

**FEDERAL LAW NO. 86-FZ OF JUNE 22, 1998 ON MEDICINES (with the Amendments and Additions of January 2, 2000, December 30, 2001, January 10, June 30, 2003, August 22, December 29, 2004, October 16, December 18, 2006)**

**Adopted by the State Duma on June 5, 1998**  
**Approved by the Federal Council on June 10, 1998**

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 issue of normative legal acts, actions aimed at control and supervision, rendering governmental services, 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.

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 (pharmaceutical substances);

**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 civil legislation;

**illegal copies of medicines** are medicines traded with the violation of civil legislation;

**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;

**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;

**Organization 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.

**falsified medicine** means a medicine accompanied by false information on the composition and (or) the manufacturer of the medicine;

**off-grade medicine** means a medicine that has become worthless and (or) a medicine with an expired term of use.

## **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 specific types of 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;

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

5) of the state control of prices for medicaments.

2. The state regulation of relations arising in the sphere of medicines' circulation shall be effected by the federal executive body whose jurisdiction includes the functions of developing the governmental policy and of normative legal regulation in the area of medicines' circulation, by the federal executive body whose jurisdiction includes the exercise of state control and supervision in the sphere of medicines' circulation, by the federal executive body exercising the functions of rendering state services and managing state property, as well as law enforcement functions, except for the functions of control and supervision, in the area of medicines' circulation, and by executive bodies of the subjects of the Russian Federation.

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

The Government of the Russian Federation shall:

1) ensure the pursuit in the Russian Federation of a uniform state policy in the sphere of providing the population of the Russian Federation with medicines;

2) shall endorse the amount of, and the procedure for making, payments for the state registration of medicines;

3) shall determine the procedure for importation and exportation of medicines registered in the Russian Federation.

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

Executive bodies of the subjects of the Russian Federation in charge of medicines' circulation shall work out and implement regional programmes providing the population of the subjects of the Russian Federation with medicines.

- 1) Abolished as of January 1, 2005
- 2) Abolished as of January 1, 2005
- 3) Abolished as of January 1, 2005

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

**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 functions of developing the state policy and or normative legal regulation in the area of medicines' circulation.

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

1) the federal executive body whose jurisdiction includes the exercise of functions of developing the state policy and of normative legal regulation in the sphere of the circulation of medicines;

2) the federal executive body whose authority covers the exercise of the state control and supervision in the area of medicines' circulation, and territorial bodies thereof;

3) the federal executive body exercising the functions of rendering governmental services, of state property management and law enforcement functions, except for the functions of control and supervision, in the sphere of medicines' circulation;

4) Abolished as of January 1, 2004

5) the information system that supplies the subjects of the circulation of medicines with requisite data.

**Article 9.** Abolished as of January 1, 2004

**Article 10.** Abolished as of January 1, 2004

**Article 11.** Abolished as of January 1, 2004

**Article 12.** Abolished as of January 1, 2004

**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 executive body whose authority covers the exercise of the functions of developing the state policy and of normative legal regulation in the area of circulation of medicines.

2. Medicines shall be produced by the organisation 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 executive body whose authority covers the exercise of the functions of developing the state policy and of normative legal regulation in the area of circulation of medicines.

4. Patent medicines shall be produced and their sale effected in accordance with civil legislation.

**Article 14.** The State Control of the Production of Medicines

1. The state control over the manufacture of medicines in the territory of the Russian Federation shall be exercised by the federal executive body whose authority covers the exercise of the state control and supervision in the area of medicines' circulation and by territorial bodies thereof.

2. Abolished as of January 1, 2005

*See the text of Item 2*

3. The federal executive body whose authority covers the exercise of the state control and supervision in the area of medicines' circulation shall inspect organisations engaged in manufacturing medicines and shall draw up opinions on the conformity of the organization of production and of the quality control of medicines to the rules of the organization of production and of exercising the quality control of medicines.

