Original Article

The common pharmaceutical market of the Eurasian economic union: regulatory analysis

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ABSTRACT

The common market of the Eurasian Economic Union (EAEU) is formed according to a constantly updated large regulatory framework that regulates both various processes in the medicinal products circulation sector (preclinical and clinical studies, evaluation, registration, production, pharmacovigilance, quality control, etc.), and individual issues of pharmacy. System analysis of subordinate documents of various levels and grouping with the allocation of significant blocks based on common principles and rules for the medicinal product circulation within the EAEU is the purpose of the present study. Logical modeling based on hierarchical and chronological analyses was used to distinguish significant blocks of interrelated regulatory acts governing the main components of the medicinal product circulation in the framework of the common market of the EAEU.

Keywords: common market of medicinal products; the Eurasian Economic Union; the Eurasian Economic Commission.

Introduction

The Eurasian Economic Union (EAEU) is an international regional economic integration organization established by the Treaty in 2014, whose member states are the Republic of Armenia, the Republic of Belarus, the Republic of Kazakhstan, the Kyrgyz Republic, and the Russian Federation.

The formation of the common market of medicinal products within the framework of the EAEU is carried out since January 1, 2016. Medicinal products, registered in the EAEU member states must be brought into compliance with the requirements and rules of the Union by December 31, 2025. From ancient times, the use of medicinal plants for the treatment and prevention of diseases has always attracted attention in human societies all over the countries [1-4].

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Methods

The study of the system of EAEU regulatory acts in the field of medicinal product circulation was carried out based on the following documents and principles.

Top-level documents, namely, interstate acts that come into force after the ratification procedures carried out by each of the EAEU member state (adoption bodies: The Supreme Eurasian Economic Council (Treaty); the Eurasian Intergovernmental Council (Agreement, Protocols);

Documents of the Eurasian Economic Commission (EEC), i.e. direct action documents that prevail over the national normative acts of the member states, and come into force within the terms specified in the operative part:

Decisions of the EEC Council, i.e. documents signed by the vice-premiers of five EAEU member states (23 documents, as of August 2019);

Decisions of the EEC Board are documents that are adopted by a Board of ten ministers and signed by the Chairman of the EEC Board (18 documents, as of August 2019);

The EEC recommendations are lower-level documents that establish a standard for applying regulation in the medicinal product circulation, whose implementation is recognized as meeting the norms of Good practices of the EAEU. At that, any of the pharmaceutical market players may justify a different approach to this process, but in this case, this market actor is obliged to document the equivalence of security standards, quality, and effectiveness of this process to the standard, set out in the recommendation (15 documents, as of August 2019).

Determining subordination and relationship of the Agreement on common principles and rules for the medicinal product circulation and the documents of the EEC on the formation of a common market for medicinal products.

Highlighting significant blocks of normative documents depending on the components defined by the authors as a consequence of logical generalization based on hierarchical and chronological analyses:

General requirements for medicinal products: conceptual framework, pharmacopeial regulation, control, and supervisory activities over the circulation of medicinal products, pharmacovigilance, pharmaceutical inspections, information databases on medicinal products;

Requirements for certain stages of the medicinal products' life cycle: preclinical and clinical research (testing) in the EAEU member states, registration and evaluation, production, sale, wholesale trade, transportation, and storage.

Identification of EEC documents on specific issues of medicinal product circulation (interchangeability, herbal medicinal products).

Results

The common market for medicinal products must meet the standards of good pharmaceutical practices, while its creation is based on the following principles [5-7]:

- harmonizing and unifying the requirements of the legislation of the EAEU member states in the medicinal product circulation;
- ensuring the unity of mandatory requirements for the quality, effectiveness, and safety of medicinal products being in circulation in the territory of the Union;
- developing and applying the same or comparable research and control methods when evaluating medicinal products;
- adopting uniform rules in the circulation of medicinal products;
- harmonizing the legislation of the EAEU member states in the field of control (supervision) in medicinal products circulation;
- implementing licensing, control, and supervisory functions by the relevant authorized bodies of the EAEU member states.

The common market of medicinal products has been functioning since January 1, 2016, according to an international treaty – the Agreement on common principles and rules for the circulation of medicinal products within the framework of the EAEU of December 23, 2014 (hereinafter – the Agreement).

