DECISION
OF THE GOVERNMENT OF THE RUSSIAN FEDERATION
NO. 1539 OF DECEMBER 25, 1998
ON THE IMPORTATION INTO AND EXPORTATION FROM THE RUSSIAN FEDERATION OF MEDICAMENTS AND PHARMACEUTICAL SUBSTANCES
(with the Amendments and Additions of February 22, 2000)

In execution of the Federal Laws on the State Regulation of the Foreign Trade Activity, and on the Medicaments, the Government of the Russian Federation resolves:

1. To approve the annexed Regulations on the Importation into and Exportation from the Russian Federation of Medicaments and Pharmaceutical Substances.

2. To invalidate the Decisions of the Government of the Russian Federation No. 647 of May 27, 1997 on the Importation and Exportation of Medicaments and Pharmaceutical Substances (Sobraniye zakonodatelstva Rossiyskoy Federatsii, 1997, No. 22, item 2606), and No. 1606 of December 19, 1997 on the Supplementing of Item 2 of the Regulations on the Importation and Exportation of Medicaments and Pharmaceutical Substances, approved by the Decision of the Government of the Russian Federation No. 647 of May 27, 1997 (Sobraniye zakonodatelstva Rossiyskoy Federatsii, 1998, No. 1, item 124).

3. This Decision shall enter into force 60 days after its publication.

Chairman of the Government
of the Russian Federation — Yevgeny Primakov

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

See the Regulations on the Procedure for Completing Customs Formalities in Respect of Medical Goods, Raw Materials and Component Parts for the Manufacture Thereof by Applying a Special Goods Declaration Procedure, endorsed by Order of the State Customs Committee of the Russian Federation and the Ministry of Public Health of the Russian Federation No. 792/321 of August 13, 2001

1. These Regulations determine the procedure for the importation by licences into the Russian Federation of medicaments and pharmaceutical substances (hereinafter referred to as medicaments) by the list according to Annexes No. 1 and 2, and also for the exportation of medicaments from the Russian Federation.

2. The following juridical persons may import medicaments into the territory of the Russian Federation.

enterprises that are manufacturers of medicaments (for the purpose of their own manufacture of medicaments);

enterprises that are wholesalers of medicaments;

scientific-research institutions, institutes and laboratories (for the development, the conduct of investigation and the control of the quality efficiency and safety of medicaments);

According to the Federal Law No. 86-FZ of June 22, 1998, the presence of a permit of the federal body for the control of the quality of medicaments for the importation of a concrete lot of goods shall give the right to the importation of medicaments by scientific-research institutions

foreign enterprises that are manufacturers of medicaments and enterprises that are wholesalers of medicaments provided they have their own representative offices on the territory of

the Russian Federation.

3. The following juridical persons may export medicaments from the territory of the Russian Federation:

enterprises that are manufacturers of medicaments;

enterprises that are wholesalers of medicaments.

Natural persons may export medicaments in quantities necessary for personal use.

4. The importation into the Russian Federation of medicaments mentioned in Annexes No. 1 and 2 to these Regulations shall be effected on the basis of the licence for the importation of medicaments issued by the Ministry of Trade of the Russian Federation, and also on the basis of a certificate of an enterprise. that is the manufacturer of medicaments, attesting that the imported medicaments have been manufactured in conformity with the state standards of the quality of medicaments established by the normative acts of the Russian Federation (hereinafter referred to as the quality certificate).

The medicaments that are being imported must be registered in the Russian Federation in the established procedure.

On the Procedure for the State Registration of the Foreign-Made Medical Articles and Medical Hardware in the Russian Federation see Instruction approved by Order of the Ministry of Public Health of the Russian Federation No. 237 of June 29, 2000

5. It shall be permissible to import into the Russian Federation medicaments (including unregistered medicaments) without a licence for the importation of medicaments or a permit of the Ministry of Public Health of the Russian Federation or the Ministry of Agriculture and Foodstuffs of the Russian Federation, if they are designed for:

personal use by natural persons coming to the territory of the Russian Federation;

personnel of the diplomatic corps or representatives of the international organizations accredited in the Russian Federation;

the treatment of passenger of transport vehicles coming to the territory of the Russian Federation;

the treatment of animals in zoological gardens in the presence of the relevant application of the veterinary service of the Ministry of Agriculture and Foodstuffs of the Russian Federation.

In the presence of a permit of the Ministry of Public Health of the Russian Federation or the Ministry of Agriculture and Foodstuffs of the Russian Federation it shall be permissible to import a concrete lot of:

medicaments (including unregistered medicaments) for the conduct of clinical investigations, registration or reregistration;

medicaments (including unregistered medicaments) for the development, the conduct of investigation and the control of the quality, efficiency and safety of the medicaments by scientific-research institutions, institutes or laboratories;

registered medicaments designed for humanitarian purposes.

