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Study of the Single Space of the Eurasian Economic Union: Legal Regulation of Circulation of Medicinal Products

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Abstract

The article above provides some facts about peculiarities of regulation of circulation of medicinal products on the territory of single economic space of the Eurasian Economic Union (EAEU). In 2014-2017, the agreements regulating the circulation of medicinal products on the territory of the member states came into force. Participants of the circulation of medicines must take into account the provisions of the regulatory control of the EAEU. However, a number of norms of international law are still not reflected in Russian laws. The purpose of this study is to analyze the complex of regulatory legal acts of the EAEU regulating the circulation of medicines and the perspectives for its development. The author gives an assessment of the work that has been done to harmonize the legislation of Russia and the EAEU. The analysis of problems of such harmonization in the sphere of legal regulation of medicines' circulation is given. The expediency of expansion of supranational structures in mechanisms of cooperation on development of the market of medicinal products is shown. Some measures to increase the positive dynamics in the market of medicines of the EAEU have been proposed.

Keywords: medicinal products, EAEU, regional integration, harmonization.

INTRODUCTION

Maintenance and improvement in human's health is one of the most important problems and tasks in the development of the society. Article 41 of the constitution of the Russian Federation ensures the right of every citizen to health protection, the implementation of which in modern conditions is practically impossible without the use of medicines (up to 90% of appointments of doctors are for medical therapy) [1]. Thus, the state faces the task of providing the population with quality and affordable medicines.

The use of medicines due to their social significance, danger to life or health of citizens also necessitates the state regulation of the circulation of medicinal products (production, trade, consumption). However, despite the ongoing harmonization of the legislation with the legislation of the World Trade Organization (WTO), in Russia and the EAEU, the Enforcement mechanism of legislative requirements for the circulation of medicines is not sufficiently effective [2].

In accordance with the provisions of the State report of Federal Supervision Agency for Customer Protection and Human Welfare, the number of violations detected in the sphere of circulation of medicinal products is very high [3]. In 2016, under the supervisory functions of Federal Supervision Agency for Customer Protection and Human Welfare, 7,243,018 packs of poor-quality and counterfeit drugs were withdrawn from the circulation and processed, 1,149,410 units of poor-quality, falsified and counterfeit medical devices were withdrawn, the circulation of 1,938 medicine lots that created risk of harm to life and health of citizens was stopped, which amounted to 0.81% of the total number of lots that went into circulation in 2016 (according to AIS (Automated Information System) of Federal Service for Supervision in Healthcare, 237,968 lots).

Today, the success of the implementation of the state policy of the Russian Federation in the field of protecting the health of citizens, especially in terms of providing the population with affordable and high-quality medicines, largely depends on the balanced combination of needs and tasks of national development with global trends at both the global and regional levels. This requires the development and implementation of a politically verified and scientifically sound integrated economic and legal strategy containing program implementation mechanisms, taking into account the imbalance of regional development and active interaction with the external economic environment.

Modern processes taking place in the global economic space, including the single space of the EAEU, place special emphasis on the analysis of the system of cross-country interaction, including certain areas of development of economic sectors. This statement can be fully attributed to the market of medicinal products. The issues of joint regulation of medicines' circulation within the framework of the EAEU haven't been widely reflected in the scientific literature yet. This subject is represented in research papers by A.P. Meshkovsky, V.N. Koreshkov, R.P. Shabrov, L.A. Reutskaya and some others. These works were performed before the regulatory legal acts of the EAEU regulating the circulation of medicinal products entered into force and had already lost their relevance. However, at present, the problems of regulating the circulation of medicinal products within the framework of the EAEU have not been fully resolved. In addition, it should be noted that the processes associated with the harmonization of national legislations within the framework of modern economic and political unions of states, such as the EU, the EAEU and others, determine the trends in the development of modern international economic and legal regulation. Enumerated factors determine the need for further research of the processes associated with such regulation and, accordingly, the relevance of this study.

Thus, the purpose of this study should be defined as the analysis of the process of harmonization of Russian legislation regulating the circulation of medicinal products with regulatory control within the framework of the EAEU and its current status.

