On Approval of the Rules on Importation and Exportation of Medicines, Products of Medical Purposes and Medical Equipment

Resolution of the Government of the Republic of Kazakhstan No. 711 of 31 May 2012

In accordance with Articles 80 and 81 of the Code of the Republic of Kazakhstan "On Public Health and Health Care System" of 18 September 2009, the Government of the Republic of Kazakhstan **HAS DECIDED**:

1. To approve the attached:

1) Rules for Import of Medicines, Products of Medical Purposes and Medical Equipment;
2) Rules for Export of Medicines, Products of Medical Purposes and Medical Equipment.

2. This Resolution shall enter into force upon expiration of ten calendar of its first official publication.

Prime Minister
of the Republic of Kazakhstan *K. Massimov*

Approved
by Resolution of the Government
of the Republic of Kazakhstan
No. 711 of 31 May 2012

Rules for Import of Medicines, Products

vehicles that entered the customs territory of the Customs Union, treatment of participants of international cultural and sports events and participants of international expeditions shall be carried out without permission of the state authority in the field medicines, products of medical purposes and medical equipment (hereinafter - the Authorized body).

7. Permission for import into the territory of the Republic of Kazakhstan of unregistered (including for medicine exhibitions without the right of their further sale, importation of unregistered pharmaceutical ingredients produced under conditions of good manufacturing practice) and coordination of registered in the Republic of Kazakhstan medicines shall be issued by the Authorized body or its territorial units in the form stipulated in Annexes 1 and 2 to these Rules.

8. To coordinate import of medicines registered on the territory of the Republic of Kazakhstan the Applicant shall submit to the Authorized body the following documents:

1) to conduct clinical trials, and (or) test:

an application;

a copy of the certificate of state registration (re-registration) of a sole proprietor - for individuals or a copy of the certificate of state registration (re-registration) - for legal entities;

a copy of agreement (contract) or invoice (bill) with translation into Kazakh or Russian languages;

copy of the Order of the Authorized body for permission to conduct clinical trials of medicines;

copies of the manufacturer’s documents confirming the quality of medicines intended for clinical trials;

list of submitted documents;

2) to provide humanitarian assistance:

an application;

a copy of the certificate of state registration (re-registration) of a sole proprietor - for individuals or a copy of the certificate of state registration - (re-) for legal entities;

Letter of local bodies of healthcare state administration of oblasts, cities of national status and capital or healthcare organizations with a license for medical activities, confirming supporting of this humanitarian campaign with obligation to monitor the designated use of non-commercial goods;

proof of humanitarian nature of cargo addressed to the recipient, with translation into Kazakh or Russian languages;

plan of designated use (distribution) of humanitarian assistance;

list of submitted documents;

3) to prevent and / or response to emergencies:

an application;

a copy of the certificate of state registration (re-registration) of a sole proprietor - for individuals or a copy of the certificate of state registration (re-registration) - for legal entities;

a copy of agreement (contract) or invoice (bill) with translation into Kazakh or Russian languages;

a letter from the local executive bodies confirming the emergency situation;

list of submitted documents.

To coordinate the import of medicines registered on the territory of the Republic of Kazakhstan (except for subparagraphs 1-3 of paragraph 8) the Applicant shall submit to the territorial unit of the Authorized body the following documents:

an application;

a copy of the license to conduct pharmaceutical activity with attached Annex indicating the sub-activity related to production of medicines, products of medical purposes and medical equipment or related to wholesale distribution of medicines, products of medical purposes and

medical equipment, or a copy of the license to conduct medical activities of health care organizations (if medicinal products are imported by a health organization);

a copy of the licenses and annexes to license to conduct activities related to the field of circulation of narcotic drugs, psychotropic substances and precursors (when imported drugs contain narcotic drugs, psychotropic substances and precursors);

a copy of agreement (contract) containing provisions on sale of imported medicines, products of medical purposes and medical equipment only in the territory of the Republic of Kazakhstan, as well as a copy of specification indicating the name of manufacturer and country of origin of medicines, products of medical purposes and medical equipment with translation into State or Russian languages;

a copy of the certificate of state registration (re-registration) as a sole proprietor - for individuals or a copy of the certificate of state registration (re-registration) - for legal entities;

a copy of document of manufacturer or its authorized representative confirming the distribution rights to import medicines from the territory of a third country, with translation into Kazakh or Russian languages;

list of submitted documents.

Applications for coordination of import of medicines referred to in paragraph 8 shall be submitted on paper and electronic media (CD-R, CD-RW, Flash, DVD-R, DVD-RW) as per the form indicated in Annex 3 to these Rules.