4. On the instructions of the federal executive body whose authority covers the exercise of the state control and supervision in the area of medicines' circulation, territorial bodies thereof shall periodically inspect the organisations engaged in manufacturing medicines that are situated in the territories of appropriate subjects of the Russian Federation;

5. The federal body of executive power whose authority covers the state control and supervision in the area of medicines' circulation and territorial bodies thereof shall have the right:

1) to have a free access to any organization 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.

#### **Article 15. The Licensing of Production of Medicinal Drugs**

1. The license for the manufacture of medicines shall be issued to an organization producing medicines by the federal executive body whose authority covers the exercise of the state control and supervision in the area of medicines' circulation.

2. The license for the manufacture of medicines shall be issued on the basis of an application of an organization engaged in the production of medicines that contains the list of medicines the manufacturing organization is ready to produce.

3. In order to obtain the license, the applicant for it shall submit the following documents to the federal executive body whose authority covers the exercise of the state control and supervision in the area of medicines' circulation:

a description of the basic technological processes ensuring the quality of the medicinal drugs;  
the local government bodies' consent to the deployment of the medicinal drug production facility in a given territory;

properly-attested copies of the Russian Federation patents or the licence agreements permitting the production and sale of patented medicinal drugs.

4. The license for the manufacture of medicines shall be issued for a term of five years.

#### **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 Russia:

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

2) the name of the organization-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 organization-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 of executive power whose authority covers the exercise of functions of developing the state policy and of normative legal regulation in the area of medicines' circulation.

#### **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 of executive power whose authority covers the exercise of functions of developing the state policy and of normative legal regulation in the area of medicines' circulation.

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

4. Excluded.

#### **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 organisation 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 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 of executive power whose authority covers the exercise of functions of developing the state policy and of normative legal regulation in the area of medicines' circulation.

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 of executive power whose authority covers the exercise of functions of developing the state policy and of normative legal regulation in the area of medicines' circulation.

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 of executive power whose authority covers the exercise of functions of developing the state policy and of normative legal regulation in the area of medicines' circulation 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 of executive power whose authority covers the exercise of functions of developing the state policy and of normative legal regulation in the area of medicines' circulation 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 of executive power whose authority covers the exercise of functions of developing the state policy and of normative legal regulation in the area of medicines' circulation 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 making payment for state registration;
- 3) the legal address of the organisation-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;
- 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 of executive power whose authority covers the exercise of functions of developing the state policy and of normative legal regulation in the area of medicines' circulation 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 executive body whose authority covers the exercise of the functions of working out the state policy and of normative legal regulation in the area of medicines' circulation. 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**

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

1. Medicines registered in the Russian Federation shall be brought into the territory of the Russian Federation in accordance with the legislation in the procedure determined by the Government of the Russian Federation.

2. Abolished as of January 1, 2005

3. Abolished as of January 1, 2005

4. Abolished as of January 1, 2005

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 of executive power whose authority covers the exercise of the state control and supervision in the area of medicines' circulation.

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 organisation, which certifies that imported medicines have been produced in conformity with the state standard of the quality of medicines, established by the federal body of executive power whose authority covers the exercise of the functions of working out the state policy and of normative legal regulation in the area of medicines' circulation.

8. In order to protect the market of medicines and the medicine-producing organisations 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, faulty medicines. 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 of executive power whose authority covers the exercise of the function of working out the state policy and normative legal regulation in the area of medicines' circulation.

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

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

1) organisations producing medicines for the purposes of their own production;

2) organisations 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 executive body whose authority covers the exercise of the state control and supervision in the area of medicines' circulation to bring in a concrete batch of medicines;

4) foreign organisations 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 the appropriate legalization, 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 the appropriate legalization.

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. Abolished as of January 1, 2005**

### **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 if 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) the permit of the federal executive body whose authority covers the exercise of the state control and supervision in the area of medicines' circulation for the importation of a concrete batch of medicines in the instances established by Article 20 of this Federal Law.

**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 organisations producing medicines and the organisations engaged in wholesale trade in medicines.

