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**On Circulation of Medicines**

**Adopted by the State Duma**

**March 24, 2010**

**(as amended by Federal Laws of July, 27 2010, № 192-FZ; of October 11, 2010, No. 271-FZ, of November 29, No. 313-FZ, of December 06, 2011 No. 409-FZ, of June 25, 2012 No. 93-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 testing, clinical trials, expert examination, evaluation, state registration, standardization and quality control, manufacture, compounding, storage, transportation, import into the Russian Federation, export from the Russian Federation, advertising, dispensation, distribution, transfer, use and destruction of medicines.

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

**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.

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 Terms 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 derived from 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 substances are medicines in the form of active substances of biological, biotechnological, mineral or chemical origin, being pharmacologically active, meant for manufacturing and compounding of medicinal products and determining efficacy thereof;

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

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

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

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 ones prevailing in the morbidity structure of the Russian Federation;

7) immunobiological medicinal products are medicinal products of biological origin meant for immunological diagnostics, prophylaxis and treatment of diseases;

8) narcotic medicines are medicinal products and pharmaceutical substances containing narcotic drugs and included in 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 Single Convention on Narcotic Drugs, 1961;

9) psychotropic medicines are medicinal products and pharmaceutical substances containing psychotropic substances and included in 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 Convention on Psychotropic Substances, 1971;

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

11) originator medicine is a medicine containing a pharmaceutical substance obtained for the first time, or a new combination of pharmaceutical substances, efficacy and safety of which has been confirmed by the results of preclinical testing of medicines and clinical trials of medicinal products;

12) generic medicine is a medicine containing the same pharmaceutical substance or a combination of the same pharmaceutical substances in the same dosage form as the originator medicine has, and put into circulation after the originator medicine has been put into circulation;

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

14) herbal medicinal product is a medicinal product manufactured or compounded 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 medicine is a medicine manufactured or compounded using a special technology;

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

17) trade name of a medicine is the name assigned to a medicine by the developer thereof;

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

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

20) normative documentation is a document containing a list of quality characteristics 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 characteristics and (or) quality control methods for a dosage 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;

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

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

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

25) batch of a medicine is a certain quantity of a medicine manufactured 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;

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

28) circulation of medicines is development, preclinical testing clinical trials, expert examination, state registration, standardization and quality control, manufacturing, compounding, storage, transportation, import into the Russian Federation, export from the Russian Federation, advertising, dispensation, distribution, transfer, use and destruction of medicines;

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

30) developer of a medicine is an institution holding rights to the results of preclinical testing of a medicine, clinical trials of a medicinal product, as well as to manufacturing technology of a medicine;

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

32) manufacturer of medicines is an institution manufacturing medicines in compliance with the requirements hereof;

33) pharmaceutical activities are activities including wholesaling of medicines, storage thereof, transportation and (or) retailing of medicinal products, dispensation thereof, storage, transportation and (or) compounding of medicinal products;

34) wholesaler of medicines is an institution engaged in wholesaling, storage and transportation of medicines in compliance with the requirements hereof;

35) pharmacy institution is an institution or a division of a medical institution engaged in retailing medicinal products, storage, compounding and dispensation of medicinal products for medical use in compliance with the requirements hereof;

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

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 monograph 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 testing of a medicine are 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 trials of a medicinal product are studies of diagnostic, therapeutic, prophylactic and pharmacological properties of a medicinal product in the process of use thereof by a human being or an 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 adverse reactions of 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 the 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 the 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 trials conducted to determine the rate of absorption and excretion of the pharmaceutical substance and the quantity of the pharmaceutical substance reaching the systemic blood flow, the results of which trial allow drawing an inference of bioequivalence of a certain dosage form and dosage rate of a generic medicinal product to the originator medicinal product;

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 dosage 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 medicinal 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 testing of a medicine and a clinical trial of a medicinal product for medical use;

49) patient information sheet is a document containing popular information 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 important 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 the Package Leaflet thereof for prophylaxis, diagnostics, treatment of disease, or for rehabilitation;

51) serious adverse reaction is an adverse 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 reaction is an adverse reaction of the body (including, but not limited to those caused by the use of a medicinal product in compliance with the Package Leaflet thereof), the essence and severity of which does not correspond to the information on the medicinal product provided in the Package Leaflet;

53) medicinal product prescription is a written prescription for a medicinal product issued in a standard form by a medical or veterinary practitioner so entitled for the purpose of dispensation of the medicinal product or compounding and dispensation thereof;

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 to dispense, or compound and dispense a medicinal product in order to make provisions for treatment in the medical institution or veterinary institution.

## **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**

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;
- 2) approval of general pharmacopeia monographs and pharmacopeia monographs and enactment of the state pharmacopeia;
- 3) provision of state control (supervision) in the sphere of circulation of medicines;
- 4) licensing of manufacturing 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;
- 6) issue of permits for conducting clinical trials of medicinal products; maintenance of the register of issued permits for the conduct of clinical trials of medicinal products;
- 7) state registration of medicinal products; maintenance of the state register of medicines;
- 8) inspection of manufacturing of medicines for compliance with the good manufacturing practices; issue of conclusions on compliance of medicines manufacturers with the requirements of the good manufacturing practices;
- 9) state registration of maximum ex-works prices for the vital and essential medicinal products determined by the manufacturers of the 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;

10) establishment of the procedure for import of medicines into the Russian Federation and export of medicines from the Russian Federation;

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

12) evaluation and certification of specialists;

13) approval of professional training programs;

14) safety monitoring of medicinal products;

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;

#### **Article 6. Powers of Executive Bodies of Subject of 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 in the list of vital and essential medicinal products;

3) Control (supervision) in the sphere of circulation of medicines of prices for the medicinal products included in the list of vital and essential medicinal products by wholesalers, pharmacy institutions and individual entrepreneurs holding pharmaceutical licenses.

### **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 monographs and pharmacopeia monographs.

2. General pharmacopeia monographs and pharmacopeia monographs are developed and included in the state pharmacopeia in the manner prescribed by the authorized federal executive body.

3. A pharmacopeia monograph for an original medicine shall be developed and included in the state pharmacopeia within the period of validity

of the exclusive right certified by the patent for the original medicine under consent of the developer thereof.

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 monographs and (or) pharmacopeia monographs 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 web-site in the manner prescribed by this body.

#### **Chapter 4. State Control over Circulation of Medicines**

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

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

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

3. If the manufacturing of medicines needs to be expanded by introducing new dosage forms and types of pharmaceutical substances, the manufacturer of medicines shall obtain a new license for manufacturing of medicines.

##### **Article 9. Government Control (Supervision) in the Sphere of Circulation of Medicines**

1. Government control (supervision) in the sphere of circulation of medicines shall include:

1) licensing control in the sphere of drug manufacture and in the sphere of pharmaceutical activities;

2) federal government supervision in the sphere of circulation of medicines.

2. Licensing supervision in the sphere of drug manufacture and in the sphere of pharmaceutical activities shall be controlled by the authorized federal executive body and executive bodies of the Russian Federation subjects within their competence and under the procedure stipulated in Federal Law No. 294-FZ On Protection of Rights of Legal Entities and Individual Entrepreneurs when Exercising Government Control (Supervision) as well as Municipal Control dated December 26, 2008 taking into consideration peculiarities of preparation

of and carrying out the inspections prescribed by Federal Law No. 99-FZ On Licensing of Certain Types of Activity dated May 4, 2011.

3. Federal government supervision in the sphere of circulation of medicines shall be exercised by the authorized federal executive bodies (hereinafter referred to as the “Government Supervision Bodies”) within their competence and under the procedure stipulated by the Government of the Russian Federation.

4. Federal government supervision in the sphere of circulation of medicines shall include:

1) preparation of and inspecting observance of the requirements to preclinical and clinical drug trials, storage, transportation, import to the Russian Federation, selling, marketing, administration and destruction of the medicines stipulated in this Federal Law and other Regulations of the Russian Federation passed in accordance herewith by the pharmaceutical entities as well as observance of the methods of fixing the limits of wholesale and retail increments to actual manufacturers’ prices for the medicines included into the list of essential and the most important medicines (hereinafter referred to as the “Mandatory Requirements”) by the authorized executive bodies of the Russian Federation;

2) preparation of and inspecting compliance of the circulating drugs with the Mandatory Quality Requirements;

3) issue of import permits for the drugs to the territory of the Russian Federation;

4) preparation of and monitoring drug safety;

5) application of the actions aimed at repression of violations of the Mandatory Requirements and (or) elimination of the consequences of such violations under the procedure stipulated in the laws of the Russian Federation, issue of the instructions to rectify the discovered violations of the Mandatory Requirements and prosecution of violators.

5. To the relations associated with execution of federal government supervision in the sphere of circulation of drugs, preparation of and inspecting the pharmaceutical entities there shall be applied the provisions of Federal Law No. 294-FZ On Protection of Rights of Legal Entities and Individual Entrepreneurs when Exercising Government Control (Supervision) as well as Municipal Control dated December 26, 2008.

