UDC 346.7
DOI https://doi.org/10.32837/chern.v0i4.129

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SPECIFICS OF PHARMACEUTICAL MARKET DEVELOPMENT IN UKRAINE

The paper analyses legal regulation of the pharmaceutical market in Ukraine. It outlines areas of concern that affect the pharmaceutical market and reasons for slow growth of economic activities in a respective field. The paper indicates the importance of creating conditions for sustainable development of the pharmaceutical market. Studying the domain of legal regulation of the domestic pharmaceutical market, the authors have analyzed the policies conducted in the sector of circulation of medicines. Thus, the main objective of state policy in regulating the pharmaceutical market is to create conditions for the public to exercise its right to affordable and quality healthcare provision.

The authors have established that the state strategy of implementing a policy of provision the public with medicines does not fully meet current global standards and requirements due to the fact that implementation of far-reaching development plans for the relevant industry is not carried out in all areas, there is no proper monitoring of relevant legislation implementation, the system of bringing regulations into line with legal subordination is not used properly.

Current legislation regarding turnover of pharmaceutical products has got a lot of controversies and omissions related to social-political and economic transformations, which are constantly taking place in global politics as well as in the country.

In order to find ways to improve legal regulation of the circulation of medicines, the authors have analyzed international legal standards for circulation of medicines, which proves the effectiveness of European legislation in this area.

As a general conclusion, it should be noted that the main features of legal regulation of the pharmaceutical market in Ukraine is that its regulation is conceptual in nature, aimed at ensuring specific rights and freedoms of citizens, but requires improvements through implementing EU standards in national legislation.

Moreover, legal regulation of the circulation of medicines in Ukraine is carried out through the use of a set of legal instruments and arrangement of social relations that arise in the process of manufacture, storage and sale of medical products.

Key words: medicines, market of medicines circulation, normative-legal regulation, state policy.

Кулак Н. В., Шевченко О. А., Шевченко Т. О. **ОСОБЛИВОСТІ РОЗВИТКУ РИНКУ ОБІГУ ЛІКАРСЬКИХ ЗАСОБІВ В УКРАЇНІ**

Статтю присвячено аналізу нормативно-правового регулювання ринку обігу лікарських засобів в Україні. Визначено проблемні аспекти, що мають негативний вплив на ринок обігу лікарських засобів та є причинами гальмування росту господарської діяльності у відповідній сфері. Вказано важливе значення розвитку ринку ліків для економіки країни та забезпечення інтересів суспільства у сфері захисту здоров'я. У ході наукового дослідження сфери нормативно-правового регулювання вітчизняного ринку обігу лікарських засобів автори здійснили аналіз політики, що проводиться державними установами у сфері обігу лікарських засобів. Акцентовано увагу на необхідність застосування кардинальних державних заходів створення сприятливих умов для формування ринку обігу лікарських засобів. З'ясовано, що головною метою державної політики у сфері регулювання ринку обігу лікарських засобів є створення умов для реалізації прав громадян на охорