

Federal law N 86-Φ3 of June 22, 1998
"On Medicines "
(with amendments as for January 2, 2000, December 30, 2001, January 10, June 30, 2003,
August 22, December 29, 2004)

Adopted By the State Duma on June 05, 1998.
Approved by the Council of Federation on June 10, 1998.

Federal law N 122-Φ3 of August 22, 2004, stipulated amendments to the preamble hereof that shall become valid from January 01, 2005.

See the text of preamble in the previous version

This Federal law stipulates the legal basis for the subjects providing drugs distribution, establishes system of the state bodies providing issue of statutory legal acts, control and supervision, official services, law enforcement practice according to this Federal law, distributes authorities of the executive bodies in the field of drugs distribution.

Chapter I. General Provisions

Article 1. The subject of regulation of this Federal law

1. This Federal law regulates relations arising in connection with development, production, manufacturing, non-clinic and clinic trials of drugs and other actions in the field of drugs distribution, quality, effectiveness, and safety control, sales of drugs and other actions in the field of drugs distribution.

2. This Federal law sets a priority of the state control over production, manufacturing, quality, effectiveness, safety of drugs.

Article 2. The scope of this Federal law

This Federal law is applied to the relations arising in the field of drugs distribution in the territory of the Russian Federation unless another is stipulated by the legislation of the Russian Federation.

Article 3. The legislation of the Russian Federation for drugs

1. The legislation of the Russian Federation for drugs consists of this Federal law, other federal laws and statutory legal acts of the Russian Federation and the laws and other statutory legal acts of the subjects of the Russian Federation.

2. The features of distribution of narcotic and psychoactive drugs are regulated by the federal laws.

See Federal law N 3-Φ3 of January 08, 1998 "Of narcotic and psychoactive drugs "

3. If the international treaty of the Russian Federation stipulates other rules than those set in this Federal law, then the provisions of the international treaty shall prevail.

Federal law N 122-Φ3 of August 22, 2004, (in the wording of the Federal law N 199-Φ3 of December 29, 2004) stipulates amendments of the article 4 of this Federal law that become valid from January 01, 2005.

See the text of the article in the previous version

Article 4. Basic provisions used in this Federal law

The following basic provisions are used for the purposes of this Federal law:

drugs – substances used for prophylaxis, diagnosis, treatment of disease, contraception, made of blood, plasma, organs and tissues of humans or animals, plants, minerals by synthesis or biotechnologies. Drugs include plant, animal or synthetic substances with pharmacological properties and used for production and manufacturing of drugs (pharmaceutical substances);

medical products – dosed drugs ready for use;

immunobiological drugs – drugs destined for immunological prophylaxis and immunological therapy;

narcotic drugs – drugs included in the list of narcotic substances made and updated according to the Unified concept of narcotic drugs of the year 1961 and the legislation of the Russian Federation;

psychoactive substances – substances included in the list made and updated according to the Convention of psychoactive substances of the year 1971 and the legislation of the Russian Federation;

patent drugs – drugs which rights for production and sale are protected by the patent laws of the

Russian Federation;

illegal copies of drugs – drugs put into distribution with violation of patent laws of the Russian Federation;

original drugs – drugs put into distribution with registered proper names;

reproduced drugs – drugs put into distribution after expiration date of the exclusive patent rights for original drugs;

quality of drugs – conformity of drugs to the state quality standard for drugs;

See Industry standard OCT 91500.05.001.00 "Quality standards for drugs. Basic provisions ", approved by the order of the Ministry of Public Health of the RF No 388 of November 01, 2001

See Rules of certification in the Certification scheme for drugs of GOST-R certification scheme approved by the resolution of Gosstandart of the RF N 36 of May 24, 2002.

See Regulations on certification scheme for drugs within GOST-R certification scheme approved by the resolution of Gosstandart of the RF N 121 of December 02, 2002.

safety of drugs – characteristics of drugs based on the comparative analysis of their effectiveness and evaluation of risk of harm for health;

effectiveness of drugs – characteristics of positive influence of drugs on the disease;

pharmacopeia article – state standard for drug with the list of parameters and methods of quality control for drugs;

state pharmacopeia – collected pharmacopeia articles;

registry number – coded number given to the drug while state registration;

quality certificate for drug – document confirming the conformity of drug quality to the state quality standard for drug;

drugs distribution – general concept of activities including development, research, production, manufacturing, storage, package, transportation, state registration, standardization and quality control, sale, marking, advertising, use of drugs, elimination of unsuitable or expired drugs and other actions in the field of drugs distribution;

subjects of drugs distribution – physical and legal persons providing drugs distribution;

pharmaceutical activities – activities provided by the wholesale companies and pharmaceutical institutions in the field of drugs distribution including wholesale and retail drug trade, manufacturing of drugs;

manufacturer of drugs – company manufacturing drugs according to the requirements of this Federal law;

developer of drug – company that has patent rights for the drug and copyright for the results of its non-clinic trials;

wholesale of drugs – company providing wholesale of drugs according to the requirements of this Federal law;

pharmaceutical institution – company providing wholesale trade of drugs, manufacturing and sale of drugs according to the requirements of this Federal law; pharmaceutical institutions include pharmacies, pharmacies at public health institutions, pharmacy points, stores and stands;

faulty drug – drug with false information of its composition and (or) manufacturer of drug;

defective drug – drug that became unsuitable and (or) drug with expired effective date.