6. Under the procedure stipulated in the laws of the Russian Federation the officers of the Government Supervision Bodies shall have the right:

1) to obtain the documents and the information related to circulation of medicines under reasonable written requests submitted by the pharmaceutical entities, executive bodies of the subjects of the Russian Federation as well as by local government bodies;

2) without delay and on presentation of a Service Certificate and a copy of Order (Instruction) of the Government Supervision Body on Setting the Date of the Inspection to visit the territories, buildings, premises and facilities used by

the legal entities and individual entrepreneurs, being the pharmaceutical entities when operating in order to carry out the respective control measures;

3) to select samples of the medicines intended for marketing and marketed by the pharmaceutical entities in order to check their quality, carry out researches and investigations in accordance with the Rules of Taking Samples set forth by the authorized federal executive body;

4) to issue the Instructions on Elimination of the Mandatory Requirements Violations and on Application of the Remedial Actions;

5) to submit the materials related to mandatory requirements violations to the authorized bodies in order to decide the issues on initiation of criminal case on the grounds of the criminal violations.

## **Chapter 5. Development, Preclinical testing 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 testing, development of manufacturing technologies for pharmaceutical substances, development of compositions of and manufacturing 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 Testing of a Medicine for Medical Use**

1. A preclinical testing 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 testing of a medicine for medical use is conducted in compliance with the good laboratory practices approved by the authorized federal executive body.

3. Developers of medicines may involve research institutions and institutions of higher professional education, which have a necessary material

and technical base and qualified specialists in the relevant research area, to arrange and conduct a preclinical testing of a medicine for medical use.

4. A preclinical testing 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 good laboratory practices and statutory regulations on the use of animals in preclinical testing of medicines for medical use shall be carried out by the authorized federal executive body.

6. The results of a preclinical testing 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 Testing of a Medicine and Clinical Trial of Medicinal Product for Veterinary Use**

1. A preclinical testing 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 testing 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 testing 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 protocol 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 testing 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 testing 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 testing 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**

1. Medicinal products are put into civil circulation in the Russian Federation provided they have been registered with the relevant authorized federal executive body.

2. State registration is required for:

- 1) originator medicinal products;
- 2) generic medicinal products;
- 3) new combinations of previously registered medicinal products;
- 4) new dosage forms or new dosage rates of previously registered medicinal products.

3. State registration of medicinal products for medical use shall be carried out based on the results of expert examination of the medicines and ethical expert examination of the possibility of a clinical trial of the medicinal product for medical use (hereinafter – the “ethical expert examination”). State registration of medicinal products for veterinary use is carried out based on the results of expert examination of the medicines for veterinary use.

4. State registration of medicinal products shall be carried out by the relevant authorized federal executive body within the period not exceeding two hundred and ten business days upon filing an application for state registration of the medicinal product. The period specified above includes the time necessary to carry out repeated expert examination of the medicines and (or) repeated ethical expert examination 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 an application for state registration of the medicinal product together with required documents as enclosed to the date of issuance of the registration certificate for the medicinal product. The time spent on a clinical trial of the medicinal product is not considered when calculating the period of state registration.

5. No state registration is required for:

1) medicinal products compounded by pharmacy institutions, veterinary pharmacy institutions and individual entrepreneurs holding pharmaceutical licenses under medicinal product prescriptions and orders of medical institutions and veterinary institutions;

2) herbal medicinal raw materials;

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

4) medicinal products intended for export;

5) radiopharmaceutical medicinal products compounded directly in medical institutions in the manner prescribed by the authorized federal executive body.

6. State registration is forbidden for:

1) different medicinal products under the same trade name;

2) one and the same medicinal product manufactured by the manufacturer under different trade names and submitted for state registration as two or more medicinal products.

#### **Article 14. Principles of Expert Examination of Medicines and Ethical Expert Examination**

1. Expert examination of medicines and ethical expert examination are 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 medicines is carried out on a staged basis:

1) first stage: expert examination of documents submitted to obtain a permit to conduct a clinical trial of a medicinal product, excluding:

a) medicinal products permitted for medical use in the Russian Federation for over twenty years, for which bioequivalence study can not be conducted;

b) medicinal products for medical use for which international multicentre clinical trials have been conducted, partially on the territory of the Russian Federation;

2) second stage: expert examination of proposed methods of a medicine quality control, expert examination of the quality of medicine samples submitted using those methods (hereinafter – the “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 carried out after its clinical trial has been conducted.

3. Expert examination of medicines for veterinary use is carried out on a one stage basis and involves expert examination of the quality of the 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 permits for the conduct of clinical trials of medicinal products and (or) on state registration of medicinal products (hereinafter – the “the expert institution”).

#### **Article 16. Organization of Expert Examination of Medicines for State Registration Thereof**

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 of a medicine 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 “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 is entitled to apply to the head of the expert institution for submission of necessary documents, which expert shall make a relevant request to the authorized federal executive body that issued the assignment to carry out expert examination of the medicine.

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 issuance of 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 shall not be entitled to:

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 the conclusion of the expert commission. A conclusion 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 conclusion 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 issuance of a conclusion 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 of medicines 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 expert examination of medicines and a form of expert commission conclusion are established by the authorized federal executive body.

#### Article 17. **Ethical Expert Examination**

1. Ethical expert examination is carried out for the purpose of issuance of a conclusion on ethical feasibility to conduct a clinical trial of a medicinal product for medical use by the ethical council founded in the manner prescribed by the authorized federal executive body.

2. Representatives of medical, research and higher professional education institutions, as well as representatives of public and religious institutions and mass media may act as ethical council experts. Such experts shall in no way depend upon developers of medicinal products and other persons interested in the results of expert examination.

3. Remuneration to ethical council experts shall be paid under a contract concluded between the authorized federal executive body which founded the ethical council and an ethical council expert at the cost of budget allocations stipulated to authorized federal executive body, created ethical council, in the federal budget for corresponding year to ensure its activities in extent prescribed by the Government of the Russian Federation

(as amended by Federal Law of November 29, No. 313-FZ)

4. Ethical council experts bear responsibility in accordance with the legislation of the Russian Federation.

5. Ethical council composition, regulations on the council, requirements to qualification and experience of ethical council experts in expert assessment of scientific, medical and ethical aspects of clinical trials of medicinal products for medical use, procedures for arrangement and performance of ethical expert examination and a form of ethical council conclusion are established by the authorized federal executive body. The number of representatives of medicinal institutions shall not exceed a half of the total number of ethical council experts.

6. Information on ethical council composition, plan of operation and current activities shall be placed on the Internet official site of the authorized federal executive body in the manner prescribed by such body.

#### Article 18. **Submission and Review of Applications for State Registration of Medicinal Products and Submission of Necessary Documents**

1. For the purpose of state registration of a medicinal product, the developer of the medicinal product or any other legal entity authorized by such developer (hereinafter –the “applicant”) submits to the relevant authorized federal executive body carrying out state registration of medicinal products an application for state registration of the medicinal product, as well as necessary

documents in the manner prescribed by the relevant authorized federal executive body, of which the registration dossier for the medicinal product is formed (hereinafter – the “registration dossier”).

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

1) name and address of the applicant and (or) developer of the medicinal product and address of the place of manufacturing of the medicinal product;

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

3) list of substances composing the medicinal product specifying the quantity of each;

4) dosage form, dosage rate, methods of administration and use and validity period of the medicinal product;

5) description of pharmacological and pharmacodynamic or immunobiological properties of the medicinal product;

6) maximum ex-works price for the medicinal product included in the list of vital and essential medicinal products as posted by the manufacturer, in case of state registration of such product;

7) statement on the lack of the need to conduct a clinical trial and bioequivalence study of the medicinal product permitted for medical use within the territory of the Russian Federation for over twenty years, specifying normative legal acts which prove such period of use.

3. The registration dossier shall comprise the following documents:

1) draft designs of primary packages and secondary (retail) packages for the medicinal product;

2) document certifying the compliance of the manufacturer of the medicinal product to be registered with the requirements of the good manufacturing practices, issued by a competent authority of the country of origin of the medicinal product to be registered and certified in the prescribed manner, as translated into the Russian language;

3) draft normative documentation or normative document for the medicinal product or reference to a relevant pharmacopeia monograph;

4) process flow diagram for manufacturing of the medicinal product and its description, and (or) process flow diagram for manufacturing of the pharmaceutical substance and its description;

5) document certifying the compliance of the manufacturer of the pharmaceutical substance with the requirements of the good manufacturing practices, issued by a competent authority of the country of origin of the pharmaceutical substance and certified in the prescribed manner, as translated into the Russian language, containing the following information:

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

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

c) pharmaceutical substance shelf-life;

6) document containing data on qualitative indicators of the pharmaceutical substance used in manufacturing of the medicinal products;

7) normative documentation or normative document for the pharmaceutical substance, or reference to a relevant pharmacopoeia monograph;

8) information on conditions of storage and transportation of the medicinal product, and other information;

9) report on the results of preclinical testing of the medicine for medical use containing description, results and statistical analysis of the results of the preclinical testing;

10) report on the results of preclinical testing of the medicine and clinical trial of the medicinal product for veterinary use;

11) draft protocol of a clinical trial of the medicinal product for medical use;

12) investigator's brochure;

13) patient information sheet;

14) information on remunerations and compensations paid to the patients (healthy volunteers and ill patients) (hereinafter – the “patients”) involved in clinical trials of the medicinal product for medical use, bioequivalence and (or) therapeutic equivalence studies;

