacturers included in the list of vital and essential medicinal products, established limitations of wholesale margins and limitations of retail premiums and value added tax in the constituent entity of the Russian Federation. Information provided by this part also should be in pharmacy institutions in a way that is accessible to all concerned and updated as it is posted in the website "Internet" by authorities of the members of the Russian Federation. (as amended by Federal Law of December 27, 2019 No. 475-FZ)

4. ceased to be in force as of March 01, 2020 (Federal Law of December 27, 2019 No. 475-FZ).

### **Chapter 13. EFFICACY AND SAFETY MONITORING OF MEDICINAL PRODUCTS BEING IN CIRCULATION IN THE RUSSIAN FEDERATION**

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

#### Article 64. Pharmacovigilance

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

1. The medicinal products being in circulation in the Russian Federation shall be subject to the efficacy and safety monitoring in order to reveal possible negative consequences of their use, idiocracy and to prevent and protect medical staff, veterinary specialists, patients and animal owners against the use of such medicinal products.

(as amended by Federal Law of August 02, 2019 No. 297-FZ)

2. Pharmacovigilance shall be performed by the authorized federal executive body.

3. Subjects of circulation of medicines shall, in the manner established by the authorized

federal executive body, notify the authorized federal executive body about any side effects, adverse drug reactions, serious adverse drug reactions, unexpected adverse drug reactions in the use of medicinal products, idiosyncrasy, non-efficacy of medicinal products and any other facts and circumstances posing a threat to the life or health of a human or animal when using medicinal products and discovered at all stages of circulation of medicinal products in the Russian Federation and other countries.

4. Holders or owners of registration certificates for medicinal products, legal entities in the name of which approvals for the conduct clinical trials in the Russian Federation are issued or other legal entities authorized by the above persons shall, within the framework of assurance of safety of medicinal products, in accordance with the procedure established by the relevant authorized federal executive body, carry out acceptance, accounting, processing, analysis and storage of notifications about side effects, adverse drug reactions, serious adverse drug reactions, unexpected adverse drug reactions in the use of medicinal products, particularities of its interaction with other medicinal products, idiosyncrasy, and any other facts and circumstances posing a threat to the life or health of a human or animal when using medicinal products or affecting the change in correlation between the anticipated benefit and possible risk from the use of the medicinal products, received by them from subjects of circulation of medicines and government authorities.

5. In case of discovery of information on serious adverse drug reactions and unexpected adverse drug reactions in the use of medicinal products, peculiarities of their interaction with other medicinal products, idiosyncrasy, and any other facts and circumstances affecting the change in correlation between the anticipated benefit and possible risk from the use of the medicinal products, holders or owners of registration certificates of medicinal products, legal entities in the name of which approvals for the conduct clinical trials in the Russian Federation are issued or other legal entities authorized by the above persons shall take measures aimed to eliminate negative consequences of the use of such medicinal products, to prevent harm to the life or health of a human or animal, to protect them from the use of such medicinal products, and to collect additional information on efficacy and safety of such medicinal products.

6. For a failure to provide, or for concealing, information required by clause 3 of this Article, holders or owners of registration certificates of medicinal products, legal entities in the name of which approvals for the conduct clinical trials in the Russian Federation are issued or other legal entities authorized by the above persons as well as officials obtained this information by the nature of their professional activities shall be liable in accordance with the legislation of the Russian Federation.

7. If the authorized federal executive body obtains, within the framework of pharmacovigilance, any evidence of non-compliance of the medicinal product with the established requirements or any information on inconsistency of data on efficacy and safety of the medicinal product with data on the medicinal product contained in its Package Leaflet (including those identified in the course of pharmacovigilance performed by control and supervision bodies of foreign countries), the authorized federal executive body shall consider a matter on suspension of the use of such medicinal product in the manner established by this federal executive body.

#### Article 65. Suspension of a Medicinal Product

(as amended by Federal Law of December 22, 2014 No. 429-FZ)

1. In case of receipt of information on adverse reactions when using a medicinal product, which are not specified in the Package Leaflet for a medicinal product, severe adverse reactions, on particularities of its interaction with other medicinal products, which may constitute a threat to the life or health of humans or animals, as well as inconsistency of the medicinal product efficacy and safety information with the information on the medicinal product contained in the Package Leaflet, including information obtained from authorized authorities of foreign countries, when exchange of such information is performed in accordance with agreements between the authorized federal executive body and the authorized authorities of foreign countries, the authorized federal executive

body shall consider the question of possible suspension of circulation of that medicinal product in the order established by the authorized federal executive body.

