AGREEMENT
ON COMMON PRINCIPLES AND RULES OF CIRCULATION OF MEDICINAL PRODUCTS WITHIN THE EURASIAN ECONOMIC UNION

(Moscow, 23 December 2014)

Member States of the Eurasian Economic Union, hereinafter referred to as the Member States,

Based on the Treaty on the Eurasian Economic Union of 29 May 2014,

Confirming the intention to develop economic cooperation and to expand trade and economic relations,

Recognizing that the medicinal products are socially important products,

In order to create a common market of medicinal products within the Eurasian Economic Union (hereinafter – the Union),

Establishing goal to promote the health of the population of the Member States by providing access to safe, effective and quality medicines,

Recognizing the usefulness of a coordinated policy in the field of circulation of medicinal products based on mutual interest in ensuring the safety, efficacy and quality of medicinal products for human life and health, environmental protection, life and health of animals and plants, prevention of actions misleading consumers,

Aiming for creation of optimal conditions for the development of the pharmaceutical industry, improving the competitiveness of the pharmaceutical products manufactured in the territories of the Member States and for the entrance to the world market,

Seeking to eliminate unreasonable restrictions in mutual trade,

Have agreed as follows:

Article 1
Definitions

1. For the purposes of this Agreement, the terms with the following meaning are used:

“medicinal product” – is a product that constitutes or contains a substance or combination of substances that come into contact with the human body, intended for the treatment, prevention of human diseases or for restoration, correction or

changes of physiological functions by its pharmacological, immunological or metabolic effects, or for diagnostics of diseases and conditions of human being;

“medicine” – is a medicinal product in a drug form;

“good pharmaceutical practice in the field of circulation of medicinal products” (hereinafter – the Good Pharmaceutical Practice) – the rules that apply to all stages of circulation of medicinal market: Good Laboratory Practice, Good Clinical Practice, Good Manufacturing Practice, Good Distribution Practice, Good Pharmacy Practice, Good Pharmacovigilance Practice and other practices;

“circulation of medicinal products” – activities, including processes of development, pre-clinical studies, clinical studies (trials), examination, registration, pharmacovigilance, quality control, production, manufacturing, storage, transportation, importation into the customs territory of the Union and export from the customs territory of the Union, movement from the territory of one Member State to the territory of other Member States, release, distribution, transfer, use, destruction of medicinal products;

“pharmaceutical substance” – a substance intended for the production and manufacture of drug products.

2. Establishing a common market of medicinal products within the Union the Member States shall be guided by standardized terms and their definitions in accordance with the information guide on concepts and definitions in the field of circulation of medicinal products, established and maintained by the Eurasian Economic Commission (hereinafter – Commission).

Article 2
Scope of the Agreement

1. This Agreement establishes common principles and rules for the circulation of medicinal products within the Union in order to create a common market of medicinal products within the Union.

2. This Agreement shall apply to legal relations arising in the field of circulation of medicinal products within the Union.

Article 3
Regulation of circulation of medicinal products

1. Regulation of circulation of medicinal products within the Union is carried out in accordance with this Agreement, other international treaties, included in the legislation of the Union, the decisions of the Commission and the legislation of the Member States.

Decisions of the Commission governing the circulation of medicinal products shall be developed on the basis of international legal acts.

2. Member States shall submit to the Commission the proposals for the drafting of projects of acts of the bodies of the Union in the field of circulation of medicinal products.

3. In order to ensure compliance with the requirements in the field of circulation of medicinal products within the Union, the Commission has the right to adopt accept recommendations concerning the determination of optimal approaches, the implementation of which will ensure compliance with such requirements.

Article 4
Functioning of the common market of medicinal products within the Union

1. Member States form the common market of medicinal products complying with the requirements of Good Pharmaceutical Practices, according to the principles set out in Article 30 of the Treaty on the Eurasian Economic Union of 29 May 2014.

2. Member States conduct a coordinated policy in the field of circulation of medicinal products by:

a) taking measures necessary for harmonization and unification of the legislation of the Member States in the field of medicinal products;

b) adopting common rules and requirements of regulation of circulation of medicinal products;

c) ensuring the uniformity of the mandatory requirements for safety, efficacy and quality of medicinal products in the territories of the Member States and their implementation;

d) ensuring common approach to the establishment of a quality assurance system of medicinal products;

d) harmonizing the legislation of the Member States in the field of control (supervision) of circulation of medicinal products.