15) report on the results of international multicentre clinical trials of the medicinal product for medical use, partially conducted in the Russian Federation;

16) draft instructions for use of the medicinal product containing the following information:

a) name of the medicine (international nonproprietary name or chemical and trade names);

b) dosage form indicating the names and quantitative level (activity) of the pharmaceutical substances and excipients;

c) pharmacotherapeutic group of the medicinal product;

d) indications for use;

e) contraindications for use;

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

g) safety precautions on use;

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

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

j) description, if necessary, of actions to be undertaken by a physician (physician's assistant), veterinary specialist, patient or animal's owner in case of omission of one or several doses of the medicinal product;

k) possible side effects of the medicinal product;

l) interaction with other medicinal products and (or) food substances or animal food substances;

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

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

o) validity period and indication not to use the medicinal product after its expiry;

p) storage conditions;

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

r) special safety precautions to be used when destructing unused medicinal products, if necessary;

s) terms of possible use of animal products after the animal has been administered the medicinal product for veterinary use;

t) name and address of the manufacturer of the medicinal product and address of the place of manufacturing of the medicinal product;

u) dispensing conditions;

(clause “u” introduced by Federal Law of November 29, No. 313-FZ)

17) copy of the document certifying registration of the medicinal product if it is registered outside the Russian Federation translated into the Russian language and certified in the prescribed manner;

18) documents submitted in accordance with articles 19 – 23 hereof.

4. At the applicant’s request, reports on the results of clinical trials, bioequivalence and (or) therapeutic bioequivalence studies of the medicinal product conducted in the applicant’s country and other countries (including epidemiological or episootological trials of immunobiological medicinal products designed for immunobiological prophylaxis and treatment of infectious diseases, including with children), containing descriptions of the trials of the medicinal product conducted, their results and statistical analysis of the results obtained may be submitted.

5. The following documents shall be enclosed with an application for state registration of a medicinal product:

1) document certifying payment of the state duty for performance of expert examination of the documents submitted to obtain permits to conduct clinical trials of the medicinal product for medical use and ethical expert examination when applying for state registration of the medicinal product;

2) document certifying payment of the state duty for performance of expert examination of the quality of the medicine and expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product permitted for use within the territory of the Russian Federation for over twenty years when applying for state registration of the medicinal product;

3) document certifying payment of the state duty for performance of expert examination of the quality of the medicine and expert examination of a correlation between the anticipated benefit and possible risk from the use of the

medicinal product for medical use when applying for state registration of the medicinal product, for which international multicentre clinical trials have been conducted, partially within the territory of the Russian Federation;

4) document certifying payment of the state duty for performance of expert examination of the quality of the medicine and expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product for veterinary use when applying for state registration thereof.

6. The results of the nonclinical trials of medicinal products and clinical trials of medicinal products submitted by the applicant for state registration of the medicinal products shall not be obtained, disclosed, used for commercial purposes and for purposes of state registration without applicant's permission within six years from the date of the state registration of the medicinal product.

Violation of the prohibition specified by this Clause shall entail the responsibility in accordance with the legislation of the Russian Federation.

The circulation of medicines in the Russian Federation registered with violation of this Clause shall be prohibited.

(clause 6 introduced by Federal Law of October 11, 2010, No. 271-FZ)

#### **Article 19. Procedure for Making Decision on Issuance of Assignment for Performance of Expert Examination of Medicines for Expert Institution and Ethical Council**

1. Within five business days from on receipt of an application for state registration of a medicinal product, the authorized federal executive body shall review the data contained in the materials submitted by the applicant for completeness and reliability, and take decision on issuance of an assignment to carry out:

1) expert examination of the medicines, in particular expert examination of the documents submitted to obtain a permit for the conduct of a clinical trial of the medicinal product for medical use in accordance with the objectives specified in Article 38 hereof, and ethical expert examination with respect to the medicinal products, for which clinical trials have not been conducted within the territory of the Russian Federation, based on the documents specified in Sub-clauses 1 – 9, 11 – 14 and 17 of Clause 3 and Sub-clause 1 of Clause 5 of Article 18 hereof;

2) expert examination of the medicines, in particular expert examination of the quality of the medicines and expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product for medical use with respect to the medicinal products permitted for use within the territory of the Russian Federation for over twenty years, based on the documents specified in Sub-clauses 1 – 9 and 16 of Clause 3 and Sub-clause 2 of Clause 5 of Article 18 hereof, as well as the medicinal products, for which international multicentre clinical trials have been conducted, partially within the

territory of the Russian Federation, based on the documents specified in Sub-clauses 1 – 9 and 15 - 17 of Clause 3 and Sub-clause 2 of Clause 5 of Article 18 hereof;

3) expert examination of the medicine with respect to the medicinal products for veterinary use, based on the documents specified in Sub-clauses 1 – 8, 10, Items a-e, g-l and o-t of Sub-clause 16 and Sub-clause 17 of Clause 3 and Sub-clause 4 of Clause 5 of Article 18 hereof.

2. The authorized federal executive body notifies the applicant in writing of the positive decision or, in case of refusal, of the grounds for such refusal.

3. Failure to submit a complete set of the documents listed in Clauses 3 and 5 of Article 18 hereof necessary for performance of expert examinations, or submission of documents lacking a comprehensive list of necessary information is considered grounds for refusal to carry out expert examinations specified in Clause 1 of this Article.

**Article 20. Expert Examination of Documents Necessary to Obtain Permit for Conduct of Clinical Trial of Medicinal Product for Medical use and Ethical Expert Examination**

1. Expert examination of documents necessary to obtain a permit to conduct a clinical trial of a medicinal product for medical use in accordance with the objectives specified in Article 38 hereof, ethical expert examination, generation of conclusions on possibility or non-possibility of the conduct of such clinical trial by the expert council and ethical council, and forwarding of such conclusions to the authorized federal executive body shall be exercised within the period not exceeding thirty business days from the date of receipt by the expert institution of the assignment issued by the authorized federal executive body together with necessary documents specified in Sub-clauses 9, 11, 12 of Clause 3 of Article 18 hereof, and documents specified in Clause 4 of Article 18 hereof as submitted at the request of the applicant, and from the date of receipt by the expert council of the assignment issued by the authorized federal executive body together with necessary documents specified in Sub-clauses 11 – 14 of Clause 3 of Article 18 hereof.

2. The documents contained in the registration dossier and submitted to the expert institution and expert council for performance of expert examination thereof for the purpose of obtaining a permit to conduct a clinical trial of the medicinal product for medical use are subject to return to the authorized federal executive body concurrently with the relevant expert examination conclusions.

**Article 21. Procedure for Obtaining Permit to Conduct Clinical Trial of Medicinal Product for Medical use**

1. Within the period not exceeding five business days from the date of receipt of the conclusions specified in Article 20 hereof, the authorized federal

executive body shall evaluate the conclusions received to determine their compliance with the assignments for performance of the relevant expert examinations, and notify the applicant in writing of the results of the expert examinations which have been carried out and of the possibility or non-possibility of issuance of a permit to the applicant with respect to conduct a clinical trial of the medicinal product for medical use.

2. In case of a positive decision on the possibility of issuance of a permit to conduct a clinical trial of the medicinal product for medical use, the authorized federal executive body suspends performance of state registration of the medicinal product until the applicant has applied for a permit to conduct a clinical trial of the medicinal product for medical use to the authorized federal executive body.

3. In case of a negative decision on the possibility of issuance of a permit to conduct a clinical trial of the medicinal product for medical use, the authorized federal executive body stops the procedure of state registration of the medicinal product.

#### **Article 22. Decision on Conducting of Clinical Trial of Medicinal Product for Medical use**

1. To obtain a permit 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 issuance of a permit to conduct such clinical trial;  
2) information on the researchers' experience in the relevant fields and in conducting clinical trials;

3) the copy of contract of compulsory insurance of the life and health of a patient involved in clinical trials of medicinal products for medical use (hereinafter "the contract of compulsory insurance"), made in accordance to the standard rules for compulsory life and health insurance of a patient involved in clinical trials of medicinal products for medical use approved by the Government of the Russian Federation (hereinafter "the standard rules for compulsory insurance"), with specifying the maximal number of patients involved in clinical trial of medicinal products for medical use ;

(as amended by Federal Law of November 29, 2010, No. 313-FZ)

4) the details of medical organizations which are scheduled to conduct clinical trials of medicinal product for medical use (full and brief names of medical institution, legal form of medical institution, the seat and business location of medical institution, telephone, telefax, email address);

(as amended by Federal Law of November 29, 2010, No. 313-FZ)

5) estimated terms of the clinical trial of the medicinal product for medical use.

(sub-clause 5 introduced by Federal Law of October 11, 2010, No. 271-FZ)

2. Within the period not exceeding five business days from the date of receipt of the application specified in Clause 1 of this article together with 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) take decision on issuance of a permit to conduct the clinical trial of the medicinal product for medical use, or on refusal to issue such permit;

3) notify the applicant in writing of the positive decision or, in case of refusal, of the grounds for such refusal;

4) issue a permit to conduct the clinical trial of the medicinal product for medical use in the manner prescribed by the authorized federal executive body.