2. In case of a failure to perform, or improper performance of, obligations provided by clauses 3 and 4 of Article 64 of this Federal Law by holders or owners of registration certificates for medicinal products, legal entities in the name of which approvals for the conduct clinical trials in the Russian Federation are issued or other legal entities authorized by the above persons, or if the relevant authorized federal executive body has submitted a conclusion on inaccuracy of results of a clinical trial of the medicinal product for medical use, based on the results of inspection of the medical organization conducted the clinical trial with violation of good clinical practice rules and resulted in obtaining inaccurate results, or in case of a failure to fulfill an order issued by the authorized federal executive body based on the results of selective control of quality of the medicinal product, the authorized federal executive body shall consider a matter on suspension of the use of such medicinal product in the manner established by this federal executive body.

3. In the event that the authorized federal executive body receives information on non-compliance of the manufacturer of medicines with the good manufacturing practice guidelines and (or) on violation of license requirements discovered during inspection of the manufacturer of medicines or in the course of exercising license control in the field of manufacture of medicines, which have resulted or may result in the manufacture of medicinal products for medical use that have caused or may cause harm to the life or health of the population, it shall consider the matter of suspension of the use of the medicinal products for medical use in accordance with the procedure established by this body in the following cases:

1) the composition and (or) the manufacturing process of the medicinal product for medical use (with a description of manufacturing stages) are different from those claimed in the registration dossier;

2) the medicinal product for medical use is manufactured at a manufacturing site not specified in the registration dossier;

3) the manufacturer of medicines has no documents evidencing quality compliance of the medicinal product for medical use to be placed on the market with the requirements established at its state registration;

4) the manufacturer of medicines fails to eliminate, within the period agreed with the relevant authorized federal executive body, violations of the requirements of the good manufacturing practice guidelines and (or) license requirements that have been discovered during inspection of the manufacturer of medicines or in the course of exercising license control in the field of manufacture of medicines and have resulted or may result in the manufacture of medicinal products for medical use that have caused or may cause harm to the life or health of the population.

(clause 3 introduced by Federal Law of June 04, 2018 No. 140-FZ)

4. In the event that the authorized federal executive body possesses information on non-compliance of the manufacturer of medicines with the good manufacturing practice guidelines and (or) on violation of license requirements discovered during inspection of the manufacturer of medicines or in the course of exercising license control in the field of manufacture of medicines, which have resulted or may result in the manufacture of medicinal products for veterinary use that have caused or may cause harm to the life or health of animals, it shall consider the matter of suspension of the sale and use of the medicinal products for veterinary use in accordance with the procedure established by this body in the following cases:

1) the composition and (or) the manufacturing process of the medicinal product for veterinary use (with a description of manufacturing stages) are different from those claimed in the registration dossier;

2) the medicinal product for veterinary use is manufactured at a manufacturing site not specified in the registration dossier;

3) the manufacturer of medicines has no documents evidencing quality compliance of the medicinal product for veterinary use to be placed on the market with the requirements established at its state registration;

4) the manufacturer of medicines fails to eliminate, within the period agreed with the relevant

authorized federal executive body, violations of the requirements of the good manufacturing practice guidelines and (or) license requirements that have been discovered during inspection of the manufacturer of medicines or in the course of exercising license control in the field of manufacture of medicines and have resulted or may result in the manufacture of medicinal products for veterinary use that have caused or may cause harm to the life or health of animals.  
(clause 4 introduced by Federal Law of June 04, 2018 No. 140-FZ)

*From January 01, 2023 Article 65 should be supplemented with part 5, 6 Federal Law of December 27, 2019 No. 475-FZ.*

5. If marketing authorization holder or owner of medicinal product (or another legal authority) does not provide documents (information of the documents) to the federal authority necessary for registration profile expertise on medicinal product by expert council of expert institution in order to determine the interchangeability of medicinal product for medical use or if documents (information of the documents) are not fully provided, documents do not contain complete list of necessary information or unreliable information is provided, and also if the report is not presented which is stated in part 1.5 of the Article 30 of this Federal Law, the federal authority considers the issue about application suspend of this medicinal product for medical use for six months.

