DECISION OF THE GOVERNMENT OF THE RUSSIAN FEDERATION NO. 438 OF JULY 16, 2005 ON THE IMPORTATION AND EXPORTATION OF DRUGS INTENDED FOR MEDICAL USE

In accordance with the Federal Laws on Medicines and on the Principles of the State Regulation of Foreign Trade Activity, the Government of the Russian Federation resolves:

1. To approve the appended Rules for the Importation and Exportation of Medicines registered in the Russian Federation.

2. To invalidate Government Decision No. 1539 of December 25, 1998 on the Importation to the Russian Federation and the Exportation from It of Medicines and Pharmaceutical Substances (Sobraniye Zakonodatelstva Rossiyskoy Federatsii No. 1, 1999, item 190; No. 9, 2000, item 1036; No. 50, 2001, item 4735; No. 22, 2002, item 2094) in respect of the importation and exportation of drugs intended for medical use.

3. The present Decision shall come into force in 60 days after its publication.

Chairman of the Government of the Russian Federation

Mikhail Fradkov

The Rules for the Importation and Exportation of Medicines Registered in the Russian Federation (approved by Government Decision No. 438 of July 16, 2005)

1. The present Rules define the order of the importation or exportation on the territory of the Russian Federation of drugs and Pharmaceutical substances intended for medical use (hereinafter referred to as drugs) and registered in the Russian Federation.

2. The following juridical persons may bring drugs into the Russian Federation:

a) organisations - producers of medicines for their own production of drugs;

b) organisations of the wholesale trade in drugs;

c) scientific-research institutions, institutes and laboratories for the development, research and control of the quality, efficiency and safety of drugs;

d) foreign organisations that are producers of medicines and enterprises of wholesale trade in drugs, provided that they have their own representative offices on the territory of the Russian Federation.

3. It shall be forbidden to bring onto the territory of the Russian Federation medicines which are fakes or illegal copies of medicines registered in the Russian Federation, and also falsified drugs.

4. Drugs shall be brought onto the territory of the Russian Federation as per the Appendix on the basis of a licence issued by the Ministry of Economic Development and Trade of the Russian Federation.

5. To obtain a licence for the importation of medicines, the juridical person indicated in Item 2 of the present Rules (hereinafter referred to as the applicant) shall present to the Ministry of Economic Development and Trade of the Russian Federation the findings of the Federal Service for Supervision in the Sphere of Public Health and Social Development (hereinafter referred to as findings) that it is possible to issue a licence for the importation of these medicines.

6. To get findings, the applicant shall submit to the Federal Service for Supervision in the Sphere of Public Health and Social Development his application, agreed upon with the Permanent Committee for Control over Narcotics, with an enclosure of the following documents certified with the signature and the seal of the applicant:

a) a licence for the activity in the sphere of the circulation of medicines (pharmaceutical activity, the production of drugs);

b) contracts containing information about imported medicines and the conditions for the acquisition of them;

c) a contract between the exporter (importer) and the producer (consumer) of goods, if an intermediary acts in the capacity of an applicant for a licence for the importation of medicines;

d) the constituent and registration documents of the applicant (the charter, the certificate of state registration, the reference on placing on the records with a tax body);

e) the documents on the state registration of each imported medicine with an indication of relevant registration numbers.

7. The Federal Service for Supervision in the Sphere of Public Health and Social Development shall issue its findings within 15 working days from the date of filing the documents indicated in Item 6 of the present Rules.

If findings are given in the negative, the applicant shall be informed about this in writing.

8. The grounds for the negative findings are as follows:

a) the absence of the state registration of a drug;

b) the absence of the applicant's licence for activity in the sphere of the circulation of drugs or the suspension of the validity of such licence;

c) the limitation on the import of a medicine as per an international agreement or a Government decision;

d) the presence in the Federal Service for Supervision in the Sphere of Public Health and Social Development of information that the medicine being imported is a fake or an illegal copy of drugs registered in the Russian Federation or a falsified medicine.