3. Failure to submit the documents specified in Clause 1 of this article, or non-compliance of the documents submitted with the requirements of this Federal Law, or the presence of the conclusion issued by the expert institution or the conclusion issued by the Ethical council on impossibility of conducting of clinical trial of a medicinal product for medical use on the base of results of performed expert examinations provided for in Article 20 of this Federal law is considered grounds for refusal to issue a permit to conduct the clinical trial of the medicinal product.

(as amended by Federal Law of October 11, 2010, No. 271-FZ)

**Article 23. Expert Examination of Quality of a Medicine and Expert Examination of Correlation between Anticipated Benefit and Possible Risk from Use of Medicinal Product for Medical 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 medical use, generation of conclusions by the expert councils based on the results of clinical trials and forwarding of such conclusions to the authorized federal executive body shall be exercised within the period not exceeding 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 Sub-clauses 1 – 8 and 15 - 17 of Clause 3 of Article 18 hereof and a report on the clinical trial of the medicinal product for medical use conducted.

2. For the purpose of expert examinations specified in Clause 1 of this article, the applicant shall submit to the authorized federal executive body:

1) application for renewal of state registration of the medicinal product and performance of the expert examinations specified in Clause 1 of this article;

2) report on the clinical trial of the medicinal product for medical use conducted;

3) document certifying payment of the state duty for performance of expert examination of the quality of the medicine and expert examination of a

correlation between the anticipated benefit and possible risk from the use of the medicinal product for medical use when applying for state registration.

3. Within the period not exceeding five business days from the date of receipt of the application together with the documents specified in Clause 1 and Sub-clauses 2 and 3 of Clause 2 of this article, the authorized body shall:

1) examine the data contained in the report on clinical trial of the medicinal product for medical use submitted by the applicant for completeness and reliability;

2) take decision on renewal of state registration of the medicinal product and performance of the expert examinations specified in Clause 1 of this article, or on refusal to renew state registration of the medicinal product and carry out such expert examinations;

3) notify the applicant in writing of the positive decision or, in case of refusal, of the grounds for such refusal.

4. Failure to submit a complete set of the documents listed in Clause 1 and Sub-clauses 2 and 3 of Clause 2 of this article, or submission of the report on the clinical trial of the medicinal product for medical use lacking a comprehensive list of necessary information is considered grounds for refusal to renew state registration and carry out expert examinations specified in Clause 1 of this article.

5. Within fifteen business days from the date of receipt of the decision on renewal of state registration of the medicinal product and performance of expert examinations specified in Clause 1 of this article, issued by the authorized federal executive body, the applicant shall submit samples of the medicine product for medical use manufactured in compliance with the requirements of the experimental industrial regulations and (or) industrial regulations approved by the head of the medicines manufacturing company, as well as, in appropriate cases, sample of the pharmaceutical substance, test strain of microorganisms, cultured cells, samples of substances used for quality control of a medicinal product be means of comparison of a medicinal drug to them, in the quantities necessary to reproduce the quality control methods, for the purpose of expert examination of the quality of the medicinal product.

(as amended by Federal Law of November 29, 2010, No. 313-FZ)

6. On 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 writing within the period not exceeding three business days.

7. The period of submission of samples of a 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 5 and 6 of this article are not included in the period of performance of expert examinations specified in Clause 1 of this article.

8. 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 conclusions based on the results of such expert examinations.

**Article 24. Expert Examination of Quality of a Medicine and Expert Examination of Correlation between Anticipated Benefit and Possible Risk from Use of 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, generation of conclusions based on the results of expert examinations by expert councils and forwarding of such conclusions to the authorized federal executive body shall be exercised within the period not exceeding 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 Sub-clauses 1 – 8, 10, Items a-e, g-l and o-t of Sub-clause 16 and Sub-clause 17 of Clause 3 of Article 18 hereof.

2. Within fifteen business days from the date of receipt of the decision on performance of the expert examinations specified in Clause 1 of this article issued by the authorized federal executive body, the applicant shall submit samples of the medicinal product for veterinary use manufactured in compliance with the requirements of the technological regulations approved by the head of the medicines manufacturing company, as well as sample of the pharmaceutical substance in the quantities necessary to reproduce the quality control methods, for the purpose of expert examination of the quality of the medicinal product.

3. On 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 the period not exceeding 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 conclusions based on the results of such expert examinations.

#### **Article 25. Repeated Expert Examination of Medicines and Repeated Ethical Expert Examination**

1. In case of insufficient feasibility or incompleteness of the conclusion issued by the expert institution or ethical council, presence of controversial data in such conclusion, falsification of the inferences based on the results of expert examination of a medicine and (or) ethical expert examination, 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.

2. Repeated expert examination of a medicine shall be carried out within the period prescribed by the authorized federal executive body, not exceeding forty business days from the date of receipt by the expert institution of an assignment to carry out repeated expert examination of the medicine; repeated ethical expert examination shall be carried out within the period not exceeding fifteen business days from the date of receipt by the ethical council of an assignment to perform repeated ethical expert examination.

3. Financing of repeated expert examination of a medicine is not provided, and the funds transferred for the performance of such expert examination earlier are subject to return to the federal budget.

#### **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 be applied to generic medicinal products. For the purpose of such expert examination information obtained in clinical trials of the medicinal products and published in specialized editions, as well as documents containing the results of bioequivalence and (or) therapeutic equivalence studies of the medicinal product for medical use or the results of bioequivalence studies of the medicinal product for veterinary use are submitted.

2. Accelerated procedure for expert examination of medicines shall not be applied to immunobiological medicinal products, insulin products and medicinal products to be registered in the Russian Federation for the first time.

3. Accelerated procedure for expert examination of medicines shall be performed under decision of the relevant authorized federal executive body

within the period not exceeding sixty business days. In this case expert examination of the documents contained in the registration dossier for the purpose of obtaining a permit to conduct a clinical trial of a medicinal product for medical use and ethical expert examination shall be performed within the period not exceeding fifteen 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 a medicinal product shall be performed within the period not exceeding five business days.

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

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

1. Within the period not exceeding five business days from the date of receipt of the conclusions 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 relative authorized federal executive body shall:

1) evaluate such conclusions in order to determine compliance thereof with the assignment for performance of such expert examinations;

2) take 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;

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

(as amended by Federal Law of October 11, 2010, No. 271-FZ)

3. When registering a medicinal product included in the list of vital and essential medicinal products, necessary data shall be entered into the state

register of maximum ex-works manufacturers' prices for the medicinal products included in such list.

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

1. A registration certificate for a medicinal product indicating dosage 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.

#### **Article 29. Confirmation of State Registration of a Medicinal Product**

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 ninety business days from the date of receipt of an application for confirmation of state registration of the medicinal product executed in accordance with Clause 2 of Article 18 hereof.

2. Confirmation of state registration of a medicinal product is carried out based on the results of expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product as well as expert examination of the quality of the medicine, carried out in the case of amendments to normative documentation or normative document.

(as amended by Federal Law of November 29, 2010, No. 313-FZ)

3. The document certifying payment of the state duty for confirmation of state registration of the medicinal product for medical use or the medicinal product for veterinary use, and the document containing the results of safety monitoring of the medicinal product conducted by the applicant, executed as prescribed by the relevant authorized federal executive body, shall be enclosed with the application for confirmation of state registration of the medicinal product. Normative documentation or normative document, draft instructions for use of the medicinal product, draft designs of primary packages and secondary (retail) packages for the medicinal product shall be enclosed with the application for confirmation of state registration of the medicinal product again only in the case of amendments to them.

(as amended by Federal Law of November 29, 2010, No. 313-FZ)

4. Within ten business days upon the date of receipt of an application for confirmation of state registration of a medicinal product and necessary documents, the relevant 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 a correlation between the anticipated benefit and possible risk from the use of the medicinal product as well as expert examination of the quality of the medicine, carried out in the case of amendments to normative documentation or normative document;

(as amended by Federal Law of November 29, 2010, No. 313-FZ)

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

5. 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 information which shall be reflected therein is considered grounds for refusal to carry out expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product and (or) expert examination of the quality of the medicinal drug.

(as amended by Federal Law of November 29, 2010, No. 313-FZ)

6. 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 the purpose of confirmation of state registration of a medicinal product shall be carried out based on the documents specified in Clause 3 of this Article, in the manner prescribed in Clauses 5 - 8 of Articles 23 and 24 hereof.

(as amended by Federal Law of November 29, 2010, No. 313-FZ)

7. While the procedure of confirmation of state registration of a medicinal product is on, civil circulation thereof is conducted within the territory of the Russian Federation.

### **Article 30. Amendments to Documents Contained in Registration Dossier for 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 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 such amendments, or refusal to enter such amendments shall be given within the period not exceeding ninety business days from the date of receipt by the authorized federal executive body of an application for such amendments.

2. In case of amendments to the Package Leaflet for a medicinal product with respect to the data specified in Items d-o,u of Sub-clause 16 of Clause 3 of Article 18 hereof or changes in the composition of a medicinal product for medical use, changing the place of production of medicinal product for medical

use, changing the qualitative indicators of the medicinal product for medical use and (or) the methods of quality control of the medicinal product for medical use, changing the expiry date of the medicinal product for medical use, expert examination of the medicines, in particular 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 shall be carried out. In case of necessity to enter other amendments to such directions, no expert examination of the medicine for the purpose of such amendments to the data on such registered medicinal product shall be carried out.