Chapter II. State regulation of relations arising in the field of drugs distribution

Federal law N 122-ФЗ of August 22, 2004, stipulates amendments of the article 5 of this Federal law that become valid from January 01, 2005.

See the text of the article in the previous version

Article 5. State regulation of relations arising in the field of drugs distribution

1. State regulation of relations arising in the field of **drugs distribution** is provided by:

- 1) state registration of drugs;
- 2) licensing of certain kinds of activities in the field of drugs distribution;
- 3) validation and certification of specialists worked in the field of drugs distribution;
- 4) state control over production, manufacturing, quality, effectiveness, safety of drugs;

See Regulations on the state control over the effectiveness and safety of drugs in the territory of the RF approved by the order of the Ministry of Public Health N 22 of May 28, 2003.

- 5) state regulation of prices for drugs.

See Regulations on the state regulation of prices for vital and major drugs approved by the regulation of the Government of the RF N 782 of November 09, 2001.

2. State regulation of relations arising in the field of drugs distribution is provided by the federal executive body authorized for drawing out the state policy and legislative regulating in the field of drugs distribution, federal executive body authorized to provide state control and supervision in the field of drugs distribution, federal executive body providing state services, state property management and legislative functions except those for control and supervision in the field of drugs distribution, and executive bodies of the subjects of the Russian Federation.

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 6 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 6. Authorities of the Government of the Russian Federation in the field of drugs distribution

The Government of the Russian Federation:

1) provides unified state policy in the field of supply of drugs to the population of the Russian Federation;

See the List of population groups and diseases which are treated at out-patient institutions with drugs and medical products that are prescribed free of charge and the List of population groups which receive drugs at out-patient institutions with 50% discount approved by the Resolution of the Government of the RF N 890 of July 30, 1994.

- 2) approves the amount and the order of payment for the state registration of drugs;
- 3) determines the order of export and import of drugs registered in the Russian Federation.

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 7 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 7. Authorities of the executive bodies of the subjects of the Russian Federation in the field of drugs distribution

Executive bodies of the subjects of the Russian Federation in the field of drugs distribution draw out and provide regional programs for provision of population of the subject of the Russian Federation with drugs.

- 1) expired on January 01, 2005;
- 2) expired on January 01, 2005;
- 3) expired on January 01, 2005.

See Method recommendations "Of control body for pharmaceutical companies in the subjects of the Russian Federation ", approved by the Ministry of Public Health of the RF in 1997.

Chapter III. State control scheme for quality, effectiveness, safety of drugs

On the protection of rights of legal persons and individual entrepreneurs at the state control (supervision) see Federal law N 134-Φ3 of August 08, 2001.

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 8 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 8. State control scheme for quality, effectiveness, safety of drugs

1. The state control is to be provided for all drugs manufactured in and exported to the territory of the Russian Federation.

2. The order of state control over quality, effectiveness, [safety of drugs](#) is stipulated by this Federal law, standard legal acts of the Russian Federation, including those of the federal executive body authorized for drawing out the state policy and legislative regulation in the field of drugs distribution.

See Order of state quality control for drugs in the territory of the RF approved by the order of the

Ministry of Public Health of the RF N 137 of April 04, 2003.

3. The state control scheme for quality, effectiveness and safety of drugs consists of:
- 1) the federal executive body authorized for drawing out the state policy and legislative regulation in the field of drugs distribution;
 - 2) the federal executive body authorized for providing the state control and supervision in the field of drugs distribution and territorial departments of that body;
 - 3) the federal executive body providing state services, control over the state property and legislative functions except control and supervision in the field of drugs distribution;
 - 4) expired on January 01, 2005.;
- See the text of [sub-clause 4 clause 3 article 8](#)*
- 5) the information system providing [the subjects of drugs distribution](#) with necessary information.

See Regulations on the information system providing the subjects of drugs distribution with necessary information, approved by the order of the Ministry of Public Health of the RF N 224 of May 28, 2003.

Article 9. Expired on January 01, 2005.
See the text of [article 9](#)

Article 10. Expired on January 01, 2005.
See the text of [article 10](#)

Article 11. Expired on January 01, 2005.
See the text of [article 11](#)

Article 12. Expired on January 01, 2005.
See the text of [article 12](#)

Chapter IV. Production and manufacturing of drugs

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 13 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 13. Production of drugs

1. Production of drugs is a full-scale production of drugs according to the rules of production and quality control of drugs approved by the federal executive body authorized for drawing out the state policy and legislative regulation in the field of drugs distribution.

See Industry standard OCT 42-510-98 "Rules for production and quality control for drugs (GMP), enacted by joint order of the Ministry of Public Health of the RF and the Ministry of Economics of the RF N 432/ 512 of December 03, 1999.

See also National standard of the RF GOST-R 52249-2004 "Rules for production and quality control for drugs", approved and enacted by the resolution of Gosstandart of the RF N 160-cm of March 10, 2004, from January 01, 2005.

2. Production of drugs is provided by the [manufacturers of drugs](#), having [licenses](#) for production of drugs.

3. It is prohibited to produce drugs:

- 1) not passed the state registration in the Russian Federation except those drugs to be used for clinic trials;
- 2) without license for production of drugs;
- 3) with violation of rules for production and quality control for drugs approved by the federal executive body authorized for drawing out the state policy and legislative regulation in the field of drugs distribution.

4. Production and sale of patent drugs are provided according to the patent laws of the Russian Federation and the Law of the Russian Federation "Of trade marks, service marks and names of goods origins".