At the end of 2016, the pharmaceutical market volume of the EAEU countries amounted to USD 17.2 billion. The vast majority (80-85%, depending on the exchange rate) of the common market belongs to Russia (USD 14.7 billion). The share of 7% (USD 1.3 billion) is held by Kazakhstan, 5% (USD 0.8 billion) – by Belarus, 2% (USD 0.3 billion) – by Kyrgyzstan, and 1% (USD 0.1 billion) – by Armenia [8].

To implement the Agreement, the EAEU member states determine the government bodies authorized to implement and/or coordinate activities in the medicinal product circulation, which conduct consultations aimed at coordinating provisions on regulatory issues.

The Eurasian Economic Commission (hereinafter referred to as the Commission) coordinates activities aimed at harmonizing the legislation of the EAEU member states and is the depositary of the EAEU [9, 10].

Decisions of the Commission are developed based on international norms, taking into account proposals sent by EAEU member states for the development of draft acts. The Commission has the right to make recommendations concerning the identification of optimal approaches, whose implementation will ensure compliance with the requirements.

The agreement on common principles and rules for the medicinal product circulation defines the basic guidelines, as well as relevant documents which must be developed and/or approved by the Commission.

The working team on the formation of common approaches to regulating the medicinal product circulation was established according to the decision of the Board of the Eurasian Economic Commission No. 204 of October 30, 2012. The decision of the EEC Council No. 75 of November 3, 2016, has approved the Regulation on the Expert Committee on medicinal products.

Employing the system analysis, the authors determined the subordination and identified the relationships of the top-level documents, i.e. the Agreement, and EEC documents of the various levels on the regulation of the common market of medicinal products.

In consequence of logical generalization based on hierarchical and chronological analyses, significant blocks of regulatory documents were formed depending on certain components of the medicinal product circulation, and individual issues of the pharmaceutical market dynamics.

The conceptual framework, pharmacopeial regulation, control and supervision, pharmacovigilance, pharmaceutical inspections, and information databases on medicinal products are identified by the authorities as general requirements for the medicinal product circulation (Tables 1-6).

Table 1: The conceptual framework for the medicinal product circulation within the EAEU

Agreement	Recommendations of the EEC Board
Definitions	
Information directory of concepts and definitions in medicinal products circulation – unified concepts and their definitions (Article 1)	Recommendation of the EEC Board No. 12 of May 2, 2017 "Information directory of concepts used within the framework of the EAEU on the medicinal product circulation " Recommendation of the EEC Board No. 10 of March 19, 2019, "Updated information directory of concepts used within the framework of the EAEU on medicinal products circulation"

Table 2: Pharmacopeial regulation within the EAEU

The harmonization of national pharmacopeias of the EAEU member states	
Agreement	**The decision of the EEC Other documents**
The concept of harmonization of state pharmacopeias of the EAEU member states using the international experience of harmonization of national pharmacopeial requirements (Art. 5)	The decision of the EEC Board No. 119 of 22.09. 2015 on "Concept of pharmacopeias harmonization of the EAEU member states"
Pharmacopoeia of the Union is a set of pharmacopoeial articles (general and particular) approved by the Pharmacopoeia Committee of the Union (Art. 5)	Draft contents of part 1 of volume 1 of the EAEU Pharmacopoeia
Operating procedure of the Pharmacopoeia Committee of the Union (Art. 5)	The decision of the EEC Board No. 121 of 22.09. 2015 on "Regulation on the Pharmacopoeia Committee of the EAEU"

Table 3: Pharmacovigilance in the framework of the EAEU

Pharmacovigilance	
Agreement	**The decision of the EEC**
Good practice of pharmacovigilance (Art. 12)	The EEC Council by its decision No. 87 of 03.11. 2016 has approved Rules of good practice of the EAEU pharmacovigilance
The procedure for exchanging information between the authorized bodies of the member states on detected adverse responses (reactions) to medicinal products, changes in the evaluation of the risk-benefit, and measures taken when risk prevails over benefit (Art. 12)	

Table 4: State control (supervision) over the circulation of medicinal products within the EAEU