(as amended by Federal Laws of October 11, 2010, of November 29, 2010, No. 313-FZ)

3. Together with an application for amendments to the documents contained in the registration dossier for a registered medicinal product for medical use, besides the documents specified in Clause 1 of this article, the documents certifying payment of the state duty for amendments to the Package Leaflet for the medicinal product for medical use or the documents certifying payment of the state duty for change in the composition of the medicinal product for medical use shall be enclosed.

4. Within ten business days upon 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) take 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 writing of the positive decision or, in case of refusal to carry out a relevant expert examination of the medicine, or the grounds for such refusal.

5. 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 examinations specified in Clause 2 of this article.

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

7. Within the period not exceeding five business days from the date of receipt of the conclusions 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:

1) take 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

for the registered medicinal product for medical use, and return them to the applicant.

8. 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 for the registered medicinal product for medical use.

9. Civil circulation of medicinal products for medical use manufactured earlier than a decision on approval of or refusal to approve amendments to the documents contained in the registration dossier for such medicinal products has been taken by the authorized federal executive body shall be allowed.

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

1. To enter amendments to the documents contained in the registration dossier for a registered medicinal product for veterinary use, 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 the period not exceeding ninety business days from the date of receipt by the authorized federal executive body of an application for such amendments.

2. In case of amendments to the Package Leaflet for a medicinal product for veterinary use with respect to any data related to changes in the dosage rates or terms of possible use of animal products after the animal has been administered the medicine for veterinary use, expert examination of the medicine for veterinary use shall be carried out. In case of necessity to make other amendments to such a Package Leaflet, expert examination of the medicine for veterinary use shall not be carried out.

3. Together with an application for amendments to the documents contained in the registration dossier for a registered medicinal product for veterinary use, besides the documents specified in Clause 1 of this article, the documents certifying payment of the state duty for amendments to the Package Leaflet for a medicinal product for veterinary use shall be enclosed.

4. Within the period not exceeding ten business days upon 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) take 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.

5. 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.

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

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

8. Civil circulation of medicinal products for veterinary use manufactured earlier than a decision on approval of or refusal to approve the amendments to the documents contained in the registration dossier for such medicinal products for veterinary use has been taken by the authorized federal executive body shall be allowed.

### **Article 32. Cancellation of State Registration of a 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 the said authorized federal executive body;

2) The developer of the medicine 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;

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 for 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 which was earlier registered under this trade name;

6) The same medicinal product was registered under different trade names by the applicant;

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

### 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 or chemical name of and trade name);
  - b) dosage form with indication of dosage rate of the medicinal product and its quantity in consumer package;
  - c) name of developer of the medicinal product;
  - d) name and addresses of the manufacturer of the medicinal product;
  - e) pharmacotherapeutic group of the medicinal product;
  - 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 monograph and, failing the latter, of normative documentation or normative document;
  - l) date of state registration of the medicinal product and registration number thereof and;
- 2) with respect to pharmaceutical substances:
  - a) name of the pharmaceutical substance (nonproprietary or chemical name of and trade name);
  - 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 monograph and, failing the latter, of normative documentation or normative document.

2. A pharmaceutical substance not used in the manufacturing of medicinal products may be included in the state register of medicines on the basis of the developer's application, 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.

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. **Quality Evaluation of Pharmaceutical Substance not used in Manufacturing of Medicinal Products**

1. Any pharmaceutical substance not used in manufacturing of medicinal products requires quality evaluation before it is included in the state register of medicines.

2. Quality evaluation of the pharmaceutical substance referred to in Clause 1 of this Article shall be carried out, expert opinion based on the evaluation findings shall be prepared and submitted to the authorized federal executive body within sixty business days of receipt by the expert institution of the relevant assignment issued by the authorized federal executive body and the documents specified in sub-clauses 4 – 7 of Clause 3 of Article 18 of this Federal Law.

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 document to confirm payment of state duty for the inclusion of the pharmaceutical substance not used in manufacturing of medicinal products in the state register of medicines;

3) documents specified in Sub-clauses 4 - 7 of Clause 3 of Article 18 of this Federal Law.

4. Within five business days upon 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 Part 1 and Item 2 of Part 3 of this article, the authorized federal executive body shall:

1) make sure that the data contained in the documents submitted by the applicant is complete;

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 writing of a positive decision or, in the event of a negative decision, give the reasons of such rejection.

5. Failure to provide any of the documents listed in Clause 2 and Sub-clause 2 of Clause 3 of this Article will be a reason 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. On 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 writing within three business days. This term is not included in the term for the quality evaluation.

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 Sub-clause 2 of Clause 1 of Article 33 hereof, add the necessary information and notify the applicant in writing.

**Article 35. Repeated Presentation of a Medicinal Product, which Failed State Registration of Medicinal Products for State Registration of Medicinal Products**

Repeated presentation to the relevant authorized federal executive body of a medicinal product that failed state expert registration of medicinal products or was rejected for such registration, the composition of which medicinal product was changed, shall be considered as presentation of a new medicinal product for state registration regardless of whether its initial name was preserved or not.

**Article 36. Appeal of Decision on Refusal to Issue Permit for Clinical Trials of Medicinal Product, or Refusal to Perform State Registration of a Medicinal Product**

Decision of the relevant authorized federal executive body on refusal to issue a permit for clinical trial of a medicinal product, or refusal to perform state registration of a medicinal product may be appealed in the manner established by the legislation of the Russian Federation.

**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 place on its official web-site the information relating the process of state registration of medicinal products, including expert examination of medicines, and information about medicinal products and medicinal products removed from the state register of medicines not later than within five business days of receipt by the authorized federal executive body of an application for state registration of the medicinal product.

2. The term and procedure of placing information referred to in Clause 1 of this Article shall be established by the authorized federal executive body.

**Chapter 7. Clinical Trials of Medicinal Products for Medical use, Clinical Trial Contract, Rights of Patients Involved in 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 for the purpose of state registration of medicinal products and for any other purposes on one or more medical institutions as required by goods clinical practice approved by the authorized federal executive body for the following purposes:

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 by a person authorized by the developer;

2) educational institutions of higher and/or additional professional education;

3) research centres.

4. Clinical trials of medicinal products for medical use shall be conducted in the procedure prescribed by Articles 20 - 22 of this Federal Law under the permit to conduct the clinical trial of the medicinal product issued by the authorized federal executive body for the purposes specified in Clause 1 of this Article. The authorized federal executive body shall maintain a register of issued permits to conduct clinical trials of medicinal products indicating the purpose or purposes thereof in the procedure established by such body.

5. In the event of state registration of a medicinal product, the state duty for expert examination of the documents required for obtaining permits to conduct clinical trials of a medicinal product for medical use and ethical expert examination, when an application is filed for state registration of the medicinal product for the purpose or purposes referred to in Clause 1 of this Article, shall be paid once.

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. The list of medical institutions entitled to conduct clinical trials of medicinal products for medical use and the register of issued permits to conduct clinical trials of medicinal products shall duly be published and placed on the official web-site by the authorized federal executive body.

**Article 39. International Multicentre Clinical Trial of Medicinal Product for Medical Use or Post-registration Clinical Trial of Medicinal Product for Medical use**

1. An international multicentre clinical trial of a medicinal product for medical use in the Russian Federation or a post-registration clinical trial of a medicinal product for medical use shall be carried out under a permit to conduct a clinical trial of the medicinal product issued by the authorized federal executive body upon the results of the expert examination of the documents required for obtaining a permit to conduct an international multicentre clinical trial of the medicinal product or post-registration clinical trial of the medicinal product and ethical expert examination.

2. To obtain a permit to conduct an international multicentre clinical trial of a medicinal product for medical use or a post-registration clinical trial of a

medicinal product for medical use, the applicant shall submit to the authorized federal executive body:

1) application for obtaining a permit to conduct an international multicenter clinical trial of a medicinal product for medical use or a post-registration clinical trial of a medicinal product for medical use;

2) documentary proof to confirm payment of the state duty for issuance of a permit to conduct an international multicentre clinical trial of a medicinal product for medical use, or the state duty for issuance of a permit to conduct a post-registration clinical trial of a medicinal product for medical use;

3) report on preclinical testing of the medicine and a report on earlier clinical trials of the medicinal product for medical use (if any);

4) clinical trial draft protocol for the medicinal product for medical use;

5) investigator's brochure;

6) information sheets of the patients enrolled in the clinical trials of the medicinal product for medical use;

7) data about the investigators' work experience in the relevant specializations and their clinical trial experience;

7<sup>1</sup>) the details of medical organizations which are scheduled to conduct clinical trial of medicinal product for medical use (full and brief names of medical institution, legal form of medical institution, the seat and business location of medical institution, telephone, telefax, email address);

(as amended by Federal Law of November 29, 2010, No. 313-FZ)

7<sup>2</sup>) estimated terms of the clinical trial of the medicinal product for medical use;

(sub-clauses 7<sup>2</sup> introduced by Federal Laws of October 11, 2010, No. 271-FZ)

8) the copy of contract of compulsory insurance, made in accordance to the standard rules for compulsory insurance, with specifying the maximal number of patients involved in clinical trial of medicinal products for medical use;

(as amended by Federal Law of November 29, 2010, No. 313-FZ)

9) composition of the medicinal product required for obtaining a permit to conduct an international multicentre clinical trial of the medicinal product for medical use;

10) the document created by manufacturer of the medicinal product, which contains data on parameters (qualitative indicators) of the medicinal product for medical use, produced for conducting of clinical trials.