METHODS

The systematic approach has been laid in the basis of the study of such categories as "circulation of medicinal products" and "single space of the EAEU" in their unity and interrelation. The fundamental premise of the systematic approach is the principle of multilevel construction of structural relationships, according to which ordering between levels in complex systems is carried out from the highest to the lowest. One of the main methods used in the presented work for getting relevant information was the expert survey method, the results of which had significant impact on the findings of the study. The survey was conducted in 2017 among 20 experts (senior positions in pharmaceutical associations, leading manufacturers of medicines and the largest network pharmacy companies in Russia, teachers of the medical university). Also, one of the most important methods of research was a comparative legal method, irreplaceable in the analysis of international practice, international

treaties, acts of international organizations, laws and subordinate acts of states on the use of transborder water resources. In order to formulate proposals on the legal regulation of the problems of regulating medicines' circulation, it became necessary to use special methods of jurisprudence: formal legal, normative-dogmatic and legal modeling methods.

RESULTS AND DISCUSSION

The main law affecting the circulation of medicines in the Russian Federation is the Federal Law of April 12, 2010 No. 61-FZ "On the circulation of medicines" [4]. In accordance with Article 1, the scope of this Law is the relations arising in connection with the development, production, manufacture, preclinical and clinical trial of medicines, the control of their quality, effectiveness, safety, trade of medicinal products and other activities in the sphere of circulation of medicinal products. In other words, the legislator identifies the following areas of medicines' circulation: development, production, preclinical and clinical trial, quality control, efficacy and safety, medicine trade [5].

Article 4 of the same Law contains the definition of the circulation of medicinal products. The circulation of medicinal products is understood as a generalized concept of activity, which includes the development, research, production, manufacture, storage, packaging, transportation, state registration, standardization and quality control, sale, labeling, advertising, use of medicines, removal of medicaments that have become unusable, or expired medicines and other actions in the sphere of circulation of medicinal products.

1. In 2010-s, the participation of the structures of the Russian pharmaceutical sector in the work of leading international organizations - WHO, ICH (The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) and the EAEU - was expanded. The sanctions imposed on Russia did not have negative impact on such cooperation, both at the global and interregional levels (https://www.ipls-russia.ru/en/News/IPLS2017/market-news/how-sanctions-impact/) [6]. Cooperation is especially active within the framework of the Eurasian Union.

In May 2014, the presidents of Russia, Belarus and Kazakhstan signed the Treaty on the EAEU, which provided, among other things, the creation of a single market of medicinal products by January 1, 2016 (Articles 30, 31) (http://www.consultant.ru/document/Cons_doc_LAW_163855/) [7]. At the end of 2014, the Unified Principles and Rules for the circulation of medicines were agreed (http://www.consultant.ru/document/cons_doc_LAW_172765/) [8]. In these documents the provision has been made for the formation of common markets for medicinal products and medical devices and the development of a set of documents ensuring the operation of the registration systems for medicines and medical devices at the level of the EAEU, providing in the field of medicines 25 documents establishing uniform rules for proper production, clinical, distribution and laboratory practice of the EAEU, the safety requirements, the efficacy and quality of medicines, the registration against these rules and the procedure for postregistration control (monitoring) [9].

The Unified Register of Registered Medicines of the EAEU was established within the framework of the EAEU, with data base of instructions on medical use, graphic design (design) of packages and quality documents (2016) integrated into it (ttp://www.consultant.ru/document/cons_doc_LAW_207355/) [10]. The studies were conducted in accordance with the rules of good laboratory practice, the rules of good clinical practice and the requirements for medicine testing (tests), which were also approved by the Economic Commission for Europe. In addition, the pharmaceutical market of the EAEU made provisions for changes in pharmacovigilance, pharmaceutical inspections, labeling, production, wholesale trade, transportation and storage of medicinal products [11]. At the beginning of 2016, only the general vector of development was outlined in Agreement on Unified Principles of the EAEU. The main provisions were defined in the acts of the second level, which were adopted during 2016-2017.