6. If during six months since the date of application suspend of this medicinal product for medical use marketing authorization holder or owner of medicinal product (or another legal authority) does not provide documents (information of the documents) to the federal authority necessary for registration profile expertise on medicinal product by expert council of expert institution in order to determine the interchangeability of medicinal product for medical use, and also if the report is not presented which is stated in part 1.5 of the Article 30 of this Federal Law, the federal authority will decide the cancellation of state registration of this medicinal product and its exclusion out of the state registry of medicines.

Article 66. Information about pharmacovigilance results

(as amended by Federal Law of December 27, 2019 No. 475-FZ)

Federal authority implementing pharmacovigilance according to its results in the official website "Internet" posts the information about:

- 1) identification of new confirmed data about side effects, adverse reactions, serious adverse reactions, unexpected adverse reactions during medicinal product use including the impact on risk–benefit ratio of this medicinal product use;
- 2) decisions taken about amendments in the instruction for use of medicinal product, about suspend the medicinal product use, about redemption of medicinal products or resumption of medicinal product use.

#### **Chapter 14. INFORMATION ON MEDICINAL PRODUCTS. SYSTEM FOR MONITORING MOVEMENT OF MEDICINAL PRODUCTS FOR MEDICAL USE**

Article 67. Information on Medicinal Products. System for Monitoring Movement of Medicinal Products for Medical Use

(as amended by Federal Law of December 28, 2017 No. 425-FZ)

1. Information on prescription medicinal products may only be featured in specialized printed publications designated for medical, pharmaceutical and veterinary professionals. Information on medicinal products for medicines circulation professionals may be presented in the form of treatises, reference books, research papers, reports delivered at congresses, conferences, symposia, academic board meetings, as well as package leaflets for medicinal products.



(as amended by Federal Law of August 02, 2019 No. 297-FZ)

2. Information on over-the-counter medicinal products may be featured in publications and announcements in the mass media, specialized and general printed publications, Package Leaflets and other publications on subjects of medicines circulation. The advertising materials for over-the-counter medicinal product shall conform to the Package Leaflet for a medicinal product.

3. It is allowed to use any such physical storage media for information on medicinal products as will enable storage, transfer and use of this information without corruption;

ConsultantPlus: note.

Clause 4 of Article 67 becomes effective on 1 July 2020.

4. For the purposes of identification of packaging of medicinal products for medical use, manufacturers of medicines shall, in the manner prescribed by the laws of the Russian Federation, apply to the primary packaging (for medicinal products for medical use with no secondary packaging) and secondary (consumer) packaging of medicinal products for medical use means of identification, with the exception of medicinal products for medical use manufactured for clinical trials, export, and medicinal products for medical use specified in Parts 5 and 8 of Article 13 of this Federal Law; (clause 4 introduced by Federal Law of December 28, 2017 No. 425-FZ)

5. The characteristics of a means of identification and the procedure for its application as well as requirements for the structure and format of information, which the means of identification contains, shall be determined by the Government of the Russian Federation; (clause 5 introduced by Federal Law of December 28, 2017 No. 425-FZ)

6. The procedure for the creation, development, putting into operation, operation and withdrawal from operation of the system for monitoring the movement of medicinal products for medical use, procedure for the provision of information contained in the system for monitoring of the movement of medicinal products for medical use, and the procedure for the interaction of this system with other state information systems and information systems of legal entities and individual entrepreneurs specified in Parts 7 and 10 of this Article shall be established by the Government of the Russian Federation. Operators of the system for monitoring of the movement of medicinal products for medical use are the federal executive body and (or) an organisation authorised by the Government of the Russian Federation; (clause 6 introduced by Federal Law of December 28, 2017 No. 425-FZ)

ConsultantPlus: note.

Clause 7 of Article 67 becomes effective on 1 July 2020.

7. Legal entities and individual entrepreneurs engaged in the manufacture, storage, import into the Russian Federation, dispensation, sale, transfer, use and destruction of medicinal products for medical use shall ensure, in the manner and composition established by the Government of the Russian Federation with regard to activities performed by them, that information about medicinal products for medical use is entered in the system for monitoring of the movement of medicinal products for medical use; (clause 7 introduced by Federal Law of December 28, 2017 No. 425-FZ)

7.1. Medicinal products for medical use intended for people with hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, lymphoid, hematopoietic and related tissue malignancies, multiple sclerosis, for people after transplantation of the organs and (or) tissues performed before December 31, 2019, and also other medicinal products for medical use manufactured before July 1, 2020 are to be stored, transported, released, implemented, transferred, applied without means of identification before their expiry date. (sub-clause 7.1 as amended by Federal Law of December 27, 2019 No. 462-FZ)

8. Organisation of information interaction of the system for monitoring of the movement of medicinal products for medical use with other state information systems shall be ensured, inter alia, through the infrastructure that provides information and technological interaction among information systems used for provision of state and municipal services and performance of state and municipal functions in electronic form; (clause 8 introduced by Federal Law of December 28, 2017 No. 425-FZ)

9. Public information contained in the system for monitoring of the movement of medicinal products for medical use shall be posted in the information and telecommunication system Internet (including in the form of open data) in the manner established by the Government of the Russian Federation;

(clause 9 introduced by Federal Law of December 28, 2017 No. 425-FZ)

10. Manufacturers of medicines shall receive information on batches of medicinal products manufactured by them and marketed in the Russian Federation from the system for monitoring of the movement of medicinal products for medical use free of charge;

(clause 10 introduced by Federal Law of December 28, 2017 No. 425-FZ)

ConsultantPlus: note.

Clause 11 of Article 67 becomes effective on 1 July 2020.

11. For manufacture or sale of medicinal products for medical use without application of means identification or in violation of the procedure for their application or for untimely entering of data in the system for monitoring of the movement of medicinal products for medical use or entering of inaccurate data, legal entities and individual entrepreneurs specified in Parts 4 and 7 of this Article shall be liable in accordance with the laws of the Russian Federation;

(clause 11 introduced by Federal Law of December 28, 2017 No. 425-FZ)

12. The Government of the Russian Federation has the right to establish the specifics of the implementation of the system for monitoring the movement of medicinal products for medical use, including timeframes for its implementation, in respect of medicinal products for medical use included in the list of vital and essential medicinal products, medicinal products intended for people with hemophilia, cystic fibrosis, pituitary abscess, Gaucher's disease, malignant tumours of lymphoid, hematopoietic and related tissues, multiple sclerosis, individuals after transplantation of organs and (or) tissues, and other medicinal products for medical use."

(clause 12 introduced by Federal Law of December 28, 2017 No. 425-FZ)

### **Chapter 14.1. LIMITATIONS IMPOSED ON ORGANIZATIONS PERFORMING ACTIVITIES IN CIRCULATION OF MEDICINES**

(introduced by Federal Law of November 25, 2013 No. 317-FZ)

#### Article 67.1. Limitations Imposed in Performing Activities in Circulation of Medicines

1. Organizations engaged in development, production and (or) sale of medicinal products for medical use, organizations having rights to use a brand name of a medicinal product for medical use, wholesalers of medicines, pharmacy organizations (their representatives, other individuals and legal entities performing activities on behalf of such organizations), in respect of healthcare professionals and heads of medical institutions, may not:

1) give gifts, pay any money (other than remuneration under agreements in the conduct of clinical trials of medicinal products for medical use, remunerations relating to the performance by the healthcare professional of educational and (or) scientific activities), including payment for entertainment, holidays, travel to a place of holiday, or involve such persons in entertainment activities performed at expense of the above organizations;

2) make agreements for prescription or recommendation of medicinal products for medical use to patients (other than agreements for the conduct of clinical trials of medicinal products for medical use);

3) provide samples of medicinal products for medical use for the purpose of giving out to patients (unless such activities are related with the conduct of clinical trials of medicinal products for medical use);

4) provide inaccurate and (or) incomplete information on medicinal products for medical use;

5) visit them at workplaces during working hours, unless such activities are related with the conduct of clinical trials of medicinal products for medical use, with participation in the manner

established by the head of the medical institution in meetings of healthcare professionals and other events aimed to increase their professional level or provision of information relating with monitoring of safety of medicinal products;

6) encourage them to prescribe medicinal products for medical use using forms containing information of advertising nature or prescription pads preprinted with the name of a medicinal product for medical use.

2. Organizations specified in the first abstract of clause 1 of this Article and representatives thereof, in respect of pharmacy employees and heads of pharmacy organizations, may not:

1) give gifts, pay any money, including payment for entertainment, holidays, travel to a place of holiday, or involve such persons in entertainment activities performed at expense of the above organizations;

2) provide samples of medicinal products for medical use for the purpose of giving out to the population;

3) make agreements for proposal of particular medicinal products for medical use to the population;

4) provide inaccurate and (or) incomplete information on medicinal products for medical use, including those having an equivalent international non-proprietary name.