(as amended by Federal Law of November 29, 2010, No. 313-FZ)

3. In the period not longer than five business days on filing the application referred to in Sub-clause 1, Clause 2 of this Article and the appropriate documents, the authorized federal executive body shall:

1) check the data contained in the applicant's documents for completeness and accuracy;

2) make a decision on expert examination of the documents to issue a permit to conduct an international multicentre clinical trial of the medicinal

product for medical use or a post-registration clinical trial of the medicinal product for medical use and ethical expert examination, or on rejection of such expert examinations;

3) notify the applicant of the decision in writing or, in the event of rejection, indicate the reasons of such rejection.

4. Failure to submit a full package of documents prescribed in Clause 2 of this Article, or lack of sufficient list of appropriate details or information to be presented in the documents shall be a reason for rejection of expert examination of the documents required for issuance of a permit to conduct an international multicentre clinical trial of a medicinal product for medical use or a post-registration clinical trial of a medicinal product for medical use and ethical expert examination.

5. Expert examination of the documents required for obtaining a permit to conduct an international multicentre clinical trial of a medicinal product for medical use or a post-registration clinical trial of a medicinal product for medical use and ethical expert examination, and issuance of a permit to conduct an international multicentre clinical trial of medicinal product for medical use or a post-registration clinical trial of medicinal product for medical use shall be performed in the procedure established in articles 20 - 22 of this Federal Law.

6. Decision on rejection of expert examination of the documents required for obtaining a permit to conduct an international multicentre clinical trial of a medicinal product for medical use or a post-registration clinical trial of a medicinal product for medical use and ethical expert examination and on rejection of issuance of a permit to conduct an international multicentre clinical trial of a medicinal product for medical use or a post-registration clinical trial of medicinal product for medical use may be appealed in the manner prescribed by the laws of the Russian Federation.

#### **Article 40. Procedure for Clinical Trial of Medicinal Product for Medical use**

1. The head of the medical institution conducting a clinical trial of a medicinal product for medical use 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 five-year experience on programs of clinical trials of medicinal products, and at his/her suggestion appoint fellow investigators from among of the physicians of this medical institution.

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 co- investigators 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 of the medicinal product for medical use 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<sup>1</sup>. Within not later than three business days on the start of the clinical trial of a medicinal product for medical use the head of the medical institution shall notify the the authorized federal executive body, which issued the permit to conduct such clinical trial about this according to the prescribed form.

(clause 3<sup>1</sup> introduced amended 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, Article 38 of this Federal Law, shall, if the draft 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 permit to conduct such clinical trial, according to the prescribed form.

(as amended by Federal Law of October 11, 2010, No. 271-FZ)

4<sup>1</sup>. The form of notice of on amending the protocol of the clinical trial of the medicinal product for medical use should contain the following data:

- 1) the name, ID number and the date of the protocol of the clinical trial;
- 2) the date of amendments to the protocol of the clinical trial;
- 3) the name and location of the applicant;
- 4) the name of organization involved by the developer of the medicinal product for medical use to arrange the conducting of the clinical trial (if any);
- 5) the names and locations of medical center for conducting of the clinical trial of the medicinal product for medical use;
- 6) date of issue of permit for the conduct of the clinical trial and the number of the permit;
- 7) the amendments to the protocol of the clinical trial.

(clause 4<sup>1</sup> introduced by Federal Laws 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 the procedure which has established and make a decision on amending the draft protocol of the clinical trial of the medicinal product for medical use or on rejection of such amendment.

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 institution and/or the institution, which obtained a permit 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 institution and/or the institution, which obtained a permit from the authorized federal executive body to organize a clinical trial of the medicinal product. A decision

on termination of such trial shall be made by the authorized federal executive body on the basis of the written notice received from the head of the medical institution or institution, which obtained a permit from the authorized federal executive body to organize a 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 institutions referred to in Clause 3, 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 institution(s) which has/have conducted this trial;

2) trial description;

3) investigator's details (full name, place or employment, position, qualification, experience on programs of clinical trials of medicinal products, and list of clinical trials of medicinal products in which he/she participated (when) as an investigator or a co-investigator);

(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).

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 web-site. Such register shall contain data as provided for in Sub-clause 3 of Clause 8 of this Article.

11. The institution 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 institutions involved in this trial, and submit it to the authorized federal executive body, which issued a permit 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. Failure to follow 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.

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, bioptic materials) for study of the samples inside and/or outside the Russian Federation

14. The procedure for import into the Russian Federation and export outside 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.

#### **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 institution which obtained a permit from the authorized federal executive body for organization of such trial and medical institution 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 co-investigators; 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 for medical use shall be financed by:

- 1) federal funds,
- 2) funds of the institutions which have obtained a permit 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.

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 unfavourable 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 the Patient Involved in Clinical Trial of Medicinal Product for Medical Use**

1. The institution which has obtained a permit for organization of a clinical trial of a medicinal product for medical use shall insure the life and health of the patient involved in a clinical trial of a medicinal product at its own expense as an insurant by making a contract for compulsory insurance .

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 of a cause-and-effect relationship between the occurring events and participation of this present in clinical trial of medicinal product.

4. Claims for compensation of harm caused to the patient's life or health shall be satisfied 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 - RUR Two million 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 - RUR One million five hundred thousand for each patient involved in clinical trial of a medicinal product;

b) which caused second class disability - one million roubles for each patient involved in clinical trials of a medicinal product;

c) which caused third class disability - RUR Five hundred thousand for each patient involved in clinical trials of a medicinal product;

d) which did not cause disability - not more than RUR Three hundred thousand for each patient involved in clinical trial of a medicinal product.

6. The extent of benefits may be increased by a court decision.

7. The term of a compulsory insurance contract shall not be less than the term of the clinical trial of a medicinal product.

8. Terms and conditions of contract of compulsory insurance, including insurance rates of compulsory insurance, the list of documents required to enable payment of benefits, the procedure of individual identification code of a patient, the procedure of informing the insurer by the insurant of the number of patients involved in clinical trial of the medicinal product for medical use, the procedure for the payment of the insurance premium, the procedure for exercising the parties' rights and obligations prescribed by by this Federal Law and other federal laws under the contract of compulsory insurance shall be established by standard rules for compulsory insurance.

9. If harm is caused to the life of a patient involved in clinical trials 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 clinical trials 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 clinical trials of a medicinal product will be paid to the person who has incurred such expenses.

10. Benefits for compensation of harm caused to the life of a patient involved in clinical trials 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 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. The patient involved in clinical trial of a medicinal product or the beneficiary shall be obliged to provide the insurer with the patient's identification code required to enable payment of benefits, established by the insurer in accordance to 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 clinical trials 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. Benefits 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 issuing permits to conduct clinical trials of a medicinal product for medical use shall control to make sure the institution, which has obtained a permit to conduct clinical trials of a medicinal product, for medical, fulfills its obligation on compulsory life and health insurance of a patient involved in clinical trials of medicinal product for medical use as stated in this Article.

(as amended by Federal Law of November 29, 2010, No. 313-FZ)

## Chapter 8. **Manufacture and Marking of Medicines**

### Article 45. **Manufacturing of Medicines**

1. Manufacturing of medicines shall comply with good manufacturing practice and quality control of medicines approved by the authorized federal executive body.

2. Medicines in the Russian Federation shall be manufactured by manufacturers of medicines licensed to manufacture medicines.

3. Manufacture of medicines shall conform to the manufacturing 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 manufacturing stages of the medicines.

4. Only pharmaceutical substances included in the state register of the medicines may be used for manufacture of medicines.

5. It is forbidden to manufacture:

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 manufacturing of medicines;

4) medicines with violation of good manufacturing practice.

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 practice and quality control of medicines.

7. The authorized representative of the manufacturer of medicines shall be an employee, who has higher pharmaceutical, chemical or biological education or veterinary education for the manufacturing of the medicines for veterinary use, and at least five years' experience in the area of good manufacturing practice and quality control of medicines certified in the procedure established by the authorized federal executive body.

8. Manufacturers of medicines may sell or transfer medicines in the procedure established by the laws of the Russian Federation to:

1) other manufacturers of medicines for manufacturing of medicines;

2) wholesalers of medicines;

3) pharmacy institutions, veterinary pharmacy institutions, individual entrepreneurs licensed for pharmaceutical activity or for a medical activity;

4) research centres for research work;

5) medical institutions and veterinary institutions;

6) institutions that deal with the animals breeding, rearing and keeping.