9. To obtain permission to import medicines unregistered in the territory of the Republic of Kazakhstan the Applicant shall submit to the Authorized body the following documents:

1) to conduct clinical studies, and (or) test:

an application;

a copy of the certificate of state registration (re-registration) as a sole proprietor - for individuals or a copy of the certificate of state registration (re-registration) - for legal entities;

a copy of agreement (contract) or invoice (bill) with translation into Kazakh or Russian languages;

a copy of the order of the Authorized body to permit conducting clinical studies of medicines;

copies of the documents of manufacturer confirming the quality of medicines intended for clinical studies and (or) tests with translation into Kazakh or Russian languages;

list of submitted documents.

2) to import samples of medicines to conduct expert examination, state registration, re-registration and enter amendments to the registration dossier:

an application;

a letter of guarantee indicating that these samples shall be submitted for state registration, re-registration and entering amendments to the registration dossier in the territory of the Republic of Kazakhstan;

calculation of quantity of medicines needed for conducting expert examination for state registration, re-registration, entering amendments to the registration dossier, as established by the state expert organization in the field of medicines, products of medical purposes and medical equipment;

a copy of the invoice (bill) with translation into Kazakh or Russian languages;

list of submitted documents;

3) to hold exhibitions of medicines without the right of further sale:

an application;

a written confirmation of exhibition organizer on applicant's participation in the exhibition;

a copy of agreement (contract) or invoice (bill) with translation into Kazakh or Russian languages;

list of submitted documents;

4) for individual treatment of rare and (or) the most severe diseases, medical assistance for life-saving of a certain patient:

an application;

a copy of the license to conduct pharmaceutical activities with the Annex on the sub-activity, related to wholesale distribution of medicines, or a copy of the license to conduct medical activities by health care organizations (when medicines are imported by a healthcare organization);

a copy of the certificate of state registration (re-registration) as a sole proprietor - for individuals or a copy of the certificate of state registration (re-registration) - for legal entities;

a letter from the local state healthcare administration of oblasts, city of national status and capital or health care organizations with license for medical activities, with justification and calculation of required quantity of medicinal products;

a copy of the agreement (contract) or invoice (bill) with translation into Kazakh or Russian languages;

a copy of the manufacturer’s document confirming the quality of medicines with translation into Kazakh or Russian languages;

a copy of document from the manufacturer or its authorized representative, confirming distribution rights of supplier to import products of medical purposes, medical equipment from a third country, with translation into Kazakh or Russian languages;

list of submitted documents.

2) to provide humanitarian assistance:

an application;

a copy of the certificate of state registration (re-registration) as a sole proprietor - for individuals or a copy of the certificate of state registration - (re-) for legal entities;

3) for individual treatment of rare and (or) the most severe diseases, medical assistance for life-saving of a particular patient:

an application;

a copy of the license to conduct pharmaceutical activities with Annex on the sub-activity related to wholesale of products of medical purposes, or a copy of the license for conducting medical activities by health care organizations (when products of medical purposes are imported by a health organization);

a copy of the certificate of state registration (re-registration) as a sole proprietor - for individuals or a copy of the certificate of state registration (re-registration) - for legal entities;

a letter from the local public health administration of oblasts, city of national status and the capital or health care organizations with license for medical activities, with justification and calculation of quantity of products of medical purposes;

a copy of the agreement (contract) or invoice (bill) with translation into Kazakh or Russian languages;

a copy of the manufacturer's document confirming the quality of products of medical purposes, with translation into Kazakh or Russian languages;

a list of submitted documents;

4) to prevent and / or respond to emergency situations:

an application;

a copy of the certificate of state registration (re-registration) as a sole proprietor - for individuals or a copy of the certificate of state registration (re-registration) - for legal entities;

a copy of the agreement (contract) or invoice (bill) with translation into Kazakh or Russian languages;

a letter from the local executive bodies on occurred emergency;

a list of submitted documents;

5) to provide healthcare organizations with unparalleled unique medical equipment, registered in the Republic of Kazakhstan:

an application;

a copy of the certificate of state registration (re-registration) as a sole proprietor - for individuals or a copy of the certificate of state registration (re-registration) - for legal entities;

a copy of the license to conduct pharmaceutical activities with Annex on the sub-activity related to the wholesale distribution of products of medical purposes, medical equipment or a copy of the license to conduct medical activities by health care organizations (when medical equipment and its components are imported by a health organization);

a letter from a health organization, confirming the need for medical equipment;

a copy Tw[distributio9h 83 Tc-.aent; 35 -1.15 TD.0004.087315 TD.0004.087315cT)8.7(r)-e4

17. Period of examination of applications referred to in paragraphs 15 and 16, shall be nine days.

18. The documents referred to in paragraphs 15 and 16 of these Rules shall be numbered, laced, fixed with seal and signed by the applicant or its representative.