State control (supervision) over the circulation of medicinal products	
Agreement	**The decision of the EEC Other documents**
Procedure for exercising the state control (supervision) over the circulation of medicinal products (Art. 13)	The member states exercise state control (supervision) over the circulation of medicinal products according to the procedure established by the legislation of the member states (national legislation)
Procedure for interacting of authorized bodies of the EAEU member states to identify falsified and/or counterfeit medicinal products (Art. 13)	The Council of the EEC by its decision No. 86 of 03.11. 2016 has approved the "Procedure for interacting of the EAEU member states to identify falsified, counterfeit, counterfeit and(or) substandard medicinal products"

Table 5: Pharmaceutical inspections: statutory regulation in the framework of the EAEU

Pharmaceutical inspections	
Agreement	**The decision of the EEC**
Rules for conducting pharmaceutical inspections by pharmaceutical inspectorates (Art. 10)	- The EEC Council by its decision No. 83 of 03.11. 2016 has adopted the regulation "On approval of the rules for conducting pharmaceutical inspections"; - The EEC Council by its decision No. 91 of 03.11. 2016 has adopted the regulation "On approval of the procedure for ensuring joint pharmaceutical inspections"
General requirements for the activities of pharmaceutical inspectorates (Art. 10)	- The EEC Council by its decision No. 82 of 03.11. 2016 has adopted the regulation "On approval of common requirements for the quality system of pharmaceutical inspectorates of the EAEU member states"
Procedure for maintaining the register of pharmaceutical inspectors of the EAEU (Art. 10)	The EEC Council by its decision No. 90 of 03.11. 2016 has adopted the regulation "On approval of the procedure for forming and maintaining the register of pharmaceutical inspectors of the EAEU"

Table 6: Information databases of medicinal products and information system in the framework of the EAEU

Information databases of medicinal products	Information system
Unified register of registered medicinal products of the EAEU with integrated information databases of instructions for medical use, graphic design of packages, and regulatory documents on quality (Arts. 8, 14) Unified information database of medicinal products that do not meet the quality requirements, as well as falsified and/or counterfeit medicinal products detected in the territories of the EAEU member states (Art. 14) Unified information database on detected adverse responses (reactions) on medicinal products, including reports on the inefficiency of medicinal products (Art. 14) Unified information database on suspended, withdrawn, and prohibited medicinal products (Art. 14) Rules for creating and functioning the information system of the EAEU on medicinal products circulation (Art. 15)	The EEC Council by its decision No. 84 of 03.11.2016 has adopted the regulation "On the formation and maintenance of the unified register of registered medicinal products of the EAEU and information databases on circulation of medicinal products, (including: - The procedure to form and maintain a unified information database of medicinal products that do not meet the quality requirements, as well as falsified and/or counterfeit medicinal products detected in the territories of the EAEU member states; - The procedure to form and maintain a unified information database on undesirable responses (reactions) on medicinal products, including reports on the inefficiency of medicinal products detected in the territories of the EAEU member states; - The procedure to form and maintain a unified information database on medicinal products with suspended registration certificates, withdrawn from the market, or prohibited for medical use in the territories of the EAEU member states)".

Regulatory requirements for certain stages of the medicinal product life cycle in the framework of the common market are generalized for preclinical and clinical research (trials), registration and evaluation, production, sale, wholesale trade, transportation, and storage. (Tables 7-10).

Table 7: Preclinical and clinical studies in the framework of the EAEU

Preclinical and clinical studies (examinations) in the EAEU member states	
Agreement	**The decisions of the EEC**
Rules of good laboratory practice (Art. 6)	The EEC Council by its decision No. 81 of 03.11. 2016 has approved the rules of good laboratory practice of the EAEU on circulation of medicinal products
Rules of good clinical practice (Art. 6)	The EEC Council by its decision No. 79 of 03.11. 2016 has approved the rules of good clinical practice in the framework of the EAEU;
Requirements for conducting research (tests) of medicinal products (Art 6)	- The EEC Council by its decision No. 85 of 03.11.2016 has approved the Rules for conducting bioequivalence studies of medicinal products in the framework of the EAEU; - The EEC Council by its decision No. 89 of 03.11.2016 has approved the Rules for researching biological medicinal products.
Recommendations of the EEC Board	
- Guidelines on general issues of clinical research (No. 11 of July 17, 2018); - Guidelines for selecting the dosage of the medicinal product (No. 8 of March 12, 2019); - Guidelines for assessing and controlling DNA-reactive (mutagenic) admixtures in medicinal products, and setting the boundaries of potential carcinogenic risk (No. 23 of August 6, 2019)	