## Article 46. **Marking of Medicines**

1. Medicinal products, except for medicinal products manufactured by the pharmacy institutions, veterinary pharmacy institutions, individual entrepreneurs licensed for pharmaceutical activity, shall come into circulation if:

1) their primary packaging “(except primary packaging of the herbal medicinal products) contains the name of the medicinal product (international nonproprietary, or chemical, or trade name), batch number, date of issue (for immunobiological medicinal products), shelf-life, dosage or concentration, volume, activity in units of activity or quantity of doses printed well readable in Russian;

(as amended by Federal Law of October 11, 2010, No. 271-FZ)

2) their secondary (consumer) packaging contains printed, well readable Russian name of the medicinal product (international nonproprietary 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 units of activity or quantity of doses in the packaging, dosage form, dispensation conditions, storage conditions, caution notices.

(as amended by Federal Law of October 11, 2010, No. 271-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 chemical name and trade name), 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.

3. Medicines as serums shall come into circulation having the indication of the animal, whose blood, blood plasma, organs or tissues were used to derive these medicines from.

4. The secondary (consumer) packaging of medicines manufactured from the blood, blood plasma, human organs and tissues shall have the following notice applied on to it: “No HIV-1, HIV-2, hepatitis type C virus antibodies and no surface antigen of hepatitis type 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 and secondary (consumer) packaging of the medicinal products intended for clinical trials shall contain the inscription “For clinical trials”.

9. The packaging of the medicines meant 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 on 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**

### **Article 47. Procedure for Import of Medicines to the Russian Federation and Export of Medicines from the Russian Federation**

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 Community (hereinafter – Customs Union) and (or) Russian Federation legislation of customs.

2. The imported medicines shall be included into the state register of the medicines.

3. It is allowed to import into the Russian Federation a specific consignment of 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.

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.

5. It is forbidden to import to the Russian Federation counterfeit medicines, poor quality medicines, or infringing medicines.

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.

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) Russian Federation legislation of customs.

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. The export from the Russian Federation of medicinal products meant for humanitarian aid (assistance) or help under emergency situations shall be performed on the basis of a resolution of the Government of the Russian Federation or a resolution of public authorities of the Russian Federation constituent entities on rendering assistance to a foreign state.

#### **Article 48. Legal Entities Authorized to Import Medicines into the Russian Federation**

Medicines may be imported to the Russian Federation by:

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 centres, higher professional educational institutes, 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;

5) medical institutions and other institutions mentioned in Clauses 1 to 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 with the electronic digital signature.

**Article 49. Documents Submitted to Customs Authorities of the Russian Federation when Importing Medicines into the Russian Federation**

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) Russian Federation legislation of customs:

1) certificate of manufacturer of a medicine stating that the imported medicine is in compliance with the pharmacopeia monograph 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 at the territory of the Russian Federation.

**Article 50. Import of Medicinal Products into the Russian Federation for Personal Use and Other Non-Commercial Purposes**

1. Medicinal products may be brought to the Russian Federation ignoring the requirements provided for by Clauses 1 to 4 of Article 47, Articles 48 and 49 hereof, if they are intended for:

1) personal use by the individuals who has arrived in the Russian Federation;

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 arriving in the Russian Federation;

4) treatment of participants of international cultural and sport events and of international expeditions;

5) treatment of the zoo animals, as well as of the animals brought into the Russian Federation to take part in sport and entertainment events.

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.

3. Medicinal products meant for humanitarian aid (assistance) or help under emergency situations are imported to the Russian Federation in the order established by the Government of the Russian Federation. It is forbidden to import to the Russian Federation unregistered medicinal products meant for humanitarian aid (assistance) or help under emergency situations.

#### **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 authorities 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.

### **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, individual entrepreneurs 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.

2. Individuals may be engaged in certain pharmaceutical activities provided that they have higher or secondary pharmaceutical education, 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.

(as amended by Federal Law of July, 27 2010, № 192-FZ).

#### **Article 53. Sale, Transfer of Medicines by Wholesalers of Medicines**

Wholesalers of medicines 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 manufacturing purposes;
- 3) pharmacy institutions and veterinary pharmacy organizations;
- 4) scientific-and-research centres for research activities;
- 5) individual entrepreneurs licensed to carry out pharmaceutical activity or having a license to carry out medical activities;
- 6) medical organizations, veterinary institutions;
- 7) institutions that deal with the animals breeding, rearing and keeping.

#### **Article 54. Regulations for Medicines Wholesale**

Manufacturers and wholesalers of medicines shall perform wholesaling of medicines subject to the regulations approved by the relevant authorized federal executive bodies.

#### **Article 55. Procedure for Medicinal Products Retail**

1. Retailing of the 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, individual entrepreneurs 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, centres (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 compounded by pharmacy institutions, veterinary pharmacy institutions, individual entrepreneurs licensed to carry out pharmaceutical activity are allowed to be retailed.

2. The types of pharmacy institutions and the rules of dispensation of medicinal products for medical use through pharmacy institutions, individual entrepreneurs 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,, centres (departments) of general (family) practice) located in rural settlements which have no pharmacy offices shall be approved by the authorized federal executive body.

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 authorities carrying out functions of the state policy development, normative and legal regulation, control and supervision in the area of narcotic drugs, psychotropic substances and their precursors circulation, as well as in the area of counteracting their illicit circulation.

4. Medicinal products for veterinary use are subject to be dispensed through veterinary pharmacy institutions, veterinary organizations and individual entrepreneurs licensed to carry out pharmaceutical activity. The rules of dispensation of medicinal products for veterinary use shall be approved by the authorized federal executive body.

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 authorities of the Russian Federation constituent entities.

6. Pharmacy institutions, individual entrepreneurs licensed to carry out pharmaceutical activity are obliged to provide a minimum range of medicinal products necessary to deliver health care, as established by the authorized federal executive body.

7. In addition to medicinal products, pharmacy institutions, individual entrepreneurs 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, perfume and cosmetic products, medical and sanitary educative printed publications for healthy lifestyle promotion.

(as amended by Federal Law of July, 27 2010, № 192-FZ).

8. The activities of pharmacy institutions in 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. **Compounding and Dispensation of Medicinal Products**

1. Compounding of medicinal products by pharmacy institutions, veterinary pharmacy institutions, individual entrepreneurs 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 compounding and dispensation of medicinal products, as approved by the authorized federal executive body.

2. When they compound medicinal products, pharmacy institutions, veterinary pharmacy institutions, individual entrepreneurs 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, individual entrepreneurs with a pharmaceutical license are not allowed to compound the medicinal products registered in the Russian Federation.

3. Marking and labeling of medicinal products compounded by a pharmacy institution, a veterinary pharmacy institution and an individual entrepreneur 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 an individual entrepreneur with a pharmaceutical license shall bear responsibility for failure to comply with the rules for compounding 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, and 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, individual entrepreneurs with a pharmaceutical license or a medical license, medical organizations, veterinary institutions and other organizations involved in the circulation of medicines.

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.

## 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.

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.

3. The 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. The 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. The 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 as follows:

1) approval of the list of vital and essential medicinal products that are included into such list under international nonproprietary or chemical names and which meet the following criteria:

a) administration of the particular medicinal product for diagnostics, prevention and treatment of diseases including those prevailing in the morbidity structure of the Russian Federation;

b) the advantage of the specific medicinal product compared to other medicinal products for a particular disease, syndrome or clinical case;

c) therapeutic equivalence of the specific medicinal product to medicinal products having the similar mechanism of pharmacologic action;

2) approval of the methodology for determination of the manufacturers' maximum ex-works prices for the medicinal products included in the list of vital and essential medicinal products;

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

4) maintaining 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;

5) approval of the methodology for determination by executive authorities 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 in 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 in the list of vital and essential medicinal products;

7) approval of the procedure for giving mandatory instructions to the executive authorities 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 in 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 authorities 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 in 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 the subject of the Russian Federation accordingly within their competence and under the procedure stipulated by the Government of the Russian Federation;

10) application of sanctions for violation of the pricing procedure for the vital and essential medicinal products as provided for by the legislation of the Russian Federation.

**Article 61. State Registration of Manufacturers' Maximum Ex-Works Prices for Vital and Essential Medicinal Products and Their Sale**

1. The determined by the manufacturers of the medicinal products maximum ex-works prices for the medicinal products included in the list of vital and essential medicinal products shall be subject to state registration.

2. The maximum ex-works price for vital and essential medicinal products proposed by a manufacturer is subject to state registration, unless it exceeds the price for the same medicinal product calculated in accordance with the methodology for determination of the manufacturers' maximum ex-works prices for vital and essential medicinal products, which shall be approved in the order prescribed by the Government of the Russian Federation. This method assumes the calculation of weight-average actual ex-works price, weight-average actual import price of the medicinal product during the year, preceding the date of presenting of manufacturer's maximum ex-works price to state registration, for medicinal products being in circulation in the Russian Federation, and the calculation by the Russian manufacturers of medicinal products of costs associated to developing, manufacturing, sales, specifying by foreign manufacturers of medicinal products of minimal manufacturer's ex-works price for the medicinal product in manufacturer's country and other countries, where it is registered, with taking into account the costs associated to customs clearance (customs duty and customs fees for the customs clearance) and transport charges for medicinal products which did not come in circulation in the Russian Federation and originator medicines.