9. On the basis of a permit issued by the Federal Service for Supervision in the Sphere of Public Health and Social Development it is possible to bring onto the territory of the Russian Federation a concrete consignment of registered medicines intended for humanitarian purposes, and also of drugs designed:

to carry out clinical studies, to register and re-register of the medicines which are not registered in the Russian Federation;

to develop drugs, study and control their quality, efficiency and safety in scientific-research institutions, institutes and laboratories - in respect of both registered and non-registered medicines.

10. Upon the importation of medicines onto the territory of the Russian Federation of the medicines indicated in the Appendix to the present Rules the following documents shall be presented to customs:

a) contracts or any other documents containing information about imported medicines and about the terms for the acquisition of them;

b) a certificate of the quality (minutes on analysis) of each drug, which was issued by the manufacturing organisation;

c) information about the state registration of each imported drug with an indication of relevant registration numbers;

d) data on the consignor of drugs;

e) data on the consignee of drugs in the Russian Federation;

f) data on the person who shifts drugs;

g) a permit of the Federal Service for Supervision in the Sphere of Public Health and Social Development for the importation of a specific consignment of medicines in cases provided for by Item 9 of the present Rules.

11. It shall be permitted to bring onto the territory of the Russian Federation medicines (including those which are not registered in the Russian Federation) without a licence and a permit of the Federal Service for Supervision in the Sphere of Public Health and Social Development, if they are intended for:

a) the personal use by natural persons who arrive on the territory of the Russian Federation;

b) members of the diplomatic corps or representatives of international organisations accredited in the Russian Federation;

c) the medical treatment of passengers of the transport vehicle that arrive in the Russian Federation.

12. The following juridical persons may bring out drugs from the territory of the Russian Federation:

organisations, producers of drugs;

organisations of the wholesale trade in drugs.

13. Natural persons may bring out medicines from the territory of the Russian Federation in the amount necessary for personal use in the order defined by the customs legislation of the Russian Federation.

14. In the event of a contravention of the present Rules the applicant shall bear responsibility in accordance with the legislation of the Russian Federation.

Appendix to the Rules
for the Importation and Exportation of Drugs
Registered in the Russian Federation

The List of Drugs and Pharmaceutical Substances Intended for Medical Use Whose Importation to the Territory of the Russian Federation Is Carried Out on the Basis of a Licence

Code of CC FEA of Russia		
1.	Organic chemical compounds used as pharmaceutical substances	from 2904-2909

		|from 2912-2942 00 000 0
2.	Glauds and other organs intended for organo-therapy, dried, ground or not ground to a powder; extracts of glauds and other organs or their secretions intended for organo-therapy; heparin and its salts; other substances of human or animal origin, intended for therapeutical or prophylactic purposes and not named anywhere	from 3001
3.	Human blood; blood of animals prepared for use for therapeutical, prophylactic or diagnostic purposes; immune sera (antibody containing sera) and fractions of blood, other and monified immunologic products, including those obtained by a biotechnological method; vaccines, toxins, microorganism cultures (except for yeast) and similar products used for medical purposes	from 3002
4.	Medicines (except for medicines of commodity positions 3002, 3005 or 3006) consisting of a mixture of two or more products for use for theraupetical or prophylactic purposes, but not packed in the form of dosed medicine forms or in packages for retail sale (except for these used in veterinary service)	from 3003
5.	Medicines (except for medicines of commodity positions 3002, 3005 and 3006) consisting of mixed and unmixed products for use for therapeutical or prophylactic purposes, packed in the shape of dosed medicinal forms or in packages for retail trade (except for those used in veterinary service)	from 3004
6.	Contrasting preparations for X-ray examinations (radiopaque preparations); diagnostic reagents intended for introduction to patients	3006 30 000 0

7.	Chemical contraceptive agents made on the basis of hormones or spermicides	3006 60