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 14 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 14. State control over production of drugs

1. State control over production of drugs in the territory of the Russian Federation is provided by the federal executive body authorized for providing the state control and supervision in the field of drugs distribution and by its territorial departments.

See Regulations for the Ministry of Public Health and Social Development of the RF approved by the decree of the Government of the RF N 321 of June 30, 2004.

2. Expired on January 01, 2005.

[See the text of clause 2 article 14](#)

3. Federal executive body authorized for providing the state control and supervision in the field of drugs distribution provides the inspection of manufacturers of drugs and makes a reports on the conformity of production and quality control of drugs to the rules of production and quality control of drugs.

4. By the order of federal executive body authorized for providing the state control and supervision in the field of drugs distribution the territorial departments of that body provides periodical inspections of manufacturers of drugs located in the territories of the appropriate subjects of the Russian Federation.

5. Federal executive body authorized for providing the state control and supervision in the field of drugs distribution and its territorial departments have right:

- 1) to get unimpeded access to any manufacturer of drugs, to take samples of produced drugs;
- 2) to make copies of documents necessary for control over production and quality of drugs;
- 3) to suppress production and sale of ready drugs in cases listed in the rules of production and quality control for drugs.

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 15 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 15. Licensing of production of drugs

1. The license for production of drugs is given to the manufacturer of drugs by the federal executive body authorized for providing the state control and supervision in the field of drugs distribution.

See Regulations for licensing of production of drugs approved by the decree of the Government of the RF N 500 of July 04, 2002.

2. The license for production of drugs is given against the application of the manufacturer containing the list of drugs to be produced by the manufacturer.

3. The applicant for license is to give the following documents are to be given to the federal executive body authorized for providing the state control and supervision in the field of drugs distribution:
description of the major technological processes providing the quality of drugs;
consent of local administrative bodies for location of production of drugs in that territory;
certified copies of patent of the Russian Federation or license contracts allowing production and sale of patent drugs.

See Order of issue of reports on the conformity of production of drugs to the requirements of this Federal law approved by the order of the Ministry of Public Health of the RF N 138 of April 04, 2003.

4. The license for production of drugs is issued for at least five years.

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 16 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 16. Marking and appearance of drugs

1. Marking and appearance of drugs are to meet the requirements of this Federal law.
2. Drugs are the subject of distribution if the internal and external packing has the following well seen information in Russian:

- 1) name of the drug and its international non-proprietary name;
- 2) name of the [manufacturer of drugs](#);
- 3) series number and the date of manufacturing;

- 4) method of application;
- 5) dose and number of doses in packing;
- 6) expiry date;
- 7) terms of selling;
- 8) storage conditions;
- 9) precautions at application of drugs.

Marking and appearance of drugs see also the letter of Federal service on supervision in the field of public health and social development N 11298/04 of December 30, 2004

3. All drugs made of human blood, plasma, organs and tissues have marking: "No antibodies to human immunodeficiency virus".

Serums are subject of distribution with marking which animal blood, plasma, organs or tissues they are made of; vaccines – with pointing the nutrient solution used for generation of viruses and bacteria.

4. Drugs registered as homeopathic ones have marking: "Homeopathic".
5. Drugs to be used for animals treatment have marking: "For animals only".
6. Drugs made of plants have marking: "Radiation control passed".
7. Drugs to be used for clinic trials have marking: "For clinic trials".
8. Drugs to be used for export purposes have marking: "For export only".
9. Drugs are subject of distribution with the instruction in Russian containing the following

information:

- 1) name and legal address of the manufacturer of the drug;
- 2) name of the drug and its international non-proprietary name;
- 3) information of the components of the drug;
- 4) field of application;
- 5) contradictions for use;
- 6) side effects;
- 7) interaction with other drugs;
- 8) doses and method of application;
- 9) expiry date;
- 10) notice that the drug is not to be used after the expiry date;
- 11) notice that the drug is to be kept in place not accessible for children;
- 12) terms of selling.

See Method recommendations on preparation of "Instruction for use of drugs", allowed for medical use in the RF, approved by the Department of State Quality, Efficiency and Safety Control of Drugs and Medical Technique of the Ministry of Public Health of the RF of February 07, 2000, and ratified by the State Pharmacological Committee of the Ministry of Public Health on November 11, 1999, minutes N 9.

Inadmissibility of manufacturer's unconditioned editing of the instructions for drugs use see also the letter of the Department of the state control of drugs, medical products and medical technique of the Ministry of Public Health of the RF N 295-22/205 of September 19, 2003.

10. Additional information not included into [clauses 2 - 8](#) hereof and permissible abbreviations at marking of drugs are to be stipulated by the federal executive body authorized for drawing out the state policy and legislative regulation in the field of drugs distribution.

See Method recommendations MY 9467-015-05749470-98 "Graphic appearance of drugs. General requirements", valid from May 01, 1999 according to the letter of the Department of State Quality, Efficiency and Safety Control of Drugs and Medical Technique of the Ministry of Public Health N 293-22/11 of march 15, 1999.

Article 17. Manufacturing of drugs

1. Manufacturing of drugs at pharmaceutical institution is provided by doctors' prescription on the basis of drugs registered in the Russian Federation.

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of clause 2 of the article 17 of this Federal law that become valid from January 01, 2005.