Table 8: Registration and examination in the framework of the EAEU

Registration and examination	
Agreement	**The decisions of the EEC**
Rules of registration and examination of medicinal products, i.e. requirements for the structure, format, and content of the registration dossier, the structure, and content of evaluation report on the registration dossier, the form of the registration certificate of the medicinal product, the procedure of introducing changes into the registration dossier, the grounds for a refusal to register, revocation, suspension or termination of the registration certificate of the medicinal product (Art. 7)	- The EEC Council by its decision No. 78 of 03.11. 2016 has adopted "Rules for registration and examination of medicinal products for medical use" (Decision of the EEC Council No. 55 of 14.06. 2018, On amendments to The EEC Council by its decision No. 78 of 03.11. 2016) - The EEC Council by its decision No. 93 of 03.11.2016 has adopted the regulation "On the recognition of the results of the inspection of the production of medicinal products" - The EEC Board by its decision No. 69 of 10.05.2018 has approved the requirements for studying consistency research of medicinal products and pharmaceutical substances (* also applied in their production); - The EEC Board by its decision No. 151 of 07.09.2018 has approved "Guidelines for the preparation of a regulatory document on the quality of a medicinal product"; - The EEC Board by its decision No. 113 of July 17, 2018, has approved "Guidelines for validation of analytical methods for testing medicinal products"
Nomenclature of medicinal forms, i.e. registration and examination of medicinal products (Art. 7)	- The EEC Board by its decision No. 172 of 22.12. 2015 has approved the nomenclature of medicinal forms
Recommendations of the EEC Board:	

- Guidelines on the quality of medicinal products for inhalation and nasal preparations (No. 17 of September 7, 2018);
- Guidelines on the quality of medicinal products with the modified release for oral administration (No. 2 of January 16, 2019);
- Guidelines on the selection of trade names of medicinal products (No. 2 of April 23, 2019);
- Rules to compile group names of medicinal products (No. 13 of April 23, 2019);
- Guidelines on selecting the dosage of the medicinal product (No. 8 of March 12, 2019);
- Guidelines on assessing and controlling DNA-reactive (mutagenic) admixtures in medicinal products, and setting the boundaries of potential carcinogenic risk (No. 23 of August 6, 2019)

Table 9: The production of medicinal products: The statutory regulation in the framework of the EAEU

Production of the medicinal products	
Agreement	**The decisions of the EEC**
Rules of good manufacturing practice –production of medicinal products based on a permit (license) for the production of medicines issued according to the legislation of the EAEU member states (Art. 9)	- The EEC Council by its decision No. 77 of 03.11. 2016 has approved the rules of good manufacturing practice of the EAEU - The EEC Board by its decision No. 69 of 10.05.2018 has approved the requirements for stability studies of medicinal products and pharmaceutical substances (* are also applied for registration and examination)
Certification procedure of authorized persons of medicinal products manufacturers (Art. 9)	The EEC Council by its decision No. 73 of 03.11. 2016 has approved the "Certification procedure of authorized persons of medicinal products manufacturers"
Procedure to form and maintain the register of authorized persons of medicinal products manufacturers in the EAEU (Art. 9)	The EEC Council by its decision No. 74 of 03.11.2016 has approved the regulation "On forming and maintaining procedure of the register of authorized persons of medicinal products manufacturers in the EAEU"
Register of authorized persons of medicinal products manufacturers of the EAEU –certified authorized persons of medicinal products manufacturers (Art. 9)	Unified Register of authorized persons of medicinal products manufacturers of the EAEU www.eurasiancommission.org/ru/act/texnreg/
Recommendations of the EEC Board:	
- Guidelines for the medicinal products manufacturing validation (No. 19 of September 26, 2017) - Requirements for water used for pharmaceutical needs when producing medicinal products (No. 31 of December 13, 2017) - Guidelines for the production of ready-made medicinal products (No. 3 of January 29, 2019)	

Table 10: Sales, wholesale trade, transportation, and storage of medicinal products within the EAEU