See the Regulations on the Procedure for the Importation into the Territory of the Russian Federation of Specimens of Medicaments and Pharmaceutical Substances Not Registered in the Russian Federation, and also of Medicaments Being Imported As Humanitarian Aid, approved by the Ministry of Public Health of the Russian Federation and the State Customs Committee of the Russian Federation Nos 01/31-11 and 01-23-5044 of March 17, 1998

6. Enterprises in whose authorized funds the share of foreign investments constitutes more than 30 per cent may effect, for their own needs, the importation of medicines mentioned in Annexes No. 1 and 2 to these Regulations without a licence for the importation of medicines on the basis of the certificate of the products being imported for their own needs, or the quality certificate, unless otherwise stipulated by the legislation of the Russian Federation and the international agreements of the Russian Federation. The certificate of products being imported for enterprises' own needs shall be issued if the aspirant for a licence has a conclusion of the Ministry of Public

Health of the Russian Federation on the conformity of the quality of the imported products to the requirements established on the territory of the Russian Federation for the manufacture of medicaments applied for medical purposes, or a conclusion of the Ministry of Agriculture and Foodstuffs of the Russian Federation on the conformity of the quality of the imported products designed for the manufacture of medicaments applied in veterinary medicine to the requirements established in the Russian Federation.

7. The licence for the importation of medicaments shall be issued in accordance with the Regulations on the Procedure for the Licensing of the Export and Import of Goods (Works, Services) in the Russian Federation after the agreeing-upon with the Ministry of Public Health of the Russian Federation (concerning the medicaments applied for medical purposes) or with the Ministry of Agriculture and Foodstuffs of the Russian Federation (concerning the medicaments applied in veterinary medicine).

See the Regulations on the Procedure for the Importation into the Territory of the Russian Federation of Specimens of Medicaments and Pharmaceutical Substances Not Registered in the Russian Federation, and Also of Medicaments Being Imported As Humanitarian Aid, approved by the Ministry of Public Health of the Russian Federation and the State Customs Committee of the Russian Federation Nos 01/31-11 and 01-23-5044 of March 17, 1998

8. The aspirant for the licence for the importation of medicaments shall submit to the Ministry of Public Health of the Russian Federation or to the Ministry of Agriculture and Foodstuffs of the Russian Federation an application of the pattern established by the Ministry of Trade of the Russian Federation preliminarily agreed upon with the Standing Committee for the Control of Narcotic Drugs attached to the Ministry of Public Health of the Russian Federation (in column "Special conditions), and copies, attested by the signature and the seal of the aspirant for the licence, of the following documents:

a) the licence for one of the types of activity connected with the turnover of medicaments (pharmaceutical activity, manufacture of medicaments, storage of medicaments, distribution of medicaments);

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

b) the contract (agreement);

c) the agreement between the exporter (or the importer) and the manufacturer or the consumer of the commodity, if the aspirant for the licence is an intermediary;

d) the constituent and registration documents (the charter, the certificate of the state registration, the reference on the registration at the tax body);

e) the information about the state registration of each of the medicaments with the indication of the relevant registration numbers (in the case of importation);

f) the data about the juridical person transferring the medicaments.

The belonging of medicaments to products applied for veterinary purposes shall be confirmed by the presence of specifications (GOST) for the preparations of domestic manufacture or a registration certificate of the Veterinary Department of the Ministry of Agriculture and Foodstuffs of the Russian Federation and the instructions on the application for the import preparations.

9. When agreeing upon an application for the obtention of the licence for the importation of medicaments, the Ministry of Public Health of the Russian Federation or the Ministry of Agriculture and Foodstuffs of the Russian Federation shall fill in the column "Agreed upon" of the application form.

10. The federal bodies of the executive power mentioned in Item 7 of these Regulations way refuse the agreeing-upon of an application for the obtention of the licence for the importation of medicaments because of the absence of the registration certificates for the medicaments mentioned in the application, or the communication of unveracious data about a transaction on

about contract terms detrimental to the economic interests of the Russian Federation. In case of a refusal of the agreeing-upon of an application, the relevant reasoned decision must be communicated to the aspirant of the licence in written form.

11. The Ministry of Public Health of the Russian Federation or the Ministry of Agriculture and Foodstuffs of the Russian Federation shall, within 15 working days from the date of the submission of the documents for the agreeing-upon, inform the aspirant for the licence for the importation of medicaments about the agreeing-upon of the licence or about the refusal thereof.

12. The submission to the customs bodies of the Russian Federation of the licence for the importation of medicaments or a copy thereof, or of the permit of the Ministry of Public Health of the Russian Federation, the Ministry of Agriculture and Foodstuffs of the Russian Federation or copies thereof, or the quality certificate or a copy thereof shall be effected in the procedure determined by the State Customs Committee of the Russian Federation.