[See the text of that clause of the article in the previous version](#)

2. Manufacturing of drugs is provided at pharmaceutical institution having a license for pharmaceutical activities and according to the rules for manufacturing of drugs approved by the federal

executive body authorized for drawing out the state policy and legislative regulation in the field of drugs distribution.

3. Marking and appearance of drugs manufactured at pharmaceutical institution are to meet the above rules.

4. Deleted.

See the text of [clause 4 article 17](#)

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 18 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 18. Responsibility for non-observance of the rules for production and quality control for drugs and the rules of manufacturing of drugs

1. The manufacturer of drugs is held liable for non-observance of the rules for production and quality control of drugs.

2. Pharmaceutical institution is held liable for non-observance of the rules for manufacturing of drugs and for appearance, packing and [quality of drugs](#), manufactured at pharmaceutical institution.

3. Physical persons being responsible for manufacturing and quality of drugs incur disciplinary, administrative and criminal liability for violation of provisions of this Federal law.

Chapter V. State registration of drugs

Federal law N 122-Φ3 of August 22, 2004 (in the wording of Federal law N 199-Φ3 of December 29, 2004) stipulates amendments of the article 19 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 19. State registration of drugs

1. Drugs may be produced, sold and used in the territory of the Russian Federation if only being registered by the federal executive body authorized for providing state control and supervision in the field of drugs distribution.

According to the decree of the Government of the RF N 155 of April 06, 2004, the Federal service on supervision in the field of public health and social development provides state registration of drugs.

See Rules of the state registration of drugs approved by the Ministry of Public Health of the RF N 01/29-14 of December 01, 1998.

Registration of domestic drugs (substances) see Instruction of the Ministry of Public Health and medical industry of the RF of May 28, 1996.

The state registration of [narcotic drugs](#) and psychoactive substances used as drugs and being the subject of the state control according to the Federal law "of narcotic drugs and psychoactive substances", is accompanied by entering these drugs and substances in the appropriate lists according to the order stipulated by the Federal law "Of narcotic drugs and psychoactive substances".

The drugs to be used for treatment of animals are to pass state registration at the federal executive body authorized for providing the state control and supervision in the field of drugs distribution.

See Rules of the state registration of drugs for animals and feed additives approved by the order of the Ministry of Agriculture N 48 of April 01, 2005.

2. The following drugs are the subject of the state registration:

1) new drugs;

2) new combinations of previously registered drugs;

3) previously registered drugs manufactured in new dosing forms, with new dosage or another additional substances;

4) [reproduced drugs](#).

3. Drugs manufactured at pharmacies according to the doctor's prescriptions, are not the subject of the state registration.

4. It is possible to use non-registered drugs at clinic trials or trials of drugs to be used for animals.

5. State registration of different drugs with the same name and multiple state registration of the same drug with one or several names is prohibited.

6. State registration of drugs is provided by the federal executive body authorized for providing the state control and supervision in the field of drugs distribution within the period not exceeding 6 months from the date of application for the state registration of the drug.

The federal executive body authorized for providing the state control and supervision in the field of drugs distribution determines the rate of changes made in dosage and additional substances of the drug that draws the necessity of its state registration with new name.

7. The application for the state registration is to be delivered to the federal executive body authorized for providing the state control and supervision in the field of drugs distribution by the applicant, which could be a developer of the drug or another legal person acting on behalf of the developer of the drug.

8. Registered drug is to be entered in the state registry of drugs.

9. The following documents and information is to be delivered to the federal executive body authorized for providing the state control and supervision in field of drugs distribution by the applicant:

- 1) application for the state registration of the drug;
- 2) receipt for payment for the state registration of the drug;

On the receipts for state duty payment see the letter of the Federal service on supervision in the field of public health and social development N 01И-55/05 of February 16, 2005.

According to the Tax Code of the Russian Federation the state duty for the state registration of drugs equals 2000 rubles from January 01, 2005.

3) legal address of the manufacturer of the drug;

4) names of the drug including international non-proprietary name, scientific name in Latin, essential synonyms;

5) original name of the drug if it is registered as a trade mark according to the laws of the Russian Federation of trade marks, service marks and names of the goods origins;

6) list of components of the drug and their volume;

7) instruction for application for the drug made according to the requirements of this Federal law;

8) quality certificate for the drug;

9) information of manufacturing of the drug, initial text of [pharmacopeia article](#);

10) methods of quality control for the drug;

11) results of non-clinic trials of the drug;

12) results of pharmacological and toxicological tests for the drug;

13) results of clinic trials of the drug;

14) results of veterinary trials if the registration is to be provided for the drug to be used for animals;

15) samples of the drug for quality expertise;

16) price proposals for the drug;

See Order of price proposals for the drug at its registration (re-registration) stipulated in the letter of the Department of the state quality, effectiveness, safety control of drugs and medical technique N 290-22/23 of February 29, 2000.

17) documents confirming registration of the drug if it is registered outside the Russian Federation.

10. Federal executive body authorized for providing the state control and supervision in the field of drugs distribution may provide compact procedure of the state registration of drugs. Provisions for compact procedure of state registration is drawn out and published by the federal executive body authorized for drawing out the state policy and legislative regulation in the field of drugs distribution. Compact procedure of state registration of drugs does not mean reduction of requirements for quality, effectiveness, safety of drugs.

11. Compact procedure of the state registration of drugs can be applied if registration is provided for a reproduced drug that is equivalent to the [original drug](#) registered in the Russian Federation but manufactured by another technology and with other auxiliary substances.

