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 of Medical Purposes and Medical Equipment

1. General provisions

1. These Rules for Import of Medicines, Products of Medical Purposes and Medical Equipment (hereinafter - the Rules) have been developed in accordance with Article 80 of the Code of the Republic of Kazakhstan "On Public Health and Health Care System" of 18 September 2009.

2. These Rules determine the procedure for import of medicines, products of medical purposes and medical equipment to the Republic of Kazakhstan.

3. Import of medicines and pharmaceutical ingredients (hereinafter - medicines) of States non-members of the Customs Union, shall be conducted in accordance with the Regulations on Order of Entry into the Customs Territory of the Customs Union of Medicines and Pharmaceutical Ingredients, approved by Decision of the Interstate Council (the Supreme Body of the Customs Union) at the highest level No. 19 of 27 November 2009, Decision of the Commission of the Customs Union No. 748 of 16 August 2011.

4. These Rules contain the following definitions:

1) Good Manufacturing Practice - part of quality assurance system that ensures the production and quality control of medicines according to the standards relating to their designation and requirements of the registration dossier;

2) proof of the humanitarian nature of the consignment sent to the recipient - agreement, invoice (bill of lading), commercial invoice, contract, specification with information indicating information on gratuitousness of cargo, manufacturer, country of origin, product form, quantity, expiry date;

3) plan of intended use (distribution) of humanitarian aid - a document approved by the head of healthcare organization containing information on the date, place, name, quantity of distribution of humanitarian assistance;

4) operational document of medical equipment - manual, passport for medical equipment;

5) registration dossier - a required set of documents and materials submitted along with the application for state registration, re-registration of medicines, products of medical purposes and medical equipment, and amendments to the registration dossier.

2. Procedure of Import of Medicines, Products of Medical Purposes and Medical Equipment

Import of medicines

5. In case of importing of medicines from states that are non-members of the Customs Union into the territory of the Republic of Kazakhstan, they shall be subject to the customs procedure in accordance with Decision of the Commission of the Customs Union No. 748 of 16 August 2011.

6. Import of medicines (including unregistered) for non-commercial purposes for personal use by individuals, employees of the diplomatic corps and representatives of international organizations, treatment of the passengers and crew of vehicles, train crews and drivers of

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 list of submitted documents;

5) to prevent and / or respond to emergencies:

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 local executive bodies on occurred emergency;

a list of submitted documents;

6) to provide humanitarian assistance in the cases determined by the Government of 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-) 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 on supporting this humanitarian campaign with obligation to control the non-commercial designated use of goods;

a document proving humanitarian nature of the goods with indicated address of receiver, with translation into Kazakh or Russian languages;

plan of intended use (distribution) of humanitarian aid;

a document proving the quality of imported medicines, with translation into Kazakh or Russian languages;

list of submitted documents;

7) to import of unregistered pharmaceutical ingredients produced under conditions of the good manufacturing practice:

an application;

a copy of the license to conduct pharmaceutical activities with the Annex on the sub-activity related to the production of medicines, or wholesale distribution of medicines, or a copy of the license for carrying out medical activities;

a copy of the agreement (contract) with provisions on sale of imported medicines only in the territory of the Republic of Kazakhstan, as well as a copy of the specification indicating name of the manufacturer and country of origin of pharmaceutical ingredients with translation into Kazakh 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 from the manufacturer or its authorized representative, confirming the distribution rights to import pharmaceutical ingredients from the territory of a third country, with translation into Kazakh or Russian languages;

a copy of the certificate on conformity of production to requirements of good manufacturing practices with indicated date of the last inspection with translation into Kazakh or Russian languages;

list of submitted documents.

Applications for issuance of permit to import medicines specified in sub-paragraphs 1), 2), 3), 4), 5), 6) and 7) of this paragraph shall be submitted on paper and electronic media (CD-R, CD-RW, Flash, DVD-R, DVD-RW) as per the form in Annex 4 to these Rules.

Medicines with shelf life at least 12 months shall be allowed to be imported as humanitarian assistance. Importing medicines with less shelf life shall be permitted by the authorized body taking into account the specific name of a medicine and particular batch.

10. Period of examination of applications referred to in paragraphs 8 and 9, shall be nine days.

11. Documents referred to in paragraphs 8 and 9 of these Rules shall be numbered, laced, affixed with seal and signed by the applicant or its representative.

Procedure for import of products of medical purposes and medical equipment

12. Import of products of medical purposes, medical equipment shall be conducted on the basis of coordination (or permits), except as provided in paragraph 21 hereof.