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.** Abolished as of January 1, 2005

**Article 27.** Cooperation between the Customs Agencies of the Russian Federation and the Federal Body for of Executive Power Whose Authority Covers the Exercise of the State Control and Supervision in the Area of Medicines' Circulation

1. The federal body of executive power whose authority covers the exercise of the state control and supervision in the area of medicines' circulation 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 of executive power whose authority covers the exercise of the state control and supervision in the area of medicines' circulation 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 Organisations Producing Medicines

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

- 1) other organisations producing medicines for production purposes;
- 2) organisations of wholesale trade in medicines;
- 3) pharmaceutical establishments;
- 4) scientific-research institutions for research purposes.

**Article 29.** The Sale of Medicines by Organisations of Wholesale Trade in Medicines

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

- 1) other organisations of wholesale trade in medicines;
- 2) organisations producing medicines for production purposes;
- 3) pharmaceutical establishments;
- 4) scientific-research institutions for research purposes;
- 5) the individual entrepreneurs holding medical activity licences.

**Article 30.** Excluded.

**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 medicine with expired effective dates, faulty medicines.

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

3. The order of destroying medicines which have become unfit for use, medicines with expired effective dates and faulty medicines shall be worked out subject to the requirements of the safety of



people, animals and the environment and shall be endorsed by the federal executive body whose authority covers the exercise of the functions of working out the state policy and of normative legal regulation in the area of medicines' circulation.

4. It shall be forbidden to sell faulty medicines, as well as 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 whose authority covers the exercise of the functions of working out the state policy and of normative legal regulation in the sphere of medicines' circulation. Additions to the list shall be published every year.

4. The types of pharmaceutical establishments and the order of the administration of medicines shall be determined and approved by the federal executive body whose authority covers the exercise of the functions of working out the state policy and of normative legal regulation in the sphere of medicines' circulation.

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 whose authority covers the exercise of the functions of working out the state policy and of normative legal regulation in the sphere of medicines' circulation.

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 activities of pharmaceutical institutions of the Armed Forces of the Russian Federation, of other troops, military units and bodies, where military service is provided for by laws, shall be regulated by this Federal Law and the regulations endorsed by appropriate federal executive bodies.

Control over the observance of the provisions of the present Federal Law by the said pharmaceutical establishments shall be 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 Pharmaceutical Activity**

1. Pharmaceutical activity shall be subject to licensing in compliance with the legislation of the Russian Federation.

2. The conditions sine qua non for the making of the decision to issue a licence shall be the filing of the following documents by the contender for the licence: documents confirming the licence contender's right to use the premises for the purpose of pursuing pharmaceutical activity, the availability of certificates held by the specialists performing pharmaceutical activity and also a sanitary-epidemiological statement on the compliance of the premises with the provisions of sanitary rules.

## **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 organizations producing medicines within the framework of scientific-research works performed under the agreement between the organization developing medicines and the organization 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 civil legislation.

#### **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 executive power whose authority covers the exercise of the functions of working out the state policy and of normative legal regulation in the area of medicines' circulation.

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 of executive power whose authority covers the exercise of the functions of working out the state policy and of normative legal regulation in the area of medicines' circulation and by its, and the territorial bodies, 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 of executive power whose authority covers the exercise of the state control and supervision in the area of medicines' circulation 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 accredited with the federal executive body whose authority covers the exercise of the state control and supervision in the area of medicines' circulation.

4. 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 whose authority covers the exercise of the state control and supervision in the sphere of medicines' circulation.

#### **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 of executive body whose authority covers the exercise of the state control and supervision in the area of medicines' circulation on the conduct of clinical investigations of medicines;

2) the agreement on clinical investigations of a 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 executive power whose authority covers the exercise of the state control and supervision in the area of medicines' circulation;

4) on the conditions of sickness insurance of patients participating in clinical investigations of a medicine.

5) on the terms and conditions of the civil liability insurance of the persons engaged in medicines' clinical investigations.

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. Abolished as of January 1, 2005
5. Abolished as of January 1, 2005

**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 whose authority covers the exercise of the state control and supervision in the area of medicines' circulation and territorial bodies thereof 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**

Abolished as of January 1, 2005.

## **Chapter XI. Information About 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.** Abolished.

## **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 organisation 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 organisation-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 organisation 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

No, 86-FZ