

**FEDERAL LAW
NO. 86-FZ OF JUNE 22, 1998
ON MEDICINES
(with the Amendments and Additions of January 2, 2000)**

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Chapter I.	General Provisions	(Articles 1-4)
Chapter II.	The State Regulation of Relations Arising, in the Sphere of the Circulation of Medicines	(Articles 5-7)
Chapter III.	The State System of Control over the Quality, Efficacy and Safety of Medicines	(Articles 8-12)
Chapter IV.	The Production and Manufacture of Medicines	(Articles 9-18)
Chapter V.	The State Registration of Medicine	(Article 19)
Chapter VI.	The Importation of Medicines to the Russian Federation. The Exportation of Medicines from the Russian Federation	(Articles 20-27)
Chapter VII.	Wholesale Trade in Medicines	(Articles 28-31)
Chapter VIII.	Retail Trade in Medicines	(Articles 32-34)
Chapter IX.	The Development, Preclinical and Clinical Investigations of Medicines	(Articles 35-41)
Chapter X.	The State Guarantees of the Accessibility of Medicines	(Article 42)
Chapter XI.	Information About Medicines. The Advertising of Medicines	(Articles 43-44)
Chapter XII.	Responsibility for the Harm Caused to Human Health by the Application of Medicines	(Articles 45)
Chapter XIII.	Concluding Provisions	(Articles 46-47)

The present Federal Law creates the legal basis for the activity of the subjects of circulating medicines, establishes a system of governmental bodies carrying out the law-enforcement practice in accordance with the present Federal Law and distributes the powers of the executive bodies in the sphere of the circulation of medicines.

Chapter I. General Provisions

Article 1. The Subject-matter of the Regulation of the Present Law

1. The present Federal Law shall regulate relations arising in connection with the elaboration, production, manufacture, pre-clinical and clinical investigations of medicines, with the control of their quality, efficacy, safety, the trade of medicines and with other activities in the sphere of the circulation of medicines.

2. The present Federal Law shall establish the priority of state control over the production and manufacture, the quality, efficacy and safety of medicines.

Article 2. The Sphere of Application of the present Federal Law

The present Federal Law shall apply to the relations arising in the sphere of the circulation of medicines on the territory of the Russian Federation, unless otherwise stipulates by the legislation of the Russian Federation.

Article 3. The Legislation of the Russian Federation on Medicines

1. The legislation of the Russian Federation on medicines consists of the present Federal Law, other federal laws and other normative legal acts of the Russian Federation, and also the laws and other normative legal acts of the subjects of the Russian Federation.

2. The specific aspects of the circulation of narcotic medicines and psychotropic substances shall be regulated by the present Federal Law, the rules of the international agreement shall apply.

See [Federal Law No. 3-FZ of January 8, 1998 on Narcotic Medicines and Psychotropic substances](#)

3. In case when international agreement of the Russian Federation establish other rules then in the present Federal Law then the rules of the international agreement shall be applied.

Article 4. Basic Concepts Used in the Present Federal Law

The following basis concepts shall be used for the purposes of the present Federal Law:

medicines are substances used for the purposes of the preventive treatment, diagnosis and cure of deceases, and the prevention of pregnancy, received from blood, blood plasm, and also organs and tissues of man or animals, plants, minerals by metals of synthesis or with the use of biological technologies. Medicines also include substances of vegetative, animal or synthetic origin, possessing pharmacological activity and designed for the production and manufacture of medicines;

medicines items are dosed medicines ready for application;

immuno-biological medicines are medicines intended for immuno-biological prophylaxis and immunological therapy;

narcotic medicines are medicines included in the list of narcotic drugs, to be compiled and renewed in accordance with the 1961 Single Convention on Narcotic Drugs and the legislation of the Russian Federation;

psychotropic substances are substances included in the list compiled and renewed in accordance with the 1971 Convention on Psychotropic Substances and the legislation of the Russian Federation;

patent medicines are medicines, the right of producing and selling them is protected by the [patent legislation](#) of the Russian Federation;

illegal copies of medicines are medicines traded with the violation of the patent legislation of the Russian Federation;

original medicines are medicines put into circulation with registered names of their own;

reproduced medicines are medicines put into circulation after the expiration of the validity term of exclusive patent rights to original medicines;

quality of medicines means the correspondence of medicines to the state standard of their quality;

See the [Rules of Certification in the Medicinal Drugs Certification System of the GOST R Certification System endorsed by \[Decision of the State Committee for Standards and Metrology of the Russian Federation No. 2 of January 3, 2001\]\(#\)](#)

safety of medicines means the characterization of medicines based on the comparative analysis of their efficacy and the appraisal of the risk of causing inquiry to human health;

the effectiveness of medicines means the characterization of the degree of the positive influence of medicines on the running of illnesses.

pharmacopoeial item is a state standard of a medicine containing the list of indicators and methods of quality control of medicines;

state pharmacopoeia is a collection of pharmacopoeial items;

registration number is a code designation awarded to a medicine during state registration;

certificate of the quality of a medicine is a document that confirms the correspondence of the quality of a medicine to the state standard of the quality of medicines;

the circulation of medicines means the generalized concepts of activity that includes the elaboration, investigation, production, manufacture, storage, packing, transportation, state registration, standardization and quality control, sale, marking, advertising, the application of medicines, the destruction of medicines unfit for use or medicines with the expired term of fitness, and other actions in the sphere of the circulation of medicines;

the subjects of the circulation of medicines mean natural and juridical persons trading medicines;

pharmaceutical activity means the activity carried on by wholesale trading organizations and pharmaceutical establishments in the sphere of the circulation of medicine, including wholesale and retail trade in medicines and the manufacture of medicines;

enterprise producing medicines means an organization that produces medicines in conformity with the requirements of the present Federal Law;

Organization working out a medicine is an organization that has patent rights to a medicine and author's rights to the results of its preclinical investigation;

enterprise of wholesale trade in medicines is an organization that carries on wholesale trade in medicines in accordance with the requirements of the present Federal Law;

the pharmaceutical establishment is an organization that carries on retail trade in medicines, manufactures and issues medicines in keeping with the requirements of the present Federal Law; the pharmaceutical establishments include pharmacies, pharmacies of health protection establishments, pharmaceutical points, drugstores and pharmaceutical kiosks.

Chapter II. The State Regulation of Relations Arising in the Sphere of the Circulation of Medicines

Article 5. The state regulation of relations arising in the sphere of circulation of medicines

1. The state regulation of relations arising in the sphere of circulation of medicines shall effected by means of:

- 1) the state regulation of medicines;
- 2) the licensing of the activity in the sphere of the circulation of medicines;
- 3) the attestation and certification of specialists engaged in the sphere of the circulation of medicines;

See Regulation on procedure of attestation for engaging in professional (medical and pharmaceutical) activity approved by Order of Ministry of Health of Medical Industry of the Russian Federation No. 286 of December 19, 1994

4) state control of the production and manufacture of medicines, their quality, efficacy and safety.