Chapter VI. Import of drugs to the territory of the Russian Federation. Export of drugs from the territory of the Russian Federation

See Regulations for import/ export of drugs and pharmaceutical substances to/ from the Russian Federation approved by the decree of the Government of the RF N 1539 of December 25, 1998.

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 20 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 20. Order of import of drugs to the territory of the Russian Federation

1. Drugs registered in the Russian Federation are imported to the territory of the Russian Federation is provided according to the order stipulated by the Government of the Russian Federation.

2. Expired on January 01, 2005.

[See the text of clause 2 article 20](#)

3. Expired on January 01, 2005.

[See the text of clause 3 article 20](#)

4. Expired on January 01, 2005.

[See the text of clause 4 article 20](#)

5. Imported drugs are to be registered in the Russian Federation.

6. It is allowed to import to the territory of the Russian Federation a certain batch of drugs for clinic trials under the permission of federal executive body authorized for providing the state control and supervision in the field of drugs distribution.

7. It is allowed to import to the territory of the Russian Federation the drugs which quality is confirmed by the certificate of the [manufacturer of drugs](#), confirming that the imported drugs are manufactured according to the state quality standard for drugs stipulated by federal executive body authorized for drawing out the state policy and legislative regulation in the field of drugs distribution.

8. In order to protect the market and the manufacturers of drugs in the territory of the Russian Federation the Government of the Russian Federation can set special customs duties for ready import drugs according to the customs laws of the Russian Federation.

9. It is prohibited to import to the territory of the Russian Federation the drugs being false representation or [illegal copies](#) of drugs registered in the Russian Federation, false drugs. At the detection of those drugs the customs bodies of the Russian Federation confiscate those drugs with further disposal according to the order stipulated by the federal executive body authorized for drawing out the state policy and legislative regulation in the field of drugs distribution.

See Instruction of disposal of improper drugs, expired drugs and false or illegal copies of drugs registered in the Russian Federation approved by the order of the Ministry of Public Health N 382 of December 15, 2002.

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 21 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 21. Legal persons that can provide import of drugs to the territory of the Russian Federation

The following legal persons can provide import of drugs to the territory of the Russian Federation:

1) manufacturers of drugs for the purposes of domestic manufacturing of drugs;

2) wholesale drug companies;

3) scientific and research institutions and laboratories for development, research and control of quality, effectiveness and [safety of drugs](#) under the permission of federal executive body authorized for providing the state control and supervision in the field of drugs distribution for import of the certain batch of drugs;

4) foreign manufacturers of drugs and wholesale drug companies if only they have representative offices in the territory of the Russian Federation.

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 22 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 22. Import of drugs to the territory of the Russian Federation for personal use or other nonprofit purposes

1. Drugs can be imported to the territory of the Russian Federation without special permissions in cases of:

1) personal use by physical persons arriving to the territory of the Russian Federation;

2) use by diplomatic body employees or members of international organizations accredited in the territory of the Russian Federation;

3) treatment of passengers of a vehicle arriving to the territory of the Russian Federation.

2. Drugs to be used for certain animals in the zoos can be imported to the territory of the Russian

Federation without appropriate permission.

3. Cases stipulated in clauses 1 and 2 hereof allow import of drugs not registered in the territory of the Russian Federation.

4. Drugs to be used for humanitarian purposes are imported to the territory of the Russian Federation in the order stipulated by the Government of the Russian Federation.

See Instruction "Of the order of import/ export of medical products used for humanitarian purposes to/ from the territory of the Russian Federation", approved by the Ministry of Public Health of the RF N 2510/317-02-32 of January 14, 2002.

Import of unregistered drugs to be used for humanitarian purposes in the territory of the Russian Federation is prohibited.

Article 23. Expired on January 01, 2005.

See the text of [article 23](#)

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 24 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 24. Documents to be delivered to customs bodies of the Russian Federation at import of drugs to the territory of the Russian Federation

The following documents and information are to be delivered to customs bodies of the Russian Federation at import of drugs to the territory of the Russian Federation:

1) contracts and other documents containing information of imported drugs and of the terms of purchase;

2) [quality certificates](#) for drugs;

3) information of the state registration for each imported drug with the appropriate registry numbers;

4) information of the sender of drugs;

5) information of the addressee of drugs in the Russian Federation;

6) information of the person providing transportation of drugs;

7) permission of federal executive body authorized for providing the state control and supervision in the field of drugs distribution, for import of the certain batch of drugs in cases stipulated by the [article 20](#) of this Federal law.

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 25 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 25. Physical and legal persons that are permitted to export drugs from the territory of the Russian Federation

1. [Manufacturers of drugs](#) and wholesale traders can export drugs from the territory of the Russian Federation.

2. Physical persons can export drugs in the amount being necessary for personal use in the order stipulated by customs laws of the Russian Federation.

Article 26. Expired on January 01, 2005.

See the text of [article 26](#)

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 27 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 27. Cooperation of customs bodies of the Russian Federation and federal execution body authorized for providing the state control and supervision in the field of drugs distribution

1. Federal executive body authorized for providing the state control and supervision in the field of drugs distribution delivers the list of drugs registered in the Russian Federation to the customs bodies of the Russian Federation.

2. Customs bodies of the Russian Federation informs federal executive body authorized for providing the state control and supervision in the field of drugs distribution of import of drugs to the territory of the Russian Federation or of export of drugs from the territory of the Russian Federation.