Article 67.2. Requirements for the Organization and Conduct of Scientific Events, Other Events Aimed to Increase the Professional Level of Healthcare Professionals or to Provide Information Relating to Monitoring of Safety of Medicinal Products

1. When holding scientific events, other events aimed to increase the professional level of healthcare professionals or to provide information relating to monitoring of safety of medicinal products arranged by organizations specified in the first abstract of clause 1 of Article 67.1 of this Federal Law or their representatives and (or) financed by these organizations or their representatives, it is prohibited to prevent other organizations which produce or sell medicinal products for medical use with a similar mechanism of pharmacological effect from participation in such events or to create discriminating conditions for certain participants compared to other participants, namely:

1) provide different time for participants' speeches, different space for demonstration of samples of medicinal products for medical use or advertising materials about medicinal products for medical use on expositions and stands, unless such conditions are envisaged by agreements of these organizations and their representatives for financing of such events and arise from different expenses of participants for their organization;

2) establish an amount of contribution of participants of events specified in the first abstract of this clause, which exceeds the amount of expenses incurred in relation to the organization of such events and resulting in unjustified limitation of their participants.

2. Organizations specified in the first abstract of clause 1 of Article 67.1 of this Federal Law, their representatives performing organization and (or) financing of events specified in clause 1 of this Article, must provide access to information on the date, place and time of the events, plans, programs of the events and topics to be discussed, composition of participants by posting relevant information on their official websites at least two months prior to holding such events.

3. Information on events specified in clause 1 of this Article shall be referred to the federal executive body performing control and supervision functions in healthcare within the period specified in clause 2 of this Article, for its further posting on the official website of such federal executive body.

**Chapter 15. LIABILITY FOR VIOLATION OF LEGISLATION  
OF THE RUSSIAN FEDERATION IN CIRCULATION OF MEDICINES  
AND COMPENSATION FOR HARM TO HUMAN HEALTH  
CAUSED BY ADMINISTRATION OF MEDICINAL PRODUCTS**

Article 68. Liability for Violation of Legislation of the Russian Federation in Circulation of Medicines

1. Violation of the legislation of the Russian Federation for medicines circulation shall entail the responsibility in accordance with the legislation of the Russian Federation.  
(as amended by Federal Law of December 22, 2014 No. 429-FZ)

2. For a failure to provide or untimely provision of information and (or) documents, or provision of inaccurate information and (or) documents required by this Federal Law subjects of circulation of medicines shall be liable in accordance with the legislation of the Russian Federation.  
(clause 2 introduced by Federal Law of December 22, 2014 No. 429-FZ, as amended by Federal Law of June 04, 2018 No. 140-FZ)

Article 69. Compensation for Harm to Human Health Caused by Administration of Medicinal Products

1. The manufacturer of the medicinal product shall be obliged to compensate for the harm to human health caused by the administration of the medicinal product provided it is proved that:

1) the medicinal product was used for its intended purpose in accordance with the Package Leaflet for a medicinal product and the harmful action of the medicinal product was due to introduction to the civil circulation of a poor quality medicinal product;

2) the damage to health was caused by administration of the medicinal product through misleading Package Leaflet for a medicinal product issued by the manufacturer of the medicinal product.

2. If the damage to health was caused by administration of a medicinal product that became a substandard medicinal product due to a breach of storage procedure for medicines, the regulations for wholesaling of medicines, the rules for dispensation of medicinal products, the rules for manufacture and dispensation of medicinal products, then the compensation shall be provided by the medicinal product wholesaler, pharmacy institution, sole trader having a pharmaceutical license or a medical license, by health care organization (its separate subdivision (ambulance stations, paramedic's and paramedical-obstetric centers, centers (departments) of general (family) practice) located in rural settlements which have no pharmacy offices) responsible for releasing the medicinal product for distribution, or for the dispensation thereof.

(as amended by Federal Law of November 25, 2013 No. 317-FZ)

3. Compensation for harm to human health caused by administration of medicinal products or illegal actions by subjects of medicines circulation is provided in accordance with the Legislation of the Russian Federation.