Federal Law No. 5-FZ of January 2, 2000 supplemented Item 1 of Article 5 of this Federal Law with subitem 5 in the following wording

5) of the state control of prices for medicaments.

See Regulations on the State Control of Prices in Respect of Vital and Essential Medicines, approved by Decision of the Government of the Russian Federation No. 782 of November 9, 2001

2. The state regulations arising in the sphere of the circulation of medicines shall be carried out by the federal executive body and the executive bodies of the subjects of the Russian Federation whose jurisdiction covers the state control of the quality, efficacy and safety of medicines and by the federal executive body and the executive bodies of the subjects of the Russian Federation in the sphere of public health.

Article 6. The Powers of the Government of the Russian Federation in the Sphere of the Circulation of Medicines

The Government of the Russian Federation shall:

- 1) ensure the pursuit of a single state policy in the sphere of the provision of the population of the Russian Federation with medicines;
- 2) work out and implement federal programmes of the supply of medicines to the population of the Russian Federation and of the development of the medical industry;
- 3) establish the order of the social protection of citizens of the Russian Federation, the preferential or free provision of some categories of citizens of the Russian Federation with medicines;
- 4) approve the Regulations for the activity of the federal body controlling the quality of medicines.

Article 7. The Powers of the Executive bodies of the Subjects of the Russian Federation in the Sphere of the Circulation of Medicines

The executive bodies of the subjects of the Russian Federation in the Sphere of the Circulation of Medicines shall:

- 1) elaborate and implement regional programmes of the provision of the population of the subjects of the Russian Federation with medicines;
- 2) carry out expert examinations of the ecological safety of the production of medicines on the territory of the subjects of the Russian Federation;
- 3) carry out expert examinations of the sanitary and epidemiological safety of the production of medicines on the territory of the subjects of the Russian Federation.

Chapter III. The State System of Control over the Quality, Efficacy and Safety of Medicines

On the protection of legal entities' and individual entrepreneurs' rights in the case of exercise of state control (supervision) see Federal Law No. 134-FZ of August 8, 2001

Article 8. The State System of Control over the Quality, Efficacy and Safety of Medicines

1. All the medicines produced on the territory of the Russian Federation and bought into the territory of the Russian Federation shall be subject to state control.

2. The order of the exercise of the state control over the quality, efficacy and safety of medicines shall be established by the present Federal Law, the normative legal acts of the Russian Federation, including the normative legal acts of the federal executive body whose jurisdiction covers the state control of the quality, efficacy and safety of medicines and whose powers are determined in Article 9 and 10 of the present Federal Law.

3. The state system of the control of the quality, efficacy and safety of medicines includes:

- 1) the federal executive body and the executive bodies of the subjects of the Russian Federation whose jurisdiction includes the state control of the quality, efficacy and safety of medicines and the supervision over the pharmaceutical activities and other actions in the sphere of the circulation of medicines;
- 2) the scientific-research institutions, institutes and laboratories for the development and investigation of medicines and for the state control of the quality, efficacy and safety of medicines;
- 3) the expert councils of the circulation of medicines under the Government of the Russian Federation, which act in accordance with the Regulations for the Expert Councils for the Circulation of Medicines, to be approved by the Government of the Russian Federation;
- 4) the ethical councils acting under the health protection agencies in keeping with the Regulations for the Ethical Councils, to be approved by the federal executive body in the sphere of public health;
- 5) the information system that supplies the subjects of the circulation of medicines with

requisite data.

Article 9. The Federal Executive Body and the Executive Bodies of the Subjects of the Russian Federation Whose Jurisdiction Covers the Control of the Quality, Efficacy and Safety of Medicines

1. The federal body authorized by the Government of the Russian Federation for the exercise of control over the quality, efficacy and safety of medicines (hereinafter referred to as the federal body for medicine quality control) shall be the only federal executive body responsible for the state control of the quality, efficacy and safety of medicines in the Russian Federation and independent in all matters within its jurisdiction.

2. The financing of the activity of the federal body for medicine quality control shall be stipulated by a separate line in the federal budget for the respective year in accordance with its departmental structure of expenditures.

3. The powers for the exercise of the state control of the quality, efficacy and safety of medicines may not be entrusted with the federal executive body which carries out the management of the industrial production of medicines and medical articles.

4. For the purpose of ensuring the state control of the quality, efficacy and safety of medicines the federal body for medicine quality control may set up territorial bodies for the control of the quality, efficacy and safety of medicines (hereinafter referred to as the territorial bodies for medicine quality control) or may delegate to them its powers for the exercise of control over the quality, efficacy and safety of medicines by agreement with the executive bodies of the subjects of the Russian Federation.

Article 10. The Powers of the Federal Body for Medicine Quality Control

The federal body for the medicine quality control shall carry out:

- 1) the expert examination of the quality, efficacy and safety of the medicines produced in the Russian Federation;
- 2) the state registration of medicines, including the registration of homeopathic medicines;
- 3) the compilation of a state register of medicines;
- 4) the formation of an ethical committee under the federal body for the control of the quality of medicines and the provision for its activity;
- 5) the approval of the texts of pharmacopoeial items;
- 6) the compilation and the publication of the state pharmacopoeia;
- 7) the compilation of lists of medicines administered without the doctor's prescription;
- 8) the collection and generalization of the data on the application, by-effect and specific interaction of medicines;
- 9) the elaboration and confirmation of the state standard of the quality of medicines and of the state information standard;
- 10) the elaboration and the approval of the rules for the organization of the production of medicines and for the control of their quality, of the rules for the manufacture of medicines and the rules for the wholesale trade in medicines;
- 11) the expert examination of the ecological, sanitary and epidemiological safety of the production of medicines;
- 12) the elaboration and the approval of the rules of laboratory practice;
- 13) the issue of certificates of the correspondence of the organization of the production of medicines to the requirements of the present Federal Law in case of licensing the production of medicines;
- 14) the control over the observance by the enterprises producing medicines of the rules for the organization and the control of the quality of medicines;
- 15) the interaction with the federal executive bodies responsible for the licensing of the production of medicines, the clinical investigation of medicines and foreign trade activity;
- 16) the issue of permits for the importation of a concrete batch of medicines to the Russian Federation in keeping with Item 6 of Article 20, Subitem 3 of Item 1 of Article 21 of the present

Federal Law;

17) the supervision over pharmaceutical activities;

18) the attestation and certification of specialists engaged in the sphere of the circulation of medicines;

19) other powers entrusted to it by the Government of the Russian Federation in conformity with the legislation of the Russian Federation.