Sales of medicinal products	
Agreement	**The decisions of the EEC**
Unified requirements for medicinal products labeling of (Art. 8)	The EEC Council by its decision No. 76 of 03.11. 2016 has approved the requirements for labeling of medicinal products for medical use, as well as veterinary medicines
Uniform requirements for instruction on the medical use of medicinal products (Art. 8)	The EEC Council by its decision No. 88 of 03.11. 2016 has approved the requirements for the instructions on the medical use of medicinal products, and the general characteristics of medicinal products
Other issues	
- The EEC Board by its decision No. 178 of 29.12. 2015 has approved the "Rules for determining categories of medicinal products, sold over the counter, and by medical prescription" (Recommendations of the EEC Board No. 30 of 29.12.2015, "Rules for the inclusion of medicinal products, taking into account active agents included in the composition, to the categories of medicinal products, sold over the counter, and by medical prescription")	

The analysis of the regulatory activities of the Eurasian Economic Commission allowed revealing documents on regulating private issues of medicinal product circulation within the common market.

The basis for determining the interchangeability of medicinal products is established by decision No. 92 of 03.11.2016, "On certain issues of medicinal products circulation", adopted by the EEC Council [11, 12].

The EEC Council by its decision No. 15 of 26 January 2018 has approved the "Rules of good practice for growing, collecting, processing, and storing raw materials of plant origin" (Good Agricultural and Collection Practice GACP). Recommendation of the EEC Board No. 6 of May 10, 2018, contains Guidelines on the quality of herbal medicinal products. Recommendation of the EEC Board No. 6 of 12 February 2019 provides Guidance on the selection of tests and eligibility criteria for the preparation of specifications for medicinal plant raw materials, herbal pharmaceutical substances (preparations based on medicinal plant raw materials), and medicinal plant preparations. Recommendation of the EEC Board No. 6 of August 6, 2019, contains "Guidelines for controlling the risks of microbial contamination of medicinal plant raw materials, herbal pharmaceutical substances (preparations based on medicinal plant raw materials), and medicinal plant preparations".

It is important to note that in 2018-2019, important decisions were made by the EEC Board regarding Reference books and Classifiers on circulation of medicinal products which were

included in the resources of the unified system of normative reference information of the EAEU:
Anatomic-therapeutic-chemical classifier of medicinal products (No. 50 of April 10, 2018);
The classifier of types of documents of a medicinal product registration case (No. 64 of April 24, 2018);
The classifier of types of changes in the registration dossier of a medicinal product (No. 65 of April 24, 2018);
Directory of international generic names of medicinal products (No. 71 of May 10, 2018);
List of production phases (stages) of medicinal products (No. 149 of September 7, 2018);
The classifier of measurement units of active substances dosage and concentration in the medicinal product composition (No. 150 of September 7, 2018);
The classifier of types of primary packaging of medicinal products (No. 5 of January 15, 2019);
The classifier of types of secondary (consumer) packages of medicinal products (No. 6 of January 15, 2019);
The classifier of medicinal plant raw materials (No. 59 of April 16, 2019);
Reference list of pharmaceutical aids (No. 95 of June 11, 2019);
Reference book of functional purposes of pharmaceutical aids (No. 103 of June 18, 2019).

Discussion

At the International science-to-practice conference "Examination and registration of medicinal products in the EAEU – RegLek EAEU 2018", the Scientific center for the examination of medical products of the Ministry of the Health of the Russian Federation has identified the most critical issues in the professional community: creating the Pharmacopoeia of the EAEU; bringing pharmacovigilance to the requirements of the EEU; providing the interchangeability of medicinal products; considering issues of completing, submitting and bringing dossiers for medicines registered under national procedures, into compliance with the requirements of the EEU; meeting current requirements for assessing impurities in medicinal products; conducting a benefit/risk assessment of the medicinal product application; addressing the main discrepancies in the registration dossier, detected during the inspection process.
Informatization is one of the most pressing issues related to the functioning of the single market for the medicinal product circulation within the EAEU [13].

Conclusion

The coordinated policy of the EAEU member states in the course of forming a common market, which takes into account the mutual interest in providing guarantees for people's life and health, allows ensuring access to safe, effective, and high-quality medicinal products, creating optimal conditions for developing the pharmaceutical industry, increasing the competitiveness of pharmaceutical products in the domestic and foreign markets, as well as eliminating unreasonable restrictions in mutual trade.

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