**Chapter 16. FINAL PROVISIONS**

Article 70. Declaring Inoperative Certain Legal Acts (Provisions of Legal Acts) of the Russian Federation

To declare inoperative:

1) Federal Law of June 22, 1998, No. 86-FZ On Medicines (Collection of Legislative Acts of the Russian Federation 1998, No. 26, Art. 3006);

2) Federal Law of January 02, 2000, No. 5-FZ On Entering Amendments to Federal Law On Medicines (Collection of Legislative Acts of the Russian Federation 2000, No. 2, Art. 126);

3) Article 40 of Federal Law of January 10, 2003. No. 15-FZ On Entering Amendments to Certain Legal Acts of the Russian Federation in Connection with Adoption of Federal Law On Licensing Separate Activities (Collection of Legislative Acts of the Russian Federation 2003, No. 2, Art. 167);

4) Article 31 of Federal Law of June 30, 2003, No. 86-FZ On Entering Amendments to Certain Legal Acts of the Russian Federation, Declaring Inoperative Separate Legal Acts of the Russian Federation, Provision of Separate Guarantees to Employees of Bodies of Internal Affairs, Authorities Responsible for Control Over Narcotic Products and Psychotropic Substances Circulation and Tax Police Federal Authorities to Be Abolished in Connection with Taking Measures to Improve the State Administration (Collection of Legislative Acts of the Russian Federation 2003, No. 27, Art. 2700);

5) Article 101 of Federal Law of August 22, 2004, No. 122-FZ On Entering Amendments to Legal Acts of the Russian Federation and Declaring Inoperative Certain Legal Acts of the Russian Federation in Connection with Adoption of Federal Laws On Making Amendments to Federal Law On General Principles of Organization of Legislative (Representative) and Executive Public Authorities of the Russian Federation Constituent Entities and On General Principles of Organization of Local Government in the Russian Federation (Collection of Legislative Acts of the Russian Federation 2004, No. 35, Art. 3607);

6) Article 28 of Federal Law of December 18, 2006, No. 231-FZ On Promulgation of Part 4 of the Civil Code of the Russian Federation (Collection of Legislative Acts of the Russian Federation 2006, No. 52, Art. 5497).

#### Article 71. Enactment of This Federal Law

1. This Federal Law comes into force from September 01, 2010.

2. Medicines registered before the date of enactment of this Federal Law are subject to inclusion into the state registers of the medicines introducing the mentioned in clause 1 of Article 33 hereof information of these medicines without repeated procedure of the state registration of the medicinal products.

3. The state registration of the medicinal products except medicinal products for medical use submitted for the mentioned registration prior to the effective date of this Federal Law shall be exercised in accordance with this Federal Law on the basis of the documents and the data provided before coming into force date hereof.

(as amended by Federal Law of October 11, 2010 No. 271-FZ)

3.1. State registration of medicinal products for medical use submitted for the mentioned registration prior to the effective date of this Federal Law, and state registration of medicinal products for medical use submitted for expert examination of medicinal products prior to the effective date of this Federal Law in order to subsequent state registration, shall be exercised in accordance with this Federal Law on the basis of the documents and the data provided before coming into force date hereof and the statement of the state registration of the medicinal product in accordance with this Federal Law, documents and data, required for the state registration of the medicinal product in accordance with this Federal Law and provided by the manufacturer medicinal drugs or authorized by him person into authorized federal executive body before March 1, 2011 without request of payment of the state duty provided for by the legislation of the Russian Federation.

(clause 3.1 as amended by Federal Law of November 29, 2010, No. 313-FZ)

3.2. The conformation of the state registration of medicinal products for medical use submitted for the conformation of the mentioned registration prior to the effective date of this Federal Law, and the conformation of the state registration of medicinal products for medical use submitted for expert examination of medicinal products prior to the effective date of this Federal Law in order to subsequent conformation of the state registration, shall be exercised in accordance with this Federal Law on the basis of the documents and the data provided before coming into force date hereof and the statement of the conformation of the state registration of the medicinal product provided by the manufacturer medicinal drugs or authorized by him person according to this Federal Law into authorized federal executive body before March 1, 2011 without request of payment of the state duty provided for by the taxes-and-duties legislation of the Russian Federation.