Article 11. Procedure for Appealing Against the Decisions of the Federal Body for Medicine Quality Control

1. If there are disagreements between the subject of the circulation of medicines and the federal body for medicine quality control, the said federal body shall make use of conciliation with the participation of the experts of a subject of the circulation of medicines.

2. The subject of the [circulation of medicines](#) shall have the right to get acquainted with the results of conciliation.

3. Appeals and complaints of the subjects of the circulation of medicines shall be considered by the expert councils for the circulation of medicines under the Government of the Russian Federation.

Article 12. The Powers of the Federal Executive Body in the Sphere of Public Health, Bearing on the Circulation of Medicines

1. The federal executive body in the sphere of public health shall:

1) carry out the training and retraining of specialists engaged in the sphere of the [circulation of medicines](#);

2) work out and endorse normative legal acts on the matters connected with the circulation of medicine and referred by the present Federal Law to its jurisdiction;

3) draft and approve normative legal acts determining the order of pharmaceutical activities;

4) take part in the making and changing the lists of medicines, introduced in the texts of the conventions on narcotic drugs and psychotropic substances;

5) issue licenses for clinical research into medicines to the health protection institutions;

6) formulate and submit to the Government of the Russian Federation proposals on the tax, credit and financial policy in the sphere of the circulation of medicines;

7) participate in international cooperation in the sphere of the circulation of medicines;

8) elaborate and implement measures for the realization and improvement of law-enforcement practice in the sphere of the circulation of medicines in keeping with the requirements of the present Federal Law.

2. Upon the receipt of information about side effects of a medicine and about the specific interaction with other medicines, which do not correspond to the informations on its application, the federal executive body in the sphere of public health shall have the right to suspend the application of this medicine.

Chapter IV. The Production and Manufacture of Medicines

Article 13. The Production of Medicines

1. The production of medicines means the serial receipt of medicines in accordance with the rules for the organization of the production and control of the quality of medicines, approved by the federal body for the control of the quality of medicines.

2. Medicines shall be produced by the [enterprise](#) which have licenses for their production.

3. It shall be forbidden to produce the following medicines:

1) those which have not passed the state registration in the Russian Federation with the exception of medicines intended for clinical investigations;

2) those which have no license for the production of medicines;

3) those which are associated with the breach of the rules for the organization of the production of medicines and the control of their quality, approved by the federal body for the control of the quality of medicines.

4. Patent medicines shall be produced and their sale effected in accordance with the [patent legislation](#) of the Russian Federation, and also with the [Law](#) of the Russian Federation on Trademarks, Service Marks and the Names of the Places of Origin of Goods.

Article 14. The State Control of the Production of Medicines

1. The state control of the production of medicines on the territory of the Russian Federation shall be exercised by the federal body for medicine quality control and by the territorial agencies of medicine quality control.

2. The federal body for the medicine quality control shall elaborate and endorse the rules for the organization of the production of medicines and for the control of their quality.

See Regulation on Ministry of Health Security of the Russian Federation approved by Decision of the Government of the Russian Federation No. 659 of June 3, 1997

3. The federal body for medicine quality control shall verify the work of enterprises producing medicines and draw up certificates about the correspondence of the organization of production of medicines and of the control of their quality to the rules for the organization of production and quality control.

4. The territorial agencies of medicine quality control shall carry on periodical checks of the enterprises producing medicines and located on the territory of the corresponding subjects of the Russian Federation.

5. The federal body for [medicine quality control](#) and the territorial agencies for medicine quality control shall have the right:

1) to have a free access to any enterprise producing medicines and the withdraw the specimens of medicines;

2) to make copies of documents needed for the control of the production of medicines and of their quality;

3) to ban the production of medicines and the sale of medicines in cases, the exhaustive list of which is contained in the rules for the organization of the production of medicines and for the control of their quality.

Articles 15. The Licensing of the Production of Medicines

1. A license for the production of medicines shall be issued to the [enterprises-producer of medicines](#) by the federal executive body whose jurisdiction covers the licensing of the production of medicines.

See Regulation on Procedure of issuing license for industrial production and realization of producer of medicines approved by Ministry of Health of the Russian Federation of March 3, 1994

2. A license for the production of medicines shall be issued on the basis of the application by the enterprise producing medicines, which contains a list of medicines which this enterprise is ready to produce, and of the certificate of the federal body for medicine quality control testifying to the correspondence of the organization of the production of medicines to the requirements of the present Federal Law.

3. A license for the production of medicines shall be issued for a term of not less than five years.

4. To get a certificate of the correspondence of the organization of the production of medicines to the requirements of the present Federal Law, the enterprises-producer of medicines shall submit the following documents to the federal body medicine quality control:

1) documents containing the description of the main technological processes responsible for the quality of medicines;

2) documents confirming the consent of local self-government bodies with the location of a unit

of production of medicines on the given territory;

3) the data of expert examinations of the ecological, sanitary and epidemiological safety of the production of medicines;

4) the patents of the Russian Federation and the license agreements which permit the production and sale of [patent medicines](#).

5. The license for the production of medicines shall contain:

1) the list of medicines permitted for production by the enterprise-producer of medicines;

2) the data on the conditions of the production of medicines, including those on the location of equipment and the number of production premises;

3) the full names of the persons who are responsible for the production, quality and marking responsible for the production, quality and marking of medicines shall involve appropriate changes on the text of the license for the production of medicines shall not mean the substitution of a new one for the old license.

7. The enterprise-producer of medicines shall be obliged to receive a new license for the production of medicines, if changes have been made in the conditions for the production of medicines, or an additional license for the production of medicines, if the nomenclature of medicines has been changed.

8. The time for the adoption of a decision on the issue of a license for the production of medicines shall not exceed two months since the day of the filing of an application.

Article 16. The Marking and Design of Medicines

1. The marking and design of medicines shall correspond to the requirements of the present Federal Law.

2. Medicines shall be put into circulation, if the internal or external packing indicate the following essential elements in a legible print in Russian:

1) the name of a medicine and international non-patented application;

2) the name of the [enterprise-producer of medicines](#);

3) the number of series and the date of manufacture;

4) the method of application;

5) a dose and the number of doses in a packing;

6) the effective date;

7) the conditions for giving a medicine;

8) the conditions for storage;

9) precautionary measures in the administration of medicines.

3. All medicines received from blood or plasma of blood, and also from human organs and tissues shall have the inscription: "Antibodies to human immuno-deficiency virus are absent".

Sera shall be put into circulation with an indication of the blood, plasma of the blood, of the organs and tissues of which animal they were received, vaccines shall be put into circulation with an indication of the nutrient medium that was used for the reproduction of viruses and bacteria.