19. The authorized body shall main

Annex 1 to the Rules for Import of
Medicines, Products of Medical
Purposes, Medical Equipment

Form of permit for import of
unregistered medicines,
pharmaceutical ingredients

_____

(name of authorized body)

hereby permits _____

(Full name of sole proprietor, full name of legal entity,

_____

taxpayer registration number (TRN), identification number (BIN, IIN), address, telephone)

the import of medicines (pharmaceutical ingredients) unregistered in the Republic of Kazakhstan according to Specification No. __ of «___» _____ 20__ to the Contract (agreement), document confirming humanitarian nature of goods)
No. _____ of « __ » _____ 20__, concluded with the Company _____
for the following names of products:

No. p/p	Name of medicines (dosage form), pharmaceutical ingredients	Unit	Q-ty	Name of manufacture and country of origin
1	2	3	4	5

The given above medicines are designated for _____
(indicate the reason of import)

The given above pharmaceutical ingredients are produced in conditions of the good manufacturing practice.

Position of authorized person _____ full name
signature

Seal
Prepared by: _____
Telephone: _____

Annex 2 to the Rules for Import of
Medicines, Products of Medical
Purposes, Medical Equipment

Form of coordination for import
of registered medicines

_____

(name of authorized body)

coordinates _____

_____

(Full name of sole proprietor, full name of legal entity,

_____

taxpayer registration number (TRN), identification number (BIN, IIN), address, telephone)

the import of medicines into the Republic of Kazakhstan according to Specification No. __ of «___» _____ 20__ to Contract (agreement)
No. _____ of « __ » _____ 20__, concluded with the Company
_____,

for the following products:

No. p\p	Name of medicines (dosage form)	Unit	Q-ty	Name of manufacture and country of origin	Date and number of state registration of medicines in the Republic of Kazakhstan	Date of expiry of state registration of medicines in the Republic of Kazakhstan
1	2	3	4	5	6	7

The given above medicines (quantity of products) are registered and allowed for use in the Republic of Kazakhstan.

Position of authorized person _____ full name
signature

Seal
Prepared by:_____
Telephone: _____

Annex 3 to the Rules for Import of Medicines, Products of Medical Purposes, Medical Equipment

Form of Application for import of registered medicines

_____

(name of authorized body)

Application

Hereby we request to coordinate the im

Application

Taxpayer registration number (TRN), identification number (BIN, IIN) (if any) of Applicant	

Annex 4 to the Rules for Import of
Medicines, Products of Medical
Purposes, Medical Equipment

Form of application for import
of unregistered medicines
(*Pharmaceutical ingredients)*

_____

(name of authorized body)

Application

Hereby we request permission to import medicinal medicines (pharmaceutical ingredients) (please underline as necessary) unregistered in the Republic of Kazakhstan designated for _____ *(indicate the purpose of import).*

Applicant	
Legal address of Applicant	
Telephone, e-mail of Applicant	
Taxpayer registration number (TRN), identification number (BIN, IIN) (if any) of Applicant	
Supplier	
Legal address of Applicant	
Telephone, e-mail of Supplier	
Country of Supplier	
Number of Contract (agreement)	
Date of Contract (agreement)	
Number of Specification (Annex)	
Date of Specification	
Customs body for importing	
Payment currency	

Code of	Name of	Concentration	Dosage	Packaging	Pharmaceutical

Annex 7 to the Rules for Import of Medicines, Products of Medical Purposes, Medical Equipment

Form of application for import of registered products of medical purposes, medical equipment

	medical purposes, medical equipment				
	Total				

Price per unit in payment currency	Amount in payment currency	Manufacturer	Country of manufacturer	Date and number of state registration of products of medical purposes, medical equipment in the Republic of Kazakhstan	Date of expiry of state registration of products of medical purposes, medical equipment in the Republic Of Kazakhstan

Signature of Applicant _____ full name
Seal«_____» _____ 20__

Annex 7 to the Rules for Import of Medicines, Products of Medical Purposes, Medical Equipment

Form of application for import of unregistered products of medical purposes, medical equipment

_____

(name of authorized body)

Application

Hereby we request permission to import products of medical purposes, medical equipment unregistered in the territory of the Republic of Kazakhstan.