3. For the purposes of implementation of this Agreement, the Member States define the government bodies, authorized to carry out and (or) to coordinate the activities in the field of circulation of medicinal products.

4. Coordination of activities aimed at harmonizing of the legislation of the Member States in the field of circulation of medicinal products is carried out by the Commission.

5. The government bodies of the Member States as referred to in paragraph 3 of this Article, shall hold consultations in order to align positions of the Member States on the issues of regulation of circulation of medicinal products.

Article 5
Harmonization of the State Pharmacopoeia of the Member States

1. Member States shall take measures to establish the pharmacopoeial requirements of the Union through the consistent harmonization of pharmacopoeial monographs (general and specific) of the Pharmacopoeias of the Member States.

2. Harmonization of the Pharmacopoeias of the Member States is carried out by using international experience of harmonization of national pharmacopoeial requirements in accordance with the concept approved by the Commission.

3. Pharmacopoeial monographs (general and specific), approved by the Pharmacopoeial Committee of the Union, jointly form the Pharmacopoeia of the Union which is approved by the Commission.

4. Specific pharmacopoeial monographs of the Pharmacopoeia of the Union which establish requirements for the quality of medicinal products, intended for circulation within the Union, are developed in accordance with the concept as referred to in paragraph 2 of this Article.

5. Operation of the Pharmacopoeial Committee of the Union is regulated by the Commission.

6. For the purposes of registration and quality control of medicinal products intended for circulation only in the territory of the individual Member States, the requirements of the Pharmacopoeia of the Member State are applied.

Article 6
Pre-clinical and clinical studies (trials) in the Member States

In order to ensure the functioning of the common market of medicinal products within the Union, pre-clinical and clinical studies (trials) of medicinal products in the Member States are carried out in accordance with the rules of Good Laboratory Practice, the rules of Good Clinical Practice and the requirements for studies (trials) of medicinal products approved by the Commission.

Article 7
Registration and assessment of medicinal products

1. Member States shall carry out the registration and the assessment of medicinal products intended for the circulation on the common market of medicinal products within the Union in accordance with the rules of registration and assessment of medicinal products approved by the Commission.

2. Requirements for the structure, format, contents of the registration file, the structure and contents of the report on the evaluation of the registration dossier, the form of the registration certificate of the medicinal product, the procedure for amending of the registration dossier, the reasons for refusal of registration, revocation, suspension or termination of the registration certificate of the medicinal products are established in the regulations referred to in paragraph 1 of this Article.

3. For the registration and examination of medicinal products the Member States use the nomenclature of dosage forms approved by the Commission.

4. Registration under the same trade name of medicinal products with different qualitative composition of the active substances is prohibited.

5. Member States shall not permit by their laws a re-registration of medicinal products registered in their territory in accordance with the rules of registration and assessment of medicinal products approved by the Commission.

6. The following products are not the subject for the registration in the Union:

a) medicinal products prepared by the pharmacies;

b) pharmaceutical substances;

c) medicinal products intended for use as the demonstration samples;

d) medicinal products intended for pre-clinical and clinical studies (trials);

d) medicinal products brought in by an individual for personal use;

e) radiopharmaceutical medicines produced directly by the medical institutions according to the procedures established by the competent authorities of the Member States;

g) medicinal products which are not intended for the distribution in the customs territory of the Union;

h) samples of medicinal products intended for the registration, and standard samples.

7. When carrying out the registration and assessment of medicinal products the Member States jointly recognize the results of pre-clinical (non-clinical), clinical and other studies (trials) of medicinal products, the results of inspection of manufacturing facilities, pre-clinical (non-clinical), clinical studies (trials) of medicinal products, pharmacovigilance systems for compliance with the rules of Good Pharmaceutical Practices and the requirements approved by the Commission.

Member States set up the conditions for studies (trials) of medicinal products in accordance with the international standards and ensure the comparability of the results.

8. The settlement of disputes arising from the registration of medicinal products is performed by the Expert Committee on Medicinal Products (hereinafter – the Expert Committee), created by the Commission by the representatives of the Member States and operating in accordance with the procedure approved by the Commission.

9. The decision of the competent authority of the Member State to refuse to issue the registration certificate of the medicinal product may be appealed in the court of the Member State using the procedure of settlement of disputes arising from administrative and other public relations.