4. Medicines registered as homeopathic ones shall bear the inscription: "Homeopathic medicines".

5. Medicines intended for the treatment of animals shall bear the inscription: "For animals".

6. Medicines obtained from vegetable raw material shall have the inscription: "Products have passed radiation control".

7. Medicines intended for clinical research shall have the inscription: "For clinical investigations."

8. Medicines intended solely for export shall have the inscription: "For export only."

9. Medicines shall be put into circulation only with a direction for use, which contains the following data in Russian:

1) the name and legal address of the enterprise-producer of a medicine;

2) the name of a medicine and its international non-patented name;

3) information about the components of a medicine;

4) the sphere of application;

- 5) counter indications for use;
- 6) side effects;
- 7) interaction with other medicines;
- 8) doses and the method of application;
- 9) the effective date;
- 10) the indication that a medicine shall not be used upon the expiration of the effective date;
- 11) the indication that a medicine shall be kept in places not accessible to children;
- 12) the conditions for sale.

10. The introduction of data not included in [Items 2-8](#) of this Article, and also admissible abbreviations in the marking of medicines shall be established by the federal body for medicine quality control.

Article 17. The Manufacture of Medicines

1. Medicines shall be manufactured in a pharmaceutical establishment according to doctors' prescriptions only and on the basis of the medicines registered in the Russian Federation.

2. Medicines shall be manufactured in a pharmaceutical establishment having a license for [pharmaceutical activity](#) according to the rules for the manufacture of medicines, approved by the federal body for medicine quality control.

3. The marking and design of medicines made in a pharmaceutical establishment shall correspond to the said rules.

4. A license for pharmaceutical activity shall be issued to a pharmaceutical establishment by the executive body of a subject of the Russian Federation whose jurisdiction includes the licensing of pharmaceutical activity on the territory of the given subject of the Russian Federation on the basis of the findings of the respective territorial agency for medicine quality control about the correspondence of the conditions for the manufacture of medicines in a [pharmaceutical establishment](#) to the requirements of the present Federal Law.

Article 18. Responsibility for the Non-observance of the Rules for the Organization of Production of Medicines and for Medicine Quality Control and the Rules for the Manufacture of Medicines

1. An enterprise producing medicines shall bear responsibility for the non-observance of the rules for the organization of production of medicines and medicine quality control.

2. A pharmaceutical establishment shall bear responsibility for the non-observance of the rules for the manufacture of medicines, and also for the design, packing and [quality of medicines](#) made in the pharmaceutical establishment concerned.

3. Natural persons responsible for the manufacture and quality of medicines shall be indicated in the respective license for pharmaceutical activity and shall bear the disciplinary, administrative and criminal responsibility for breaking the provisions of the present Federal Law.

Chapter V. The State Registration of Medicines

Article 19. The State Registration of Medicines

1. Medicines may be produced, sold and applied on the territory of the Russian Federation, if they have been registered by the federal body for medicine quality control.

On registration of national medicines (substances) see Instruction of Ministry of Health of Medical Industry of the Russian Federation of May 18, 1996

The state registration of the [narcotic drugs](#) and psychotropic substances which are used as medicines and which are subject to state control in keeping with the [Federal Law](#) on Narcotic Drugs and Psychotropic Substances shall be accompanied by the entry of said drugs and substances in appropriate lists Drugs and Psychotropic Substances defined in the [Federal Law](#) on Narcotic Drugs and Psychotropic Substances.

Medicines intended for the medical treatment of animals shall be also subject to state

registration by the federal body for medicine quality control.

2. The following medicines shall be liable to state registration:

1) new medicines;

2) new combinations of the earlier registered medicines;

3) medicines registered earlier, but produced in other medicament forms, in a new dosage or a different composition of auxiliary substances;

4) reproduced medicines.

3. Medicines manufactured in pharmacies according to doctors' prescriptions shall not be subject to state registration.

4. It shall be permissible to apply non-registered medicines in clinical investigations of medicines or in tests of medicines intended for the treatment of animals.

5. It shall be impermissible to carry out the state registration of medicines with similar names just as the multiple state registration of one and the same medicine under one or several names.

6. The state registration of medicines shall be carried out by the federal body for medicine quality control within the period that does not exceed six months since the day of filing an application for the state registration of a medicine.

The federal body for medicine quality control shall determine the degree of changing the dosage or the composition of auxiliary substances of the registered medicine, which involves the need for its state registration as a medicine with a different name.

7. An application for the state registration of a medicine shall be filed with the federal body for medicine quality control by an applicant that may be represented by the organization that has developed the medicine or by another legal entity on the instruction of the organization-developer of the medicine.

8. The registered medicine shall be entered in the state register of medicines.

9. The applicant shall submit to the federal body of medicine quality control the following documents and data for the state registration of a medicine:

1) the application for the state registration of a medicine;

2) the receipt for the payment of a duty for state registration;

3) the legal address of the enterprises-producer of a medicine;

4) the name of a medicine, including international non-patented application, the scientific name in Latin and basis synonyms;

5) the original name of a medicine, if it has been registered as a trademark in keeping with the legislation of the Russian Federation on trademarks, service marks and names of the places of origin of goods;

6) the list of components of a medicine and their quantity;

7) the instruction on the application of a medicine, drawn up in accordance with the requirements of the present Federal Law;

8) the certificate of a medicine's quality;

9) the data on the production of a medicine and the original text of a pharmacopoeial item;

10) methods of control of a medicine's quality;

11) results of preclinical investigations of a medicine;

12) results of pharmacological and toxicological investigations of a medicine;

13) results of clinical investigations of a medicine;

14) results of veterinary investigations, if a medicine intended for the treatment of animals has been registered;

15) samples of a medicine for the expert examination of its quality;

Federal Law No. 5-FZ of January 2, 2000 supplemented Item 9 of Article 19 of this Federal Law with subitem 16 in the following wording. Subitem 16 shall be deemed to be Subitem 17

16) proposals for the price of medicaments;

17) documents confirming the registration of a medicine, if it has been registered beyond the borders of the Russian Federation.

10. The federal body for medicine quality control may use the rapid procedure of the state registration of medicines. Regulations for the rapid procedure of the state registration of medicines shall be worked out and published by the federal body of medicine quality control. The rapid procedure of the state registration of medicines shall not mean the reduction of demands on the quality, efficacy and safety of medicines.

11. The rapid procedure of the state registration of medicines may be applied, if registrars register a reproduced medicine that is equivalent to the [original medicine](#) already registered in the Russian Federation, possibly reproduced by a different technology or with a difference composition of auxiliary substances.

Chapter VI. The Importation of Medicines to the Russian Federation. The Exportation of Medicines from the Russian Federation

See the [Regulations](#) on the Importation into and exportation from the Russian Federation of Medicaments and Pharmaceutical Substances Approved by the [Decision](#) of the Government of the Russian Federation No. 1539 of December 25, 1998

Article 20. The Order of the Importation of Medicines to the Russian Federation

1. Medicines shall be brought into the territory of the Russian Federation in accordance with the legislation of the Russian Federation on the state regulation of foreign trade.