In order to understand the further development of the pharmaceutical market of the EAEU, we will carry out an analysis of the second-level acts, in which the ideas embodied in the Agreement on Unified Principles of the EAEU have been more specifically implemented. With this in view, since the end of 2014, an extremely active development of projects on the approximation of standards and methods necessary for the effective regulation of medicines' circulation within the framework of the EAEU had been carried out. At the same time, participants of the harmonization process were guided by the best international norms and practices. The ICH or EU guidelines were used as the basis for the standards being developed; in some cases, WHO, OECD (Organisation for Economic Cooperation and Development) and PIC/S (Pharmaceutical Inspection Cooperation Scheme) materials had been used or taken into account, as well as the relevant provisions of the European Directive 2001/83/EC [12]. The work on harmonization, carried out within the framework of the EAEU, corresponded to both the course of Russian strategic documents for subregional cooperation and the recommendations of WHO. It is important to note that, in the opinion of the participants of the process, the agreed norms and rules can be used to improve the national regulatory systems of the EAEU member states. In this way, more than 20 normative and methodological documents were drafted, including provisions on the Expert Committee of the EAEU for Medicinal products, Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), Good Clinical Practice (GCP), Good Laboratory Practice (GLP), as well as instructional and methodological materials on pharmacovigilance and nomenclature of dosage forms. Projects were also developed on the procedure of registration and examination of medicines, activities of Pharmacopoeia Committee of the EAEU, interaction in such areas as combating counterfeit drugs, inspecting enterprises, attesting authorized officers, and establishing a single register of authorized officers. In total, taking into account different versions of the draft of particular documents and feedback from several experts or organizations, there was a large number of working materials with a total volume of more than a thousand pages for each prepared text. The development and discussion of projects was carried out by a large team of experts from three countries - Russia, Belarus and Kazakhstan. Russian associations of pharmaceutical manufacturers (National Association of Manufacturers of Pharmaceutical and Medical Products "APF", Association of International Pharmaceutical Manufacturers (AIPM), Union of Professional Pharmaceutical Organizations (SPPO), etc.), individual manufacturers (Microgen, Biocad, Geropharm, etc.), state structures (FSBI Scientific Centre for Expert Evaluation of Medicinal Products) and independent experts actively participated in the process of harmonization [13]. In the course of these works, Russian experts have expressed their regrets about missing the right moment for the development of norms, rules, regulations and provisions that are absolutely necessary for the effective regulation of medicines' circulation at the current level and the inadmissibility of the fact that the Russian control and permitting system has been working for two decades, not having the majority of these documents [14]. At the same time, it should be understood that harmonization of pharmaceutical legislation is not an easy process, which is due to the different level of its development in the member states and the legal positions of countries on a number of key issues. As it has

been repeatedly noted by the representatives of the Ministry of Health of Russia, amendments to the Law on the circulation of medicines were prepared taking into account changes at the level of the EAEU. For example, in accordance with the requirements of the Agreement on Unified Principles of the EAEU, Russian legislation established the responsibility of holders of registration certificates within the framework of pharmacovigilance. The provisions on the registration of medicinal products also correspond to those already laid down in the Agreement on Unified Principles of the EAEU (for example, a list of medicines that are not subject to registration).

It should also be noted that a number of amendments were adopted in law No. 61-FZ in 2016, taking into account the documents of the European Economic Community (EEC) Council, but work in this direction is still far from being completed. In 2017, a number of amendments were also made to Law No. 61-FZ, however, these amendments should hardly be directly attributed to the ongoing harmonization. Obviously, it will take more than one year to make Russian legislation consistent with the EEC decisions that have already been adopted. More than 50% of the respondents agreed with this statement.

It should be noted that experts in the market of medicines do not express clear attitude to an independent set of legal norms regulating the circulation of medicinal products and also to the list and legal content of special legal principles of such regulation. Only 50% of the respondents to the expert poll, conducted by the research center of Deloitte in 2017, refer to the improvement of the legislation on medicines within the framework of the EAEU as one that is among the priority directions (https://www2.deloitte.com/content/dam/Deloitte/ru/Documents/life-sciences-health-care/russian/russian-pharmaceutical-market-trends-2017-ru.pdf) [15].

On May 6, 2017, after the ratification of the regulatory framework for the regulation of circulation of medicinal products in the Union by the EAEU countries, a package of 26 documents, prepared by the Commission together with the member states, entered into force, including 21 decisions of the EEC Council, 4 decisions and 1 recommendation of the EEC Board. The mentioned documents were accepted during 2014, 2015, 2016. (The last one at the moment is the Recommendation of the Board of the Eurasian Economic Commission of 02.05.2017 No. 12 "On the resource book of the notions used within the Framework of the Eurasian Economic Union in the sphere of circulation of medicinal products" (http://www.consultant.ru/document/cons_doc_LAW_216289/) [16]).