Article 8
Distribution of medicinal products

1. The distribution of medicinal products within the Union is allowed on condition that they have been registered in accordance with the procedure established by the Commission, and the information about them was entered in the Single Register of registered medicinal products of the Eurasian Economic Union.

2. Medicinal products registered by the competent authority of a Member State before the entry into force of this Agreement, shall be distributed in the territory of that Member State until expiration of the registration certificates issued by the competent authority of a Member State.

3. Medicinal products registered in accordance with Article 7 of this Agreement and distributed within the Union, shall be marked in accordance with the unified requirements for the labeling of medicines approved by the Commission, and they must be accompanied by the instructions for use in conformance with the unified requirements for the instructions for medical use of medicinal products approved by the Commission.

Article 9
Manufacturing of medicinal products

1. Manufacturing of medicinal products within the Union is performed in accordance with the rules of Good Manufacturing Practice, approved by the Commission, based on a permit (license) for the manufacture of medicinal products granted in accordance with the laws of the Member States.

2. Qualified person of pharmaceutical manufacturer shall be certified by the competent authority of the Member State in accordance with the procedure of certification of qualified person of manufacturers of medicinal products approved by the Commission. Certified qualified persons of manufacturers of medicinal products are included in the register of qualified persons of manufacturers of medicinal products of the Eurasian Economic Union, as created and maintained by the Commission in accordance with the procedure approved by the Commission.

3. In case of misconduct the qualified persons of manufacturers of medicinal products shall be liable in accordance with the laws of the Member States.

Article 10
Pharmaceutical inspection

1. Pharmaceutical inspections are carried out both by Pharmaceutical Inspectorates of one of the Member States and jointly by Pharmaceutical Inspectorates of the Member States in accordance with the rules established by the Commission. The inspection report is prepared upon results of the inspection in a form approved by the Commission.

2. Pharmaceutical Inspectorates of the Member States shall operate in accordance with the general requirements approved by the Commission.

3. Pharmaceutical Inspectorates of the Member States cooperate with each other in order to exchange experience, to maintain and improve the system of quality assurance of medicinal products and quality system of pharmaceutical inspectorates, to ensure the participation of pharmaceutical inspectors in events (including those held by the World Health Organization and other international organizations) aimed at enhancement of their qualification.

4. Commission, taking into account the proposals of the Member States, shall maintain the Register of pharmaceutical inspectors of the Eurasian Economic Union. Creation and maintenance of the Register is performed in accordance with the procedure approved by the Commission.

5. Member States shall ensure operation of pharmaceutical inspectorates of the Member States.

Article 11
Wholesale distribution, transportation and storage of medicinal products

Wholesale distribution, transportation and storage of medicinal products in the territories of the Member States are carried out in accordance with the rules of Good Distribution Practice approved by the Commission.

Article 12
Pharmacovigilance

1. Member States shall ensure the effective functioning of the national pharmacovigilance system in accordance with the Good Pharmacovigilance Practice approved by the Commission and the legislation of the Member States.

2. Member States shall establish in their legislation provisions for liability of holders of registration certificates of medicinal products and of other subjects involved in the circulation of medicinal products, violating the mandatory requirements in the field of pharmacovigilance.

3. The competent authorities of the Member States ensure the control of fulfillment of pharmacovigilance obligations by the holders of registration certificates of medicinal products that are in circulation in the territories of the Member States in accordance with the Good Pharmacovigilance Practice and the legislation of the Member States.

4. The exchange of information between the competent authorities of the Member States on the identified adverse reactions (effects) to medicinal products, changes in the evaluation of risk-benefit ration of medicinal products circulated in the territories of the Member States and the measures taken in case if risks exceed benefits is carried out according to the procedure approved by the Commission.

5. Expert Committee examines discrepancies in the positions of the Member States on the evaluation of risk-benefit ration of medicinal products circulated in the territories of the Member States.

6. Member States shall exchange information on the results of the inspection of the pharmacovigilance system of the holder of the registration certificate of medicinal product in order to determine their compliance with the legislation of the Member States.

Article 13
State control (supervision) of circulation of medicinal products

1. Member States shall perform the state control (supervision) of circulation of medicinal products in accordance with the legislation of the Member States.