2. Medicines shall be brought into the territory of the Russian Federation under a license for the foreign trade in medicines (hereinafter referred to as a license for foreign trade) and in cases, provided for by [Item 6](#) of this Article, [Subitem 3 of Item 1 of Article 21](#) of the present Federal Law - according to the permit of the federal body for medicine quality control for the importation of a concrete batch of medicines.

3. It shall be forbidden to bring medicines into the territory of the Russian Federation without a license for foreign trade or without a permit of the federal medicine quality control for the importation of a concrete batch of medicines in those cases when the present Federal Law provides for the submission of the said license or permit.

4. It shall be permissible to bring medicines into the territory of the Russian Federation for personal or any other nonprofit use without a license for foreign trade or a permit of the federal body for medicine quality control for the importation of concrete batch of medicines only in cases, provided for by [Article 22](#) of the present Federal Law.

5. Imported medicines shall be registered in the Russian Federation.

6. It shall be permissible to bring to the Russian Federation a concrete batch of non-registered medicines intended for clinical investigations of medicines with the permission of the federal body for medicine quality control.

7. It shall be possible to bring into the territory of the Russian Federation medicines whose quality has been confirmed by the certificate of a [medicine-producing enterprise](#), which certifies that imported medicines have been produced in conformity with the state standard of the quality of medicines, established by the federal body for medicine quality control.

8. In order to protect the market of medicines and the medicine-producing enterprises on the territory of the Russian Federation, the Government of the Russian Federation may introduce special customs duties on imported ready-made medicines in compliance with the customs legislation of the Russian Federation.

9. It shall be forbidden to bring into the territory of the Russian Federation the medicines which are imitations or [illegal copies](#) of the medicines, registered in the Russian Federation. Upon the discovery of such medicines the customs agencies of the Russian Federation shall confiscate them with subsequent destruction in the order prescribed by the federal body for medicine quality control.

Article 21. Legal Entities Authorized to Bring Medicines into th Territory of the Russian Federation

The following bodies may bring medicines into the territory of the Russian Federation:

- 1) enterprises producing medicines for the purposes of their own production;
- 2) enterprises for wholesale trade in medicines;
- 3) scientific-research institutions, institutes, and laboratories for the development, investigation and control of the quality, efficacy and [safety of medicines](#) given the permit of the federal body for medicine quality control to bring in a concrete batch of medicines;
- 4) foreign enterprises producing medicines and enterprises for wholesale trade in medicines, provided that they have their own representative offices on the territory of the Russian Federation.

Article 22. The Importation of Medicines to the Russian Federation for Personal Use and Other Non-profit Purposes

1. Medicines may be brought into the territory of the Russian Federation without a license for foreign trade or without a permit of the federal body for medicine quality control for the importation of a concrete batch of medicines, if they are intended for:

- 1) personal use by natural persons who arrive in the Russian Federation;
- 2) purposeful use by the personnel of the diplomatic corps or by the representatives of the international organizations accredited in the Russian Federation;
- 3) medical treatment of passengers of transport vehicles arriving in the Russian Federation.

2. Medicines intended for the medical treatment of animals in zoological gardens may be brought into the territory of the Russian Federation without a license for foreign trade or without a permit of the federal body for medicine quality control for importing a concrete batch of medicines.

3. In cases provided for by Items 1 and 2 of this Article it shall be permissible to bring into the territory of the Russian Federation medicines which have not been registered in the Russian Federation.

4. Medicines intended for humanitarian purposes shall be brought into the territory of the Russian Federation in the order defined by the Government of the Russian Federation.

It shall be forbidden to bring into the territory of the Russian Federation non-registered medicines intended for humanitarian purposes.

Article 23. Licenses for Foreign Trade

1. A license for foreign trade shall be issued to an enterprise-producer of medicines or to an [enterprise of wholesale trade in medicines](#) by the federal executive body which is competent to issue licenses for foreign trade.

2. A license for foreign trade shall be issued for a term of up to five years.

Article 24. Documents to Be Submitted to the Customs Agencies of the Russian Federation in Case of the Importation of Medicines to the Russian Federation

The following documents and information shall be submitted to the customs agencies of the Russian Federation in case of the importation of medicines to the Russian Federation:

- 1) contracts or other documents containing information about imported medicines and the conditions of their acquisition;
- 2) [certificates of the quality](#) of medicines;
- 3) information about the state registration of each imported medicine with an indication of relevant registration numbers;
- 4) data on the consignor of medicines;
- 5) data on the consignee of medicines in the Russian Federation;
- 6) data on the person who transfers medicines;
- 7) a copy of the license for foreign trade or a permit of the federal body for medicine quality control for the importation of a concrete batch of medicines.

See the [Regulations](#) on the Procedure for Completing Customs Formalities in Respect of Medical Goods, Raw Materials and Component Parts for the Manufacture Thereof by Applying a Special Goods Declaration Procedure, endorsed by [Order](#) of the State Customs Committee of the Russian Federation and the Ministry of Public Health of the Russian Federation No. 792/321 of

August 13, 2001

Article 25. Natural and Juridical Persons Who Are Permitted to Bring Medicines out of the Russian Federation

1. Medicines may be brought out of the territory of the Russian Federation by the [enterprises producing medicines](#) and the enterprises engaged in wholesale trade in medicines, which have licenses for foreign trade.

2. Natural persons may bring out medicines in quantities necessary for personal use in the order prescribed by the customs legislation of the Russian Federation.

Article 26. The Licensing of the Exportation of Medicines from the Russian Federation

1. Medicines shall be brought out of the territory of the Russian Federation under the license for foreign trade, which is drawn up in the order, established by the legislation of the Russian Federation on the state regulation of foreign trade.

2. The following data shall be entered in the text of the license for foreign trade associated with the exportation from the Russian Federation of medicines serving as a raw material for the production of [medicinal preparations](#):

1) the name and legal address of an exporter;

2) the name of medicines which are permitted for exportation from the of the Russian Federation.

Article 27. Cooperation between the Customs Agencies of the Russian Federation and the Federal Body for Medicine Quality Control

1. The federal body for medicine quality control shall place at the disposal of the customs agencies of the Russian Federation the list of medicines registered in the Russian Federation.

2. The customs agencies of the Russian Federation shall inform the federal body for medicine quality control about the importation of medicines to the Russian Federation and the exportation of medicines from the Russian Federation.

Chapter VII. Wholesale Trade in Medicines

Article 28. The Sale of Medicines by Enterprises Producing Medicines

Enterprises producing medicines may sell them or place them at the disposal of the following bodies:

1) other enterprises producing medicines for production purposes;

2) [enterprises of wholesale trade in medicines](#);

3) pharmaceutical establishments;

4) scientific-research institutions for research purposes.