13. The exportation from the Russian Federation of medicaments mentioned in Annexes No. 1 and 2 to these Regulations shall be effected by the licence for the foreign trade activity with medicaments in the presence of information about the absence in the composition of the exportable medicaments of narcotic drugs, psychotropic substances and their precursors controllable in the Russian Federation and mentioned in the List approved by the Decision of the Government of the Russian Federation No. 681 of June 30, 1998 (Sobraniye zakonodatelstva Rossiyskoy Federatsii, 1998, No. 27, item 3198), poisonous and drastic substances and substances included in Tables I and II of the UN Convention on the Struggle against the Illegal Turnover of Narcotic Drugs and Psychotropic Substances of 1998, whose nomenclature was approved by the Decision of the Government of the Russian Federation No. 930 of August 3, 1996 (Sobraniye zakonodatelstva Rossiyskoy Federatsii, 1996, No. 34, item 4122). The indicated information shall be submitted in the procedure determined by the Ministry of Public Health of the Russian Federation, the Ministry of Agriculture and Foodstuffs of the Russian Federation and the State Customs Committee of the Russian Federation.

14. The aspirant for the licence for the importation of medicaments, in case of violation of these Regulations, shall bear responsibility in accordance with the legislation of the Russian Federation.

Decision *of the Government of the Russian Federation No. 148 of February 22, 2000 amended Annex 1 to this Decision*

The amendments shall come into force *as of April 1, 2000*

See the previous wording of the Annex

Annex No. 1
to the Regulations on the Importation into and Exportation from the Russian Federation of Medicaments and Pharmaceutical Substances

List of Medicaments and Pharmaceutical Substances Being Applied for Medical Purposes Whose Importation into the Russian Federation Shall Be Effected under Licences

	CC FEA of Russia code
Organic chemical compounds used as pharmaceutical substances	from 2904-2909 from 2912-2942
Glands and other organs for organo-therapeutic uses, dried, whether or	from 3001

not powdered; extracts of glands or other organs or of their secretions for organo-therapeutic uses; heparin and its salts; other human or animal substances prepared for therapeutic or prophylactic uses, not elsewhere specified or included	
Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera and other blood fractions and modified immuno-logical products, whether or not obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products used for medical purposes	from 3002
Medicaments (excluding medicaments of commodity items 3002, 3005 or 3006) consisting of two or more constituents which have been mixed together for therapeutic or prophy-lactic uses, not put up in measured doses or in forms or packings for retail sale (excluding medicaments used for veterinary medicine)	from 3003
Medicaments (excluding medicaments of commodity items 3002, 3005 or 3006) consisting o mixed or unmixed products for therapeutic or prophy-lactic uses, put up in measured doses or in forms or packings for retail sale (excluding medicaments used in veterinary medicine)	from 3004
Opacifying preparations for X-ray examinations; diagnostic reagents de-signed to be administered to the patient	3006 30 000 0
Chemical contraceptive preparations based on hormones or spermicides	3006 60

Decision *of the Government of the Russian Federation No. 148 of February 22, 2000 amended Annex 2 to this Decision*

The amendments shall come into force *as of April 1, 2000*

See the previous wording of the Annex

Annex No. 2
to the Regulations **on the Importation into and**

Exportation from the Russian Federation of Medicaments and Pharmaceutical Substances

List of Medicaments Being Applied in Veterinary Medicine Whose Importation into the Russian Federation Shall Be Effected under Licences

	CC FEA of Russia code
Amino acids	from 2922 41 000 0 from 2922 49 from 2930 40 000 0 from 2930 90 120 0 from 2930 90 140 0 from 2930 90 160 0
Coumarins (zoocoumarines)	from 2932 21 000 0
Provitamins and vitamins for animals	from 2936
Hormones for agricultural animals	from 2937
Glycosides and alkaloids for veterinary medicine	from 2938 from 2939
Veterinary antibiotics	from 2941
Forms of veterinary preparations of animal tissues and organs ready for use with therapeutic and prophylactic purposes	from 3001 10 from 3001 20 900 0 from 3001 90 990 0
Antisera of animals blood	from 3002 10 100 0
Other blood fractions for veterinary medicine	from 3002 10 910 0 from 3002 10 990 0
Vaccines for veterinary medicine	3002 30 000 0
Animal blood prepared for prophylactic, therapeutic or diagnostic uses	from 3002 90 300 0
Cultures of micro-organisms (vaccinal and other strains)	from 3002 90 500 0
Other veterinary biopreparations: sets and preparations for the diagnosis and typification of the infecting infecting agents manufactured on the basis of animal blood and cultures of microorganisms	from 3002

Medicines for veterinary medicine	from 3003 from 3004
Animal-blood-grouping reagents	from 3006 20 000 0
Complex diagnostic or laboratory reagents for veterinary medicine	from 3822 00 000 0
Insecticides, fungicides and disinfectants for veterinary medicine	from 3808 10 from 3808 20 from 3808 40
Poisoned bait in the form of an edible product	from 3808 90
Soap for veterinary medicine; organic surface-active substances and preparations for use in veterinary medicine as soap containing medicaments (medicinal) additives	from 3401
Organic surface-active agents (other than soap) for veterinary medicine; surface-active preparations and washing preparations for veterinary medicine	from 3402