Chapter VII. Wholesale trade of drugs

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 28 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 28. Sale of drugs by manufacturers of drugs

Manufacturers of drugs can sale drugs or transfer at the disposal to:

- 1) other manufacturers of drugs for production purposes;
- 2) [wholesale drug companies](#);
- 3) pharmaceutical institutions;
- 4) scientific and research institutions for research and scientific works.

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 29 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 29. Sale of drugs to wholesale drug companies

Wholesale drug companies can sale drugs or transfer at the disposal to:

- 1) other wholesale drug companies;
- 2) manufacturers of drugs for production purposes;
- 3) [pharmaceutical institutions](#);
- 4) scientific and research institutions for research and scientific works;
- 5) individual entrepreneurs having licenses for providing medical activities.

Article 30. Deleted.

See the text of [article 30](#)

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 31 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 31. Prohibition of sale of non-standard drugs or illegal copies of drugs registered in the Russian Federation

1. It is prohibited to sale improper drugs, expired drugs, false drugs.
2. Improper drugs, expired drugs and false drugs are to be disposed.
3. The order of disposal of improper drugs, expired drugs, false drugs is worked out considering the interests of people, animals and environment and approved by federal executive body authorized for drawing out the state policy and legislative regulation in the field of drugs distribution.

See Instruction on the order of disposal of improper drugs, expired drugs and false or illegal copies of drugs registered in the Russian Federation approved by the order of the Ministry of Public Health of the RF N 382 of December 15, 2002

4. It is prohibited to sale false drugs and [illegal copies of drugs](#) registered in the Russian Federation.

Chapter VIII. Retail drug trade

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 32 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 32. Order of retail drug trade

1. Retail drug trade is provided by pharmaceutical institutions. Retail trade is only permitted for the drugs registered in the Russian Federation.
2. Prescription drugs are to be sold in the pharmacies and pharmacy points only. Over-the-counter drugs can be sold in pharmaceutical stores and stands also.
3. List of prescription drugs is to be revised and approved once in five years by the federal executive body authorized for drawing out the state policy and legislative regulation in the field of drugs

distribution. Additions to the list are published annually.

List of over-the-counter drugs is approved by the order of the Ministry of Public Health of the RF N 287 of July 19, 1999, and becomes valid from October 01, 1999.

4. Kinds of pharmaceutical institutions and the order of drugs sale are determined and approved by the federal executive body in the field of public health.

Industry standard 91500.05.0007-2003 "Rules for sale (realization) of drugs at pharmaceutical institutions. Basic provisions" is approved by the order of the Ministry of Public Health of the RF of March 04, 2003.

Order of drugs sale at pharmaceutical institutions/ companies is approved by the order of the Ministry of Public Health N 328 of August 23, 1999.

5. The decision of opening of new [pharmaceutical institution](#) is taken by local administrative body.

6. Retail trade of drugs for animals is to be provided at pharmacies, veterinary pharmacies or by veterinarian.

7. Pharmaceutical institutions are to sell drugs in ready for use forms and in the amount necessary for execution of doctor's prescriptions.

8. Pharmaceutical institutions are to have minimal assortment of drugs necessary for medical aid stipulated by the federal executive body authorized for drawing out the state policy and legislative regulation in the field of drugs distribution.

9. Together with drugs the pharmaceutical institutions have right to purchase and to sell medical purpose goods, disinfectants, personal hygiene goods, optical goods, natural and artificial mineral water, health, children and dietary food, cosmetics and perfumes.

10. Activities of pharmaceutical institutions of Armed Forces of the Russian Federation, other forces, military units and bodies where military service is stipulated by the laws, are to regulate by this Federal law and provisions approved by the appropriate federal executive bodies.

Execution of the provisions of this Federal law by the above pharmaceutical institutions is controlled by the appropriate ministries and other federal executive bodies.

Article 33. Pharmaceutical activities of physical persons at pharmaceutical institutions

Physical persons can provide certain kinds of [pharmaceutical activities](#) if only they have higher or secondary pharmaceutical education and certificate of specialist.

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 34 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 34. Licensing of pharmaceutical activities

1. Pharmaceutical activities are the subject of licensing according to the laws of the Russian Federation.

See Regulations for licensing of pharmaceutical activities approved by the decision of the Government of the RF N 489 of July 01, 2002.

2. Obligatory terms for taking a decision on license issue are the delivery of the documents confirming the right of the applicant for the rooms to be used for pharmaceutical activities, the existence of certificates for providing pharmaceutical activities by specialists and sanitary-and-epidemiologic report on the conformity of the rooms with the sanitary rules.

Chapter IX. Development, non-clinic and clinic trials of drugs

See Regulations for Commission on non-clinic and clinic trials of drugs and its members approved by the order of Federal service for supervision in the field of public health and social development N 115-Пp/05 of January 26, 2005.

Article 35. Development of new drugs

1. Development of new drugs includes search of new pharmacological active substances, further study of their pharmacological properties and non-clinic trials.

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the clause 2 of article 35 of this Federal law that become valid from January 01, 2005.

[See the text of the clause in the previous version](#)

2. Financing of new drugs development is provided at the expense of:
 - 1) federal budget funds;
 - 2) funds of [developers of drugs](#);
 - 3) funds of manufacturers of drugs for the research works performed according to the contract between the developer of drugs and manufacturer of drugs;
 - 4) other financial sources including charitable funds and target investments of physical and legal persons.
3. Rights of the developer of new drug are protected by patent laws of the Russian Federation and the laws of copyrights and neighbouring rights of the Russian Federation.