Article 29. The Sale of Medicines by Enterprises of Wholesale Trade in Medicines

Enterprises of wholesale trade in medicines may sell medicines or place them at the disposal of the following units and persons:

1) other enterprises of wholesale trade in medicines;

2) enterprises producing medicines for production purposes;

3) [pharmaceutical establishments](#);

4) scientific-research institutions for research purposes;

5) natural persons who have licenses for private medical practice.

Article 30. The Licensing of Wholesale Trade in Medicines

See the [Regulations on the Licensing of Pharmaceutical Activities and Wholesale Trade in Medicinal Preparations and Medical-Purpose Articles approved by Decision of the Government of](#)

the Russian Federation No. 387 of April 5, 1999

1. Wholesale trade in medicines may be carried out given a license for this activity, issued by the federal executive body or the executive body of a subject of the Russian Federation which are authorized to conduct licensing operations.

2. A license for wholesale trade in medicines, issued by the said federal executive body, shall be valid on the territory of the Russian Federation.

3. A license for wholesale trade in medicines, issued by the said executive body of a subject of the Russian Federation, shall be valid on the territory of the given subject of the Russian Federation. It may be also valid on the territory of any other subject of the Russian Federation, if there is an agreement to this effect between the said executive bodies of the subjects of the Russian Federation.

4. The federal body for medicine quality control shall elaborate and approve the rules for wholesale trade in medicines.

5. The rules of wholesale trade in medicines shall define the order and the conditions for the issue and extension of a license for wholesale trade in medicines and formulate the conditions for the refusal to issue or extend the validity term of the said license and to suspend its validity or annual it.

6. The federal body for medicine quality control and the territorial agencies for medicine quality control shall verify the observance of the rules for wholesale trade in medicines and in the event of breaches of these rules shall submit to the executive bodies authorized to carry out licensing their findings on the need to cancel the license for wholesale trade in medicines or to suspend the validity of the said license pending the removal of the breaches of the rules for wholesale trade in medicines.

Article 31. The Prohibition of the Sale of Medicines of a Non-Standard Quality or of Illegal Copies of Medicines Registered in the Russian Federation

1. It shall be prohibited to sell medicines which have become unfit for use and medicines with expired effective dates.

2. Medicines which have become unfit for use and medicines with expired effective dates shall be liable to destruction.

3. The order of destroying medicines which have become unfit for use and medicines with expired effective dates shall be worked out subject to the requirements of the safety of people, animals and the environment and shall be endorsed by the federal body for medicine quality control.

4. It shall be forbidden to sell medicines which represent illegal copies of the medicines registered in the Russian Federation.

Chapter VIII. Retail Trade in Medicines

Article 32. The Order of Retail Trade in Medicines

1. Retail trade in medicines shall be carried out by the pharmaceutical establishments. They may only sell medicines registered in the Russian Federation.

2. Medicines given according to the doctors' prescriptions shall be subject to sale only through pharmacies and pharmaceutical points. Over-the-counter drugs may be also sold in drugstores and pharmaceutical kiosks.

3. The list of over-the-counter drugs shall be reviewed and endorsed once in five years by the federal executive body in the sphere of public health. Additions to the list shall be published every year.

See List of over-the-counter drugs approved by Order of Ministry of Health of the Russian Federation No. 79 of March 18, 1997

4. The types of pharmaceutical establishments and the order of the administration of

medicines shall be determined and approved by the federal executive body in the sphere of public health.

5. A decision on the opening a new [pharmaceutical establishment](#) shall be taken by the respective local self-government body.

6. Retail trade in medicines intended for the medical treatment of animals shall be carried out in a pharmacy or a veterinary pharmacy or by a veterinary officer.

7. The pharmaceutical establishments shall be obliged to sell medicines only in ready-made form and in quantities necessary for the fulfilment of doctors' prescriptions.

8. The pharmaceutical establishments shall be obliged to provide a minimum assortment of medicines necessary for rendering medical aid, which is established by the federal executive body in the sphere of public health.

9. In addition to medicines the pharmaceutical establishments shall have the right to acquire and sell medical articles, disinfectants, objects of personal hygiene, optics, natural and artificial mineral water, medical, dietetic and baby food, cosmetics and perfumery.

10. The present Federal law and the regulations, approved by the respective ministries and federal executive bodies shall regulate the work of the pharmaceutical establishments of the Armed Forces of the Russian Federation, the Frontier Troops of the Russian Federation, the Internal Troops of the Ministry of Internal Affairs of the Russian Federation, the Federal Security Service Troops, the Government Communication Troops of the Federal Agency of Government Communication and Information under the President of the Russian Federation, the Civilian Defence Troops of the Russian Federation, of the ministries and other federal executive bodies in which the legislation of the Russian Federation provides for military service.

Control over the observance of the provisions of the present Federal Law by the said pharmaceutical establishments shall exercised by the corresponding ministries and other federal executive bodies.

Article 33. The Pharmaceutical Activity of Natural Persons in Pharmaceutical Establishments

Natural persons may engage in [pharmaceutical activities](#), if they have a higher or secondary pharmaceutical education and a certificate of the specialist.

Article 34. The Licensing of the Pharmaceutical Activity of Pharmaceutical Establishments

See the [Regulations on the Licensing of Pharmaceutical Activities and Wholesale Trade in Medicinal Preparations and Medical-Purpose Articles approved by \[Decision of the Government of the Russian Federation No. 387 of April 5, 1999\]\(#\)](#)

1. A license for pharmaceutical activity shall be issued to a pharmaceutical establishment for a term of up to five years by the executive bodies of a subject of the Russian Federation, authorized to carry out the licenses activity.

2. To get a license for pharmaceutical activity, the pharmaceutical establishment shall submit the following documents to the executive body of a subject of the Russian Federation, authorized to carry out the licensed activity:

- 1) the application of a standard form;
- 2) the charter of the pharmaceutical establishment that contains a list of all types of pharmaceutical activity which this establishment intends to carry out;
- 3) the certificate of the registration of the pharmaceutical establishment by a local self-government body;
- 4) documents confirming the right to use premises for pharmaceutical activity;
- 5) documents confirming the fact that specialists have the certificates which entitle them to carry out the pharmaceutical activity in the given pharmaceutical establishment;
- 6) the findings of the agencies of internal affairs on the technical readiness of premises and on their security system for the storage of toxic and psychotropic substances and [narcotic drugs](#), if the

indicated type of activity is provided for the charter of the pharmaceutical establishment;

7) the findings of sanitary and epidemiological bodies and fire-prevention supervision bodies on the suitability of premises for the activity stipulated by the charter of a pharmaceutical establishment.

3. The period for the consideration of submitted documents and for the issue of a license for pharmaceutical activity shall not exceed one month.

4. The inconsistency of submitted documents with the requirements of the present Federal Law may be reason for the refusal to issue a license for pharmaceutical activity. The reasons for the refusal shall be formulated in the document that is given to the respective pharmaceutical establishment by the executive body of a subject of the Russian Federation authorized to carry out the licensed activity.