13. Coordination of import of registered products of medical purposes, medical equipment into the territory of the Republic of Kazakhstan shall be conducted by the territorial divisions of the authorized body (hereinafter - the territorial division) in the form set out in Annex 5 of these Rules.

14. Coordination of import of registered products of medical purposes, medical equipment intended for humanitarian assistance, preventing and / or responding to emergencies into the territory of the Republic of Kazakhstan, issuance of permit for import of products of medical purposes, medical equipment unregistered in the Republic of Kazakhstan shall be carried out by the authorized body in the form set out in Annexes 5 and 6 of these Rules.

15. To coordinate import of products of medical purposes, medical equipment registered in the territory of the Republic of Kazakhstan the applicant shall submit to the territorial unit or an authorized body the following documents:

1) to import registered products of medical purposes, medical equipment:

an application;

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

a copy of the agreement (contract) with the provisions on sale of imported products of medical purposes, medical equipment only in the territory of the Republic of Kazakhstan, as well as the specification with name of the manufacturer and country of manufacturer of products of medical purposes, medical equipment with translation into Kazakh 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 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;

letter of local state healthcare administration of oblasts, city of national status and the capital or health care organizations with the license for medical activities, on supporting this humanitarian campaign with obligation to control non-commercial designated use of goods;

a document proving humanitarian nature of cargo address to the recipient with translation into Kazakh or Russian languages;

a plan of intended use (distribution) of humanitarian assistance;

a list of submitted documents;

3) to prevent and / or respond to emergencies:

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 situation;

a list of submitted documents.

Applications for coordination of import of products of medical purposes, medical equipment, referred to in sub-paragraphs 1), 2) and 3) of this section shall be submitted on paper and electronic media (CD-R, CD-RW, Flash, DVD-R, DVD-RW) in the form referred to in Annex 7 to these Rules.

16. To obtain permission to import products of medical purposes, medical equipment unregistered in the territory of the Republic of Kazakhstan the applicant shall submit to the authorized body the following documents:

1) when importing samples of products of medical purposes, medical equipment for state registration, re-registration and entering amendments to the registration dossier:

an application;

a letter of guarantee to submit samples for state registration, re-registration and entering amendments to the registration dossier in the territory of the Republic of Kazakhstan;

calculation of quantity of products of medical purposes, medical equipment needed to conduct experts examination for state registration, re-registration, entering amendments to the registration dossier, as agreed with the state expert organization in the field of medicines, products of medical purposes, medical equipment;

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

a list of submitted documents;

2) to hold exhibitions of products of medical purposes, medical equipment, without the right to further sale:

an application;

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

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

a list of submitted documents;

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

a conclusion of the state experts organization in the field of products of medical purposes, medical equipment circulation on the uniqueness of medical equipment for the Republic of Kazakhstan and the absence of analogues of medical equipment, registered in the Republic of Kazakhstan, on medical devices belonging to the set of unique medical equipment (when medical device which is an integral part of the unique medical equipment is imported into the Republic of Kazakhstan).

To obtain conclusion on the uniqueness and the absence of analogues of medical equipment, registered in the Republic of Kazakhstan, on medical devices belonging to the set of unique medical equipment the applicant shall submit to the state expert organization in the field of products of medical purposes, medical equipment the following documents:

a document certifying the registration of medical equipment in the country of manufacturer and (or) the free sale certificate;

a document proving compliance of production conditions with the national and (or) international standards (GMP, ISO, EN);

a document confirming compliance of medical equipment to the national or international regulatory documents (Declaration of Conformity, Certificate of Conformity) of the seller's country;

technical specification with indication of technical specifications, list of the main components and component parts and consumables;

results of clinical studies and (or) tests;

manual of medical equipment in the State and Russian languages;

color photographs of 13 x 18 cm (displaying appearance of products, components, consumables);

data on the manufacturer indicating: name, type of activity, address, form of incorporation, list of divisions, subsidiaries and service center with their status and authority;

a list of submitted documents;

6) 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 the agreement (contract) or invoice (bill) with translation into Kazakh or Russian languages;

a copy of order of the authorized body on permission to conduct clinical studies of products of medical purposes, medical equipment;

copies of documents of the manufacturer certifying the quality of products of medical purposes, medical equipment, intended for clinical studies, and (or) tests with translation into Kazakh or Russian languages;

a list of submitted documents;

7) to render humanitarian assistance in the cases determined by the Government of 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-) for legal entities;

a letter of the local state healthcare administration of oblasts, city of national status and the capital or health care organizations with the license for medical activities, on supporting this humanitarian campaign with obligation to control the non-commercial designated use of goods;

a document proving humanitarian nature of goods addressed to the recipient, with translation into Kazakh or Russian languages;

a plan of intended use (distribution) of humanitarian assistance;

a document proving the quality of imported products of medical purposes, medical equipment, with translation into Kazakh or Russian languages;

a list of submitted documents.