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 36 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 36. Non-clinic trials of drugs

1. The purpose of non-clinic trials of drugs is getting scientific assessments and evidence of effectiveness and safety of drugs.
2. Non-clinic trials of drugs are provided by the developers of drugs according to the rules of laboratory practice approved by the federal executive body authorized for drawing out the state policy and legislative regulation in the field of drugs distribution.
3. Non-clinic trials of drugs are provided according to the approved plan with minutes and report with the results of non-clinic trials of drugs. The developer of drugs gives an opinion letter on the possibility of further clinic trials of drugs.
4. Non-clinic trials of drugs on animals are provided according to the international rules. Control over the legislative and ethic norms applied to animals use at non-clinic trials is provided by the federal executive body authorized for drawing out the state policy and legislative regulation in the field of drugs distribution and its territorial bodies.

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 37 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 37. Decision on providing clinic trials of drugs

1. The purpose of clinic trials of drugs is getting scientific assessment and evidence of effectiveness and [safety of drugs](#), information of possible side effects and interaction effects with other drugs.
2. The decision on providing clinic trials is taken by the federal executive body authorized for providing the state control and supervision in the field of drugs distribution on the basis of the following documents:
 - 1) application of the developer of the drug;
 - 2) positive opinion letter issued by the committee on ethics the federal executive body authorized for providing the state control and supervision in the field of drugs distribution;
 - 3) report and opinion letter of non-clinic trials of the drug;
 - 4) instruction for use of the drug.

See Instruction for taking a decision on providing clinic trials of drugs approved by the order of the Ministry of Public Health N 103 of March 24, 2000.

3. Clinic trials of drugs are provided at public health institutions accredited by the federal executive body authorized for providing the state control and supervision in the field of drugs distribution.

See Draft of the Provisions for accreditation of public health institutions for providing clinic trials of drugs brought to notice by the letter of Federal service on supervision in the field of public health and social development N 02И-66/05 of February 21, 2005.

4. List of public health institutions that have right for providing clinic trials of drugs is made and published by the federal executive body authorized for providing the state control and supervision in the field of drugs distribution.

See List of companies and institutions providing non-clinic and clinic trials of drugs (by February 24, 2005), sent by the letter of Federal service on supervision in the field of public health and social development N 0211-74/05 of February 28, 2005.

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 38 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 38. Legal basis for providing clinic trials of drugs and financing of clinic trials of drugs

1. The following documents constitute the legal basis for providing clinic trials of drugs:
 - 1) decision on providing clinic trials of the drug taken by the federal executive body authorized for providing the state control and supervision in the field of drugs distribution;
 - 2) contract for providing clinic trials of the drug
2. The contract for providing clinic trials of the drug is to contain the following information:
 - 1) date and volume of clinic trials of the drug;
 - 2) total cost of clinic trials program;
 - 3) form of results of clinic trials of the drug to be delivered to the federal executive body authorized for providing the state control and supervision in the field of drugs distribution;
 - 4) terms of health insurance for the patients participating in clinic trials of the drug;
 - 5) terms of liability insurance for the persons providing clinic trials of the drug.
3. Financing of clinic trials of the drug is provided at the expense of:
 - 1) federal budget funds;
 - 2) funds of developer of drugs according to the terms of the contract for providing clinic trials of drug;
 - 3) other sources.
4. Expired on January 01, 2005.

See the text of [clause 4 article 38](#)

5. Expired on January 01, 2005.

See the text of [clause 5 article 38](#)

Article 39. Clinic trials of drugs

Clinic trials of drugs permitted by the Federal service on supervision in the field of public health and social development for providing in the I quarter of the year 2005, see the letter of Federal service on supervision in the field of public health and social development N 0111-187/05 of April 26, 2005.

See also the letter of Federal service on supervision in the field of public health and social development N 0111-146/05 of April 04, 2005.

Requirements for planning, providing, documentaries and control of clinic trials see Rules for clinic practice in the RF approved by the order of the Ministry of Public Health of the RF N 266 of June 19, 2003.

1. Director of the pharmaceutical institution providing clinic trials of the drug approves the program of clinic trials of the drug and appoints the chief scientist. The chief scientist providing the program may be a doctor having at least two year participation in programs of clinic trials. The program of clinic trials of the drug is worked out with participation of commission on ethics at the public health institution providing clinic trials of the drug.
2. The chief scientist providing the program of clinic trials of the drug must know the results of non-clinic trials of that drug and he has right to get all additional information concerning the non-clinic trials of that drug.
3. The chief scientist providing the program of clinic trials of the drug chooses patients whose indications meet the requirements for participation in clinic trials of the drug.
4. The report with the results of clinic trials of the drug is made by the chief scientist providing the program of clinic trials of the drug.
5. Clinic trials of the drug may be interrupted if in their process a danger for patients' health were found. Decision on the termination of clinic trials may be taken by the chief scientists of the said trials.
6. Violation of the rules of clinic practice and falsification of the results of clinic trials draw out liability according to the laws of the Russian Federation.

Article 40. Rights of patients participating in clinic trials of drugs

1. Participation of patients in clinic trials of drugs is voluntary.
2. Patient gives his written consent for participation in clinic trials of the drug.