5. The validity of a license for pharmaceutical activity may be suspended or annulled earlier than the time fixed by [Item 1](#) of this Article in case of a breach of the order of retail trade in medicines, provided for by the present Federal Law.

6. If during a year the pharmaceutical establishment concerned fails to begin its [pharmaceutical activity](#), the validity of the license for pharmaceutical activity shall be halted and may be restored only after the presentation of documents justifying the absence of such activity to the executive body of a subject of the Russian Federation.

Chapter IX. The Development, Preclinical and Clinical Investigations of Medicines

Article 35. The Development of New Medicines

1. The development of new medicines includes the search for new pharmaceutical active substances, the subsequent study of their medicinal property, and also preclinical research.

2. The development of new medicines shall be financed from:

- 1) federal budget resources;
- 2) resources of the [organizations developing medicines](#);
- 3) resources of the enterprises producing medicines within the framework of scientific-research works performed under the agreement between the organization developing medicines and the enterprise producing medicines;
- 4) other sources of financing, including resources of charitable foundations and purpose-oriented contributions of natural and juridical persons.

3. The rights of the organization which has developed a new medicine shall be protected by the patent [legislation](#) of the Russian Federation and [legislation](#) of the Russian Federation on copy right and neighboring rights.

Article 36. Preclinical Investigations of Medicines

1. The purpose of preclinical investigations of medicines shall be the receipt by scientific methods of the evaluation of the effectiveness and safety of medicines.

2. Preclinical investigations of medicines shall be carried out by the organizations developing medicines according to the rules of laboratory practice, approved by the federal body of medicine quality control.

3. Preclinical investigations of medicines shall be carried out according to the approved plan with keeping minutes and making out a report, in which the results of preclinical investigations are entered. The organization developing medicines shall issue its opinion about the possibility of carrying out further clinical investigations of medicines.

4. Preclinical investigations of medicines shall be carried out on animals in conformity with international rules. Control over the observance of the legal and ethical norms of the use of animals during preclinical investigations of medicines shall be exercised by the federal body for medicine quality control and the territorial agencies of medicine quality control, accordingly.

Article 37. Decision on Clinical Investigations of Medicines

1. The purpose of clinical investigations of medicines shall be the receipt by scientific methods

of evaluations and proofs of the effectiveness and [safety of medicines](#), the data on the expected side effects of the application of medicines and effects of the interaction with other medicines.

2. A decision on the conduct of clinical investigations of a concrete medicine shall be taken by the federal body for medicine quality control on the basis of the following documents:

- 1) the application of the organization developing a medicine;
- 2) the positive opinion of the ethical committee of the federal body for medicine quality control;
- 3) the report and findings on preclinical investigations of a medicine;
- 4) the instruction on the application of a medicine.

3. Clinical investigations of medicines shall be carried out in public health institutions having licenses for clinical investigations of medicines.

4. Licenses for clinical investigations of medicines shall be issued by the federal executive body in the sphere of public health to the health protection institutions which ensure the conduct of clinical investigations of medicines in accordance with the rules of clinical practice, elaborated and approved by the federal executive body in the sphere of public health.

5. The list of public health institutions with the right to carry out clinical investigations of medicines shall be made and published by the federal executive body in the sphere of public health.

Article 38. The Legal Base for Clinical Investigations of Medicines and the Financing of Clinical Investigations of Medicines

1. The following documents shall constitute the legal base for clinical investigations of medicines:

1) the decision of the federal body for medicine quality control on the conduct of clinical investigations of medicines;

2) the agreement on clinical investigations of a medicine concluded between the public health institution and the [organization developing the medicine](#).

2. The agreement on clinical investigations of a medicine shall contain the following data:

- 1) on the time-limits and scope of clinical investigations of a medicine;
- 2) on the total cost of the programme of clinical investigations of a medicine;
- 3) on the form of the submission of the results of clinical investigations of a medicine to the federal body for medicine quality control;
- 4) on the conditions of sickness insurance of patients participating in clinical investigations of a medicine.

3. The clinical investigations of a medicine shall be financed from:

- 1) federal budget resources;
- 2) resources of the organization developing a medicine in keeping with the terms of the agreement on clinical investigations of the medicine;
- 3) other sources.

4. Clinical investigations of a medicine shall be financed from the resources of the organization developing the medicine in the form of payment of the bill made out by the health protection institution, which carries on the clinical investigations of the medicine, in conformity with the respective agreement on the clinical investigations of the medicine.

5. It shall be forbidden to pay for the of specialists from the health protection institution which carries on clinical investigations of a medicine directly by the organization developing this medicine, by other juridical or natural persons financing clinical investigations of the medicine.

Article 39. Clinical Investigations of Medicines

1. The director of the health protection institution which carries on clinical investigations of a medicine shall approve the programme of clinical investigations and appoint its manager. A doctor with a record of service of not less than two years may be appointed as the manager of the programme of said investigations. The programme of clinical investigations of a medicine shall be worked out with the participation of the ethical committee of the public health institution that carries on clinical investigations.

2. The manager of the programme of clinical investigations shall be informed about the results of preclinical investigations of the given medicine and shall have the right to obtain any additional data on the preclinical investigations of this medicine.

3. The manager of the programme of clinical investigations of a medicine shall choose patients who may be involved in the clinical investigations of this medicine according to medical indications.

4. A report on the results of clinical investigations of a medicine shall be made out by the manager of the programme of clinical investigations of this medicine.

5. Clinical investigations of a medicine may be interrupted, if their participants have revealed the danger for the health of patients. A decision on the termination of clinical investigations of the medicine may be taken by the manager of the programme of said investigations.

6. Breaches of the rules of clinical practice, and also the falsification of the results of clinical investigations of medicines shall entail responsibility according to the legislation of the Russian Federation.

Article 40. The Rights of Patients Participating in Clinical Investigations of Medicines

1. The participation of patients in clinical investigations shall be voluntary.

2. A patient shall give his written consent to the participation in clinical investigations of a medicine.

3. A patient shall be informed about:

- 1) a medicine and the substance of clinical investigations of the said medicine;
- 2) the expected effectiveness and [safety of a medicine](#) and the degree of risk for the patient;
- 3) the patient's actions in case of the unforeseen effects of the medicine on his state of health;
- 4) the conditions of insurance of the patient's health.

4. The patient shall have the right to refuse to take part in clinical investigations of a medicine at any stage of said investigations.

5. It shall be impermissible to conduct clinical investigations of medicines on minors, except for the cases when the medicine under investigation is intended solely for the treatment of children's diseases or when clinical investigations aim at the reception of data on the best dosage of a medicine for the medical treatment of minors. In the latter case clinical investigations of a medicine on minors shall be preceded by clinical investigations of this medicine on adults.