(as amended by Federal Law of October 11, 2010, No. 271-FZ)

2<sup>1</sup>. In calculation of maximum ex-works price the following shall be taken into account along to the data specified in Clause 2 of this Article:

1) regarding to Russian manufacturer – the price on analogous (by international non-proprietary name, certain dosage form and dosage rate) medicinal products, manufactured in the Russian Federation or in case of absence of such - the price on analogous foreign medicinal products being in civil circulation in the Russian Federation;

2) regarding to foreign manufacturer - the price on analogous (by international non-proprietary name, certain dosage form and dosage rate) medicinal products being in civil circulation in the Russian Federation”;

(clause 2<sup>1</sup> introduced by Federal Law of October 11, 2010, No. 271-FZ)

2<sup>2</sup>. On the ground of the statement submitted up to October 1 of each year by the Russian manufacturer of medicinal products, included in the list of vital and the most important medicinal products, registered maximum ex-works price

for the medicinal product in case of change of prices for raw materials, indirect costs, as well as estimated inflation on the base of the federal budget for the respective financial period and scheduled period, may be re-registered, but not more than ones per calendar year in the order established by the Clauses 2 and 2<sup>1</sup> of this Article.

(clause 2<sup>2</sup> introduced by Federal Law of October 11, 2010, No. 271-FZ)

3. It is prohibited to sell medicinal products included in the list of vital and essential medicinal products, the manufacturer's maximum ex-works price for which have not been registered.

#### **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 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.

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) name of the manufacturer of the medicinal product;
- 2) name of the medicinal product (international nonproprietary or chemical and trade names);
- 3) number of registration certificate for the medicinal product;
- 4) dosage form with indication of the dosage rate of the medicinal product and its quantity in the secondary (consumer) package;
- 5) registered maximum ex-works price in rubles;
- 6) registration date of the maximum ex-works price for the medicinal products included into the list of vital and essential medicinal products.

3. The state 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.

**Article 63. Determination by Executive Authorities of the Russian Federation Constituent Entities of Maximum Wholesale and Maximum Retail Mark-Ups to Actual Ex-Works Prices of Manufacturers of Medicinal Products for Medicinal Products for Medical Use**

1. The executive authorities of the Russian Federation constituent entities determine maximum wholesale and maximum retail mark-ups to the actual ex-works prices of manufacturers of medicinal products for the medicinal products included in the list of vital and essential medicinal products in accordance with the methodology of determination by the executive authorities 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 in the list of vital and essential medicinal products, which methodology shall be approved in the order prescribed by the Government of the Russian Federation.

2. The wholesalers and (or) pharmacy institutions, individual entrepreneurs licensed for pharmaceutical activity shall sell the medicinal products included into the list of vital and essential medicinal products at the prices, the level of which shall not exceed the amount of the actual ex-works price specified by the manufacturer of medicinal products and not higher than the registered maximum ex-works price, and wholesale and (or) retail mark-ups shall not exceed maximum wholesale and maximum retail mark-ups respectively determined by the Russian Federation constituent entity.

3. The executive bodies of the Russian Federation constituent entities shall place on the official web-site or publish the information on the registered maximum ex-works price for the medicinal products included into the list of vital and essential medicinal products, on the set in the Russian Federation constituent entity maximum wholesale mark-up and (or) maximum retail mark-up to the actual ex-works prices of the manufacturers of medicinal products for the medicinal products included into the list of vital and essential medicinal products, and on the amount mention in Clause 2 of this Article. The information provided for in this Clause shall also be placed in pharmacy institutions in the form available for all parties concerned and it shall be updated as being published.

4. The decisions of the executive authorities of the Russian Federation constituent entity on determination of maximum wholesale and maximum retail mark-ups to the registered maximum ex-works prices for the medicinal products included in the list of vital and essential medicinal products, which decisions were taken in violation of the legislation of the Russian Federation, are subject to be revoked judicially.

## Chapter 13. **Safety Monitoring of Medicinal Products Being in Circulation in the Russian Federation**

### Article 64. **Safety Monitoring of Medicinal Products**

1. The medicinal products being in circulation in the Russian Federation shall be subject to the safety monitoring in order to reveal possible negative consequences of their use, to prevent and protect patients against the use of such medicinal products.

2. The safety monitoring of medicinal products at all stages of their circulation in the Russian Federation shall be performed by the authorized federal executive body.

3. Subjects of medicines circulation shall, in the order established by the authorized federal executive body, inform of any and all cases of side effects inconsistent with the information contained in the Package Leaflet for medicinal products, of serious adverse reactions and unexpected adverse reactions that have occurred when administering the medicinal products, and of particularities of interaction of the medicinal products with other medicinal products that were registered when conducting clinical trials, as well as when administering the medicinal products.

4. Failure to inform on or non-disclosure of the data contemplated in Clause 3 of this Article by individuals to whose notice such information came by the nature of their professional occupation, shall be liable in accordance with the legislation of the Russian Federation.

5. The procedure for conduction of safety monitoring of medicinal products, registration of side effects, serious adverse reactions and unexpected adverse reactions that have occurred when administering medicinal products, including for presentation of information thereof, is to be established by the authorized federal executive body.

### Article 65. **Suspension of Medicinal Product**

When obtaining information on cases of side effects, which are not specified in the Package Leaflet for a medicinal product, serious adverse reactions and unexpected adverse reactions that have occurred when administering medicinal products, on particularities of its interaction with other medicinal products, which may constitute a threat to the life or health of patients, as well as information inconsistent with the information on the medicinal product contained in the Package Leaflet, the authorized federal executive body shall consider the question of possible suspension of that medicinal product in the order established by the authorized federal executive body.

Article 66. **Information on the Results of Safety Monitoring of Medicinal Products**

The authorized federal executive body carrying out the safety monitoring of the medicinal products being in circulation in the Russian Federation shall, subject to the monitoring results, place on the official web-site the information on decisions taken as to making amendments to the Package Leaflet for a medicinal product, suspending of the medicinal product, withdrawal of the medicinal product from circulation, or recommencement of the medicinal product.

Chapter 14. **Information on Medicinal Products**

Article 67. **Information on Medicinal Products**

1. Information on prescription medicinal products may only be featured in specialized printed publications targeting 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 Leaflet for medicinal products.

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.

Chapter 15. **Liability for Violation of Legislation of the Russian Federation for Medicines Circulation and Compensation for Harm to Human Health Caused by Administration of Medicinal Products**

Article 68. **Liability for Violation of Legislation of the Russian Federation for the Medicines Circulation**

Violation of the legislation of the Russian Federation for medicines circulation shall entail the responsibility in accordance with the legislation of the Russian Federation.

**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 medicines wholesaler, pharmacy institution, individual entrepreneurs having a pharmaceutical license or a medical license, by health care organization (its separate subdivision (ambulance stations, paramedic's and paramedical-obstetric centers, centres (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.

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 Separate 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 (Corpus of Legislative Acts of the Russian Federation 1998, No. 26, Art. 3006);

2) Federal Law of January 2, 2000, No. 5-FZ On Entering Amendments to Federal Law On Medicines (Corpus 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 (Corpus 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 (Corpus 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 (Corpus 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 (Corpus of Legislative Acts of the Russian Federation 2006, No. 52, Art. 5497).

#### **Article 71. Enactment of the This Federal Law**

1. This Federal Law comes into force on September 01, 2010.

2. The 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<sup>1</sup>. 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.

(as amended by Federal Law of November 29, 2010, No. 313-FZ)

3<sup>2</sup>. 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.

(as amended by Federal Law of November 29, 2010, No. 313-FZ)

3<sup>3</sup>. Approval of or refusal to approve amendments of the documents, contained in the registration dossier for 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 for 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 1, 2011 without request of payment of the state duty provided for by the taxes-and-duties legislation of the Russian Federation.

(as amended by Federal Law of November 29, 2010, No. 313-FZ)

3<sup>4</sup>. Issue of permits 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 exercised n 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 contract of compulsory insurance made in accordance with the standard rules

for compulsory insurance with specifying the maximal 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 taxes-and-duties legislation of the Russian Federation.

(as amended by Federal Law of November 29, 2010, No. 313-FZ)

“3<sup>5</sup>. 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 the most important medicinal products, shall be translated in roubles 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 the most important medicinal products.

“3<sup>6</sup>. 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 the most important medicinal products, shall be indexed from November 1, 2010 on the base of estimated inflation specified by the Federal Law of December 2, 2009 No. 308-FZ “On Federal Budget for 2010 and scheduled period 2011 to 2012” on 2011.

“3<sup>7</sup>. 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 are not allowed. Upon expiration of the above mentioned period the retail, transfer and use of this medicinal products may be performed up to its expiration date.

(as amended by Federal Law of November 29, 2010, No. 313-FZ)

(clauses 3<sup>1</sup>-3<sup>7</sup> introduced by Federal Laws of October 11, 2010, No. 271-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 manufacturing 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 manufacturing 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 manufacturing of medicines granted before January 01, 2014 shall be effective after January 01, 2014 till their expiry provided that the licensee meet the good manufacturing practices and quality control of the medicines mentioned in Clause 1 of Article 45 hereof.

7. The creation of state task on 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 institutions.  
(as amended by Federal Law of November 29, 2010, No. 313-FZ)

D. Medvedev  
President of the  
Russian Federation