(clause 3.2 as amended by Federal Law of November 29, 2010, No. 313-FZ)

3.3. Approval of or refusal to approve amendments of the documents, contained in the registration dossier of a registered medicinal product for medical use, and submitted prior to the effective date of the Federal Law, and approval of or refusal to approve amendments of the documents, contained in the registration dossier of a registered medicinal product for medical use, and submitted to expert examination of medicinal products prior to the effective date of the Federal Law shall be exercised on the basis of the documents and the data provided before coming into force date hereof and the statement of the state registration of the medicinal product in accordance with this Federal Law, documents and data, required for the state registration of the medicinal product in accordance with this Federal Law and provided by the manufacturer medicinal drugs or authorized by him person into authorized federal executive body before March 01, 2011 without request of payment of the state duty provided for by the taxes-and-duties legislation of the Russian Federation.

(clause 3.3 as amended by Federal Law of November 29, 2010, No. 313-FZ)

3.4 Issue of approvals for the conduct of clinical trials of medicinal products for medical use, and on the base of statements submitted prior to the effective date of this Federal Law, as well as statements submitted after the effective date of this Federal Law on the base of results of expert examinations performed prior to the effective date of this Federal Law, shall be carried out in accordance with this Federal Law on the basis of the documents and the data provided prior to effective date of this Federal Law, as well on the basis of the copy of the preliminary contract of compulsory insurance of the life and health of patients involved in the clinical trial of the medicinal product for medical use, or the copy of the contract of compulsory insurance of the life and health of patients involved in the clinical trial of the medicinal product for medical use, or copy of the compulsory insurance contract made in accordance with the standard rules for compulsory insurance with specifying the maximum number of patients involved in clinical trial of medicinal products for medical use without request of payment of the state duty provided for by the legislation of the Russian Federation on taxes and duties.

(clause 3.4 as amended by Federal Law of November 29, 2010, No. 313-FZ)

3.5 Registered in the foreign currency prior to the effective date of this Federal Law maximum foreign manufacturers' ex-works prices for the medicinal products included into the list of vital and essential medicinal products, shall be translated in rubles at exchange rate specified by Central bank of Russian Federation on the date, prescribed by the Government of the Russian Federation, without submitting of the statement of price recalculation with respective amendments to state register of manufacturers' maximum ex-works prices for the medicinal products included into the list of vital and essential medicinal products.

(clause 3.5 introduced by Federal Law of October 11, 2010, No. 271-FZ)

3.6 Registered prior to the effective date of this Federal Law maximum Russian manufacturers' ex-works prices for the medicinal products included into the list of vital and essential medicinal products, shall be indexed from November 1, 2010 on the base of estimated inflation specified by the Federal Law of December 02, 2009 No. 308-FZ "On the Federal Budget for 2010 and scheduled period 2011 to 2012" for 2011.

(clause 3.6 introduced by Federal Law of October 11, 2010, No. 271-FZ)

3.7 After March 1, 2011 the manufacturing and import of medicinal products in packaging with labeling made prior to the effective date of this Federal Law shall not be allowed. Upon expiration of the above mentioned period the retail, transfer and use of these medicinal products may be performed up to its expiration date.

(as amended by Federal Law of November 29, 2010, No. 313-FZ, of December 06, 2011 No. 409-FZ)

4. From the date of enactment of this Federal Law until April 30, 2011 inclusive, experts of the expert institution may carry out expert examination of the medicines before their certification in the manner established by the authorized federal executive body.

5. From the date of enactment of this Federal Law until December 31, 2013 inclusive the transfer to the production of medicines in accordance the good manufacturing practice and quality control of the medicines mentioned in clause 1 of Article 45 hereof shall be exercised in full scope. The

dates of the medicines manufacture to the production thereof in compliance with specific requirements of the good manufacturing practice, including the time for certification of authorized parties mentioned in clauses 6 and 7 of Article 45 hereof, shall be determined by the Government of the Russian Federation.

6. Licenses for production of medicines granted before January 01, 2014 shall be effective after January 01, 2014 until their expiration dates, provided that the licensee complies with good manufacturing practices and quality control of the medicines mentioned in clause 1 of Article 45 hereof.

7. The creation of a state assignment for expert examination of medicine for federal state-financed institution carrying out expert examination of medicines and finance support of this task shall be performed in the manner established by the Federal Law of January 12, 1996, No. 7-FZ "On Non-Commercial Organizations".

(as amended by Federal Law of November 29, 2010, No. 313-FZ)

President  
of the Russian Federation  
D. MEDVEDEV

Moscow, Kremlin  
April 12, 2010  
No. 61-FZ

---