The competent authorities of the Member States shall cooperate to identify falsified and (or) counterfeit medicinal products in accordance with the procedure approved by the Commission.

2. The competent authorities of the Member States in case of classifying a medicinal product as dangerous for life and (or) human health, inefficient, low quality, falsified and (or) counterfeit medicine shall promptly inform the Commission and notify the competent authorities of other Member States as well as within their competence, take measures to ensure prompt removal from circulation of the medicinal products that are dangerous for life and (or) human health.

Article 14
Single Register of registered medicinal products of Eurasian Economic Union and information databases in the field of circulation of medicinal products

In order to ensure the conditions for circulation of safe, effective and quality medicinal products in the territory of the Member States the Commission forms and maintains:

single register of registered medicinal products of Eurasian Economic Union (hereinafter – the Single Register) with the integrated information databases on instructions for medical use, graphic design (design) of packages and regulatory documents on quality;

unified information database on medicinal products not complying with the quality requirements, as well as falsified and (or) counterfeit medicinal products identified in the territories of the Member States;

unified information database on the identified adverse reactions (effects) to medicinal products, including reports of ineffectiveness of medicinal products;

unified information database on medicinal products that are suspended, revoked and banned for medical use.

The competent authorities of the Member States shall provide to the Commission, in accordance with the procedure established by the Commission for creation and maintenance of the Single Register, the information required for the creation of the Register and databases as mentioned in this Article.

Article 15
The information system of the Union in the field of circulation of medicinal products

Commission ensures the creation and operation of the information system of the Union in the field of medicinal products (hereinafter – information system) in order to provide information about the requirements in the field of circulation of medicinal product within the Union, information contained in the Single Register and information databases referred to in Article 14 of this Agreement, as well as pharmacovigilance data and other information groups that are foreseen by the rules of establishment and operation of the information system.

The rules of establishment and operation of the information system are approved by the decision of the Commission and determine the basis of its establishment, operation and development and sources and order of financing.

Commission and the competent authorities of the Member States use information systems, information technologies and means of their support, developed, produced or purchased by them in accordance with the decisions of the Commission, the legislation of the Member States and (or) the international treaties within the Union.

Article 16
Informational interaction of the competent authorities of the Member States in the event of measures restricting the circulation of medicinal products

A competent authority of the Member State in cases stipulated by the legislation of its state, may decide to suspend, revoke or refuse renewal of the issued registration certificate of medicinal product with immediate notification of the competent authorities of other Member States and the Commission.

Article 17
Cooperation of the competent authorities of the Member States

Competent authorities of the Member States shall cooperate in the field of circulation of medicinal products, including conducting of scientific research, scientific conferences, seminars and other events.

Competent authorities of the Member States shall take measures to exchange experiences and to organize joint training of specialists.

Article 18
Amendments to the Agreement

By mutual consent of the Member States the Agreement may be amended by separate protocols which shall constitute an integral part of this Agreement.

Article 19
Settlement of Disputes

Disputes relating to the interpretation and (or) the application of the provisions of this Agreement shall be settled as described in Article 112 of the Treaty on the Eurasian Economic Union of 29 May 2014.

Article 20
Transitional provisions

1. Medicinal products registered in the Member States before the entry into force of this Agreement shall be brought into compliance with the requirements and regulations of the Union before 31 December 2025 in accordance with the procedure established by the rules of registration and examination of medicinal products as referred to in Article 7 of this Agreement.

Member States shall allow for the confirmation of registration of medicinal products with the fixed period registration certificates issued prior to the entry into force of this Agreement at their expiration in accordance with the legislation of the Member State.

2. The relevant legal acts of the Member States are utilized until coming into force of the decisions of the Commission regulating the circulation of medicinal products.

Article 21
Entry into force

1. This Agreement shall enter into force on the date of receipt by the depositary of the last written notification of the fulfillment by the Member States of internal procedures necessary for its entry into force, but not earlier than 1 January 2016.

2. This Agreement is an international agreement concluded within the framework of the Union and it constitutes the law of the Union.

Done in Moscow on 23 December 2014 in a single original copy in Russian.

The original copy of this Agreement shall be kept in the Eurasian Economic Commission, which, acting as the depositary of this Agreement, will provide each Member State with its certified copy.

For the Republic of Belarus	For the Republic of Kazakhstan	For the Russian Federation