Applicant	
Legal address of Applicant	
Telephone, e-mail of Applicant	

Taxpayer registration number (TRN), identification number (BIN, IIN) (if any) of Applicant	
Supplier Legal address of Applicant	

Approved
by Resolution of the Government
of the Republic of Kazakhstan
No. 711 of 31 May 2012

Rules
for export of Import of Medicines, Products of Medical Purposes and Medical Equipment

1. General provisions

1. These Rules for export of medicines, products of medical purposes and medical equipment (hereinafter - the Rules) were developed in accordance with Article 81 of the Code of the Republic Of Kazakhstan "On Public Health and Health Care System" of 18 September 2009

2. These Rules define the procedure of export of medicines, products of medical purposes and medical equipment from the Republic Of Kazakhstan.

3. Permission for medicines, products of medical purposes and medical equipment shall be issued by the state authorized body in the field of medicines, products of medical purposes and medical equipment circulation (hereinafter - the authorized body) and its territorial units in compliance with Annex 1 to these Rules.

2. Procedure for medicines, products of medical purposes and medical equipment

To obtain permission for export of medicines, products of medical purposes and medical equipment the Applicant shall submit to the authorized body or its territorial units the following documents:

1) An application requesting permission to export medicines, products of medical purposes and medical equipment on the paper and electronic media (CD-R, CD-RW, Flash, DVD-R, DVD-RW) in compliance with Annex 2 to these Rules;

2) A copy of the license to conduct pharmaceutical activities with Annex on the sub-activity related to production of medicines, products of medical purposes and medical equipment or wholesale of medicines, products of medical purposes and medical equipment, or a copy of the license for conducting medical activities (when medicines, products of medical purposes and medical equipment are exported by a health organization);

3) list of submitted documents.

5. Period for examination of applications shall be five working days.

6. The documents referred to in paragraph 4 of these Rules shall be numbered, laced, affixed with seal and signature by the applicant or its representative.

7. The authorized body shall maintain the record of issued permits for export of medicines, products of medical purposes and medical equipment.

8. The authorized body and (or) its territorial units within two business days of receipt of the applicant’s document shall be required to verify the completeness of the submitted documents.

If the submitted documents are incomplete, the authorized body and (or) its territorial units shall provide the written reasoned refusal to further examine the application within the specified period of time.

9. In case of violation of the requirements of these Rules (except for requirement of completeness of the documents mentioned in paragraph 8 of these Rules), issuance of permit for export of medicines, products of medical purposes and medical equipment shall be denied.

10. Refusal to issue permit, approval for export of medicines, products of medical purposes and medical equipment can be appealed in the court.

11. In the case of failure to issue a permit, approval or reasoned refusal to issue permit, approval for import of medicines, products of medical purposes and medical equipment in a timely manner, the permit, coordination shall be deemed as issued. In this case, the authorized body and (or) its territorial units within two working days are required to issue a permit, approval for export of medicines, products of medical purposes and medical equipment.

12. Medicines, products of medical purposes and medical equipment can be exported from the territory of the Republic Of Kazakhstan without permit of authorized body in the following cases:

1) for personal use by individuals leaving the territory of the Republic Of Kazakhstan, in the amount required for a course of treatment;

2) in the set of first-aid of a vehicle leaving the Republic Of Kazakhstan, for the treatment of passengers.

Annex 1 to the Rules for Export of
Medicines, Products of Medical
Purposes, Medical Equipment

Form of permit for export of
Medicines, Products of Medical
Purposes, Medical Equipment

_____

(name of authorized body or its territorial unit)

hereby permits _____

(Full name of sole proprietor, full name oflegal entity,

_____

Taxpayer registration number (TRN),identification number (BIN, IIN), address, telephone)

the export from the Republic of Kazakhstan of medicines, products of medical purposes and medical equipment according to Specification No. __ of «___» _____ 20__ to the Contract (agreement) No. _____ of « __ » _____ 20__, concluded with the Company _____ for the following products:

No. p\p	Name of medicinal product (dosage form), medical devices, medical equipment	Unit	Q-ty	Name of manufacture and country of origin
1	2	3	4	5

Position of authorized person _____ full name

signature

Seal

Prepared by: _____

Telephone: _____

Annex 2 to the Rules for Export of

Medicines, Products of Medical Purposes, Medical Equipment
Form of application for export of Medicines, Products of Medical Purposes, Medical Equipment

_____
(name of authorized body or its territorial unit)

Application

	Total			

Pharmaceutical dosage form	Unit	Q-ty	Manufacturer	Country - manufacturer

Signature of Applicant _____ full name

signature

Seal«____» _____ 20__