Applications to obtain permit to import products of medical purposes, medical equipment specified in sub-paragraphs 1), 2), 3), 4), 5), 6) and 7) of this section shall be submitted on paper and electronic media (CD-R, CD-RW, Flash, DVD-R, DVD-RW) in the form specified in Annex 8 to these Rules.

Products of medical purposes, medical equipment with shelf life of at least 12 months as humanitarian assistance are allowed for import .

Import of products of medical purposes, medical equipment with shorter shelf life shall be permitted by the authorized body taking into account the specific name of products of medical purposes, medical equipment and a particular batch.

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 maintain records of issued permits and approvals for import of medicines, products of medical purposes, medical equipment.

20. At change of the labeling and packaging of medicines, products of medical purposes, medical equipment, they shall be allowed to import with the previously approved package up to six months after amendments made to the registration dossier.

21. Import of medicines, products of medical purposes, medical equipment by individuals for personal use in quantity required for a treatment course, in the first aid kits of the vehicle which is in the territory of the Republic of Kazakhstan, for treatment of passengers shall be carried out without a permit, coordination of the authorized body.

22. The authorized body and (or) its territorial units within two business days of receipt of the applicant's document shall verify 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.

23. In case of violation of the requirements of these Rules (except for requirement of completeness of the documents mentioned in paragraph 22 of these Rules), issuance of permit for import of medicines, products of medical purposes, medical equipment shall be denied.

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

25. 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, 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 import of medicines, products of medical purposes, medical equipment.

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 import of medicines to 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 FEACC	Name of medicines	Concentration	Dosage	Packaging (number)	Pharmaceutical dosage form	Unit	Q-ty
	Total						

Price per unit in payment currency	Amount in payment currency	Manufacturer	Country of manufacturer	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

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

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

FEACC	medicines, pharmaceutical ingredients			(number)	dosage form
	Total				

Unit of measurement	Q-ty	Price per unit in payment current	Amount in payment current	Manufacturer	Country - manufacturer

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

Annex 5 to the Rules for Import of Medicines, Products of Medical Purposes, Medical Equipment

Form of coordination of import of registered products of medical purposes, medical equipment

_____
(name of authorized body or its territorial unit)
coordinates _____
(full name of sole proprietor, full name of legal entity,

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

the import of products of medical purposes, medical equipment to the Republic of Kazakhstan according to Specification No. __ of «___» _____ 20__ to Contract (agreement), document confirming humanitarian nature of goods) No. _____ of «__» _____ 20__, concluded with the Company _____, for the following products:

No. p\p	Name of products of medical purposes, medical equipment	Unit	Q-ty	Name of manufacture and country of origin	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
1	2	3	4	5	6	7

The given above products of medical purposes, medical equipment (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 6 to the Rules for Import of Medicines, Products of Medical Purposes, Medical Equipment

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

_____
(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 unregistered in the Republic of Kazakhstan products of medical purposes, medical equipment to 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 products of medical purposes, medical equipment	Unit	Q-ty	Name of manufacture and country - manufacturer
1	2	3	4	5

The given above products of medical purposes, medical equipment (quantity of products) are designated for _____ (indicate the purpose of import).

Position of authorized person _____ full name
signature
Seal
Prepared by: _____
Telephone: _____

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

_____

(name of authorized body or its territorial unit)

Application

Hereby we request coordination of import of products of medical purposes, medical equipment registered 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 FEACC	Name of products of	Packaging (number)	Pharmaceutical dosage form	Unit	Q-ty

	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	
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 FEACC	Name of products of medical purposes, medical equipment	Packaging (number)	Pharmaceutical dosage form
	Total		

Unit	Q-ty	Price per unit in payment currency	Сумма in payment currency	Manufacturer	Country - manufacturer

Signature of Applicant _____ full name

signature

Seal«____» _____ 20__

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

We hereby request permission to export medicines, products of medical purposes and medical equipment

Applicant	
Legal address of Applicant	
Telephone, e-mail of Applicant	
Taxpayer registration number (TRN), identification number (BIN, IIN) (if any) of Applicant	
Supplier	
Manufacturer	
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 export	

Code of FEACC	Name of medicines, products of medical purposes and medical equipment	Concentration	Dosage	Packaging (number)

	Total			

Pharmaceutical dosage form	Unit	Q-ty	Manufacturer	Country - manufacturer

Signature of Applicant _____ full name

signature

Seal«____» _____ 20__