6. Researchers shall need the written consent of parents for the conduct of clinical investigations of medicines on their children under age.

7. It shall be forbidden to conduct clinical investigations on the following persons:

- 1) minors who do not have parents;
- 2) pregnant women, except for the cases when clinical investigations are conducted in respect of medicines intended for pregnant women, when necessary information can be received from clinical investigations of medicines applied to pregnant women and when such investigations fully preclude the risk of causing harm to a pregnant woman and her foetus;
- 3) servicemen;
- 4) persons serving their sentences in places of confinement, and also persons held in custody in isolation wards.

8. Clinical investigations of medicines intended for the medical treatment of mental diseases may be conducted in mental patients and on persons deemed to be legally unfit in the order prescribed by the Law of the Russian Federation on Psychiatric Aid and on Guarantees of the Rights of Individuals During Its Rendering. In this case clinical investigations of medicines shall be conducted given the written consent of the legal representatives of said persons.

9. A contract for insurance of the health of a patient participating in clinical investigations of a medicine shall be concluded between the [medicine developing organization](#) and the medical insurance organization.

Article 41. The Duty of Subjects of the Circulation of Medicines to Report About Side Effects and Specific Aspects of the Interaction of Medicines with other

Medicines

1. Subjects of the circulation of medicines shall be obliged to inform the federal executive body in the sphere of public health, the executive bodies of the subjects of the Russian Federation in the sphere of public health, the federal body for medicine quality control and the territorial agencies for medicine quality control about all cases of side effects of medicines and about the specific interaction of medicines with other medicines which do not correspond to the data on medicines contained in instructions on their application.

2. For failure to report or conceal information stipulated by Item 1 of this Article persons who were aware of this information due to their line of professional activity shall bear disciplinary, administrative or criminal responsibility in accordance with the legislation of the Russian Federation.

Chapter X. The State Guarantees of the Accessibility of Medicines

Article 42. The State System of the Guaranteed Accessibility of medicines.

The state system of the guaranteed accessibility of medicines includes:

1) federal programmes of the supply of the population of the Russian Federation with medicines and regional programmes of the supply of the population of the subjects of the Russian Federation with medicines;

2) obligatory medical insurance.

2. Federal programmes for the supply of the population of the Russian Federation shall be financed from federal budget resources.

3. The accessibility of medicines within the framework of obligatory medical insurance shall be ensured by the conclusion of tariff agreements.

4. The subjects of tariff agreements shall include within the framework of obligatory medical insurance:

1) the federal executive body in the sphere of public health and the executive bodies of the subjects of the Russian Federation in the sphere of public health;

2) the Federal Fund of Obligatory Medical Insurance and the territorial funds of obligatory medical insurance;

3) medical insurance companies and their associations;

4) medical and pharmaceutical associations.

5. The objects of the tariff agreements shall include:

1) the list of medicines given by a doctor's prescription with prices regulated by the tariff agreement;

2) prices for a limited number of medicines whose list in part of the agreement;

3) the procedure of payment by medical insurance organizations for medicines given to people free of charge or at reduced prices;

4) the procedure for the use of the resources of the federal budget and the resources of the budgets of the subjects of the Russian Federation intended for the supply of the population with medicines.

Chapter XI. Information About Medicines. The Advertising of Medicines

Article 43. Information About Medicines

1. Information about medicines shall be spread in keeping with the requirements of the state information standard.

2. Information about over-the-counter drugs may be contained in publications and advertisements of mass media, in specialized and general printed items, instructions on the application of medicines and in other editions of [subject of the circulation of medicines](#).

3. Information about medicines given by a doctor's prescription may be put only in specialized printed publications designed for the medical and pharmaceutical personnel. Information about medicines for specialists in the sphere of the circulation of medicines may be reproduced in the

form of monographs, reference books, scientific articles, scientific reports made at congresses, conferences, symposia and scientific councils, and also of instructions on the application of medicines intended for doctors.

4. It shall be permissible to use any material carriers of information about medicines, which name it possible to store, transfer and use this information without any distortion.

Article 44. The Advertising of Medicines

1. Only the over-the counter drugs may be advertised in mass media.

2. Regardless of its form the advertisement shall correspond to the pharmaceutical data on medicines received in their clinical investigations and to the requirements of the state information standard.

3. Advertisements shall not represent a medicine as a unique, most effective and safe drug, devoid of any side effects, and shall not mislead people regarding the composition, origin, novelty or patentability of the drug.

4. Advertisements shall not undermine the image of enterprises producing medicines and the belief of customers in the effect of medicines.

5. Advertisements shall not be allowed to compare the publicized medicine with other medicines with the aim of increasing its advertising effect.

6. Advertisement shall not create impression that medical consultations or surgical operations are of no use.

7. Advertisements shall not contain assertions that the effect of a medicine is guaranteed.

8. In case of a breach of the provisions of the present Federal Law dealing with the advertising of medicines the federal executive body in the sphere of public health may prohibit the further advertising of a medicine or notify advertisers about the need to change their approach to the advertisement of this medicine.

9. The size of a fine and the procedure for its payment for breaking the provisions of the present Federal Law on the advertising of medicines shall be determined in conformity with the legislation of the Russian Federation.

Chapter XII. Responsibility for the Harm Caused to Human Health by the Application of Medicines

Article 45. Reparation of Injury Caused to Human Health by the Application of Medicines

1. Injury caused to human health by the application of medicines and by the infliction actions by the subjects of the circulation of medicines shall be compensated in accordance with the Fundamental of the Legislation of the Russian Federation on the Protection of Human Health.

2. If injury has been caused to human health by the application of a medicine, the enterprise that has put out this medicine shall be obliged to compensate for the damage caused to the victim, if it proved that:

1) the medicine was applied according to a doctor's prescription, in accordance with the instruction on the use of the medicine and its harmful effect was caused by the errors in the production of the medicine;

2) injury to human health was caused by the use of the medicine due to the wrong instruction on the application of the medicine, issued by the enterprise-producer of medicines.

3. If injury to human health has been caused by the application of the medicine that has become useless as a result of breaking the rules of the wholesale trade in medicines or the rules of the pharmaceutical activity by pharmaceutical establishments, the injury shall be compensated by the enterprise of the wholesale trade in medicines or by the pharmaceutical institution, through the fault of which the said medicine was released, or made available on sale.

Chapter XIII. Concluding Provisions

Article 46. The Adjustment of Normative Legal Acts to the Present Federal

Law

The president of the Russian Federation shall be advised and the Government of the Russian Federation instructed to bring their normative legal acts into conformity with the present Federal Law.

Article 47. The Entry of This Federal Law in Force

The present Federal Law shall enter into force in three months since the day of its official publication.

President of the Russian Federation

Boris Yeltsin

Moscow, The Kremlin

June 22, 1998

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