3. Patient is to be informed:
 - 1) of the drug and the matter of clinic trials of the drug;
 - 2) of possible effectiveness, [safety of the drug](#), degree of risk for patient;
 - 3) of the actions of patient in the case of unexpected effects caused to his health by the drug;
 - 4) of the insurance terms of the patient's health.
4. Patient has right to refuse from clinic trials of the drug at any stage of trials.
5. It is prohibited to provide clinic trials with under-age persons except the case where the drug is to be used for children treatment only or where the purpose of clinic trials is to get information of the best dosing of the drug for under-age treatment. In the latter case clinic trials with under-age are to be provided after providing those trials with adults.
6. Written consent of parents is necessary for providing clinic trials with under-age persons.
7. It is prohibited to provide clinic trials with participation of:
 - 1) under-age orphans;
 - 2) pregnant women except the cases where clinic trials are provided with drugs to be used by pregnant women, where necessary information may be get at clinic trials of drugs with participation of pregnant women only and where there is no risk for pregnant woman or fetus;
 - 3) servicemen;
 - 4) imprisoned persons and persons in investigatory isolation wards.
8. It is permitted to provide clinic trials of drug to be used for mental diseases treatment with participation of mental disease patients and persons recognized to be incapable according to the law of the Russian Federation "Of mental health services and guarantee of individual rights at its providing". In that case clinic trials of drugs are to be provided under written consent of legal representatives of the said persons.
9. Contract for health insurance of the patient participating in clinic trials of the drug is to be signed between the [developer of the drug](#) and medical insurance company.

Federal law N 122-ФЗ of August 22, 2004, stipulates amendments of the article 41 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 41. Obligation of the subject of drugs distribution to inform of the cases with side effects and of the nature of the drug interaction with other drugs

1. The subjects of drugs distribution are to inform the federal executive body authorized for providing the state control and supervision in the field of public health and its territorial departments about all cases with side effects and of the nature of the drug interaction with other drugs which do not correspond the information containing in the instruction for use.

See the form of Notice of possible harmful side effect of the drug approved by the letter of Department of the state control of quality, effectiveness and safety of the Ministry of Public Health of the RF N 291-22/91 of July 26, 2001.

2. Persons who learned the cases stipulated in clause 1 hereof during their professional activities and provided hiding or not reporting of that cases are to incur disciplinary, administrative or criminal liability according to the laws of the Russian Federation.

Chapter X. State guarantees of the availability of drugs

Expired on January 01, 2005.

See the text of the [chapter X](#)

Chapter XI. Information of drugs. Advertising of drugs

Article 43. Information of drugs

1. Information of drugs is to be given according to the requirements of the state information standard.

2. Information of over-the-counter drugs may be given in publications and advertisements in mass media, special and common printed sources, instructions for use, other publications of [subjects of drugs distribution](#).

3. Information of prescribed drugs may be given in special printed sources for medical and pharmaceutical personnel only. Information of drugs for the specialists in the field of drugs distribution may be given in monographs, handbooks, scientific articles, lectures at congresses, conferences,

symposia, scientific boards and in instructions for use intended for doctors only.

4. It is permitted to use any material media for drugs information providing keeping, transfer and use of that information without garbling.

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 44 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 44. Advertising of drugs

1. Only advertising of over-the-counter drugs may be given in mass media.
2. In spite of its form the advertising is to correspond the pharmacological information of the drugs got at clinic trials of drugs and the requirements of the state information standard.

3. Advertising must not represent the drug as a unique, the most effective, safety and exclusive means with no side effects and it must not mislead the customer on its composition, origin, novelty or patenting of the drug.

4. Advertising must not do harm to the reputation of manufacturers of drugs, customs' belief in the effect of the drugs.

5. It is prohibited to compare the drug with other drugs for the purpose of advertising effect increasing.

6. Advertising must not make impression of uselessness of medical consultations or surgical operations.

7. Advertising must not contain statements of guaranteed action of the drug.

8. At violation of provisions of this Federal law concerning the advertising of drugs the federal executive body authorized for providing the state control and supervision in the field of drugs distribution may forbid further advertising of the drug or to notify the advertiser of the necessity of changing the approach to the advertising of the drug.

9. Expired on July 01, 2002.

See the text of clause 9 article 44

Chapter XII. Liability for health hazard caused by drugs use

Federal law N 122-Φ3 of August 22, 2004, stipulates amendments of the article 45 of this Federal law that become valid from January 01, 2005.

[See the text of the article in the previous version](#)

Article 45. Indemnification of health hazard caused by drugs use

1. Indemnification of health hazard caused by drugs use and illegal actions of the subjects of drugs distribution is provided according to the Foundations of laws of the Russian Federation of public health protection.

2. If there is health hazard caused by drugs use then the manufacturer of that drug must indemnify the damage to the injured person where there exist an evidence that:

1) drug was used according to prescription, instruction for use and the cause of adverse effect of the drug was the manufacturing mistakes at the drugs production;

2) health hazard was caused by use of drug with improper instruction for use issued by the manufacturer of drugs.

3. If health hazard was caused by use of drug that became unsuitable due to violation of wholesale drug trade rules or rules for pharmaceutical activities of pharmacies, then the damage is to be indemnified by the wholesale drug company or pharmaceutical institution that provided sales or distribution of the said drug.

Chapter XIII. Final Provisions

Article 46. Conformation of standard legal acts with this Federal law

To suggest the President of the Russian Federation and to commit the Government of the Russian Federation to conform their standard legal acts with this Federal law.

Article 47. Effective date of this Federal law

This Federal law becomes effective three months after the date of its official publishing.

Moscow, Kremlin
June 22, 1998
N 86-Φ3