"National markets for the medicines' circulation of the 5 states of the EAEU are united and begin to work in the format of a single space. Manufacturers of the Union members will be able to apply for registration of medicinal products and issuing them in circulation on uniform procedures and reduce administrative costs (http://www.eurasiancommission.org/ru/nae/news/Pages/5-05-2017.aspx) [17]».

For an ordinary consumer, the changes in the pharmaceutical market will be visible already in the first half of 2018 and will result in a slight decrease in prices: this period is due to the fact that it takes from 7 to 10 months since the moment of filing a medicine file for registration until its availability in the market.

Development, preclinical and clinical trial, quality control, registration, production and distribution of medicinal products will be carried out in accordance with supranational norms of the single market. This regulation is aimed at removing administrative barriers in the field of manufacturing and admission of medicines to the markets of the countries of the Union. In addition, it will facilitate the removal of medicines that do not meet safety standards and good manufacturing practices from circulation. This is the opinion of at least 60% of the respondents.

At the level of national regulation, the issues of managing of a permit for preclinical and clinical trial of medicines are left; as well as price formation of medicines and medical devices; retail; public procurement of medicines and other procedures related to issues of cost recovery in the field of drugcommerce; regulation of medical advertising, which is also appropriate, according to 66% of the respondents.

A transitional period is planned, ensuring smooth transition from national to unified regulation. This will prevent disruptions in the health care systems of the EAEU countries and help manufacturers of medicinal products to adapt to new requirements as comfortably as possible. In particular, until December 31, 2020, a manufacturer has the right to choose which rules to follow (national or uniform) while registering medicines. All medicines that have been registered under national regulations before December 31, 2020, must be reregistered under the rules of the single market until December 31, 2025. When submitting a product file for drug registration until December 31, 2018, a manufacturer is entitled to provide national documents issued by the member states of the Union and confirming the compliance of its production with the requirements of the national GMP rules instead of the EAEU GMP certificate

With overall positive development dynamics of the EAEU regulation, a number of problems remain that hamper the development of regional economic integration in the post-Soviet space, including the sphere of circulation of medicinal products. And the countries of the Eurasian Union will have yet to overcome them in order to build a solid, stable economic organization that will strengthen its influence on the world arena as well [18].

One of these problems is the lack of political will of the highest-level leaders of the member states of the EAEU to build supranational bodies. This is one of the most important reasons for the inefficiency of the regional integration of the Eurasian region [19]. Organizational structures operating on the grounds of international law do not correspond to the main goals of creating developed forms of regional integration associations [20]. Permanent supranational bodies seem to be best able to perform the functions of harmonization and legal control of the regulatory and legal acts of the EAEU, including the sphere of regulation of medicines' circulation.

CONCLUSIONS

Summing up the present work, it seems appropriate to propose a number of measures aimed at increase of the dynamics of the medicine market common for the member countries of the EAEU and overcoming administrative barriers:

- creation of a unified official information web source on investment, infrastructure, industrial and innovative national and joint projects located at various stages of implementation, as well as enterprises, consortiums, holdings of manufacturers and sellers of medicine.
- study of the need to create a support system for entrepreneurship and innovation within the framework of the EAEU, similar to the system operating in the European Union - Enterprise Europe Network (EEN) (https://een.ec.europa.eu/about/about);
- formation of an official resource for informing consumers of member states about medicinal products produced on the territory of member states to increase consumer demand;
- development of joint forecasts of supply and demand of member states for the basic types of pharmaceutical products;

- monitoring of the situation with price formation in the market of member states in case of a combination of high concentration of production and the presence of companies from third countries, that may indicate the possibility of monopolistic overpricing;
- holding meetings of joint working groups, congress and exhibition events, specialized fairs in order to promote the strengthening of economic ties between administrative and territorial entities (units) of member states, including those sharing a common border;
- information exchange and taking measures to adapt the best experience of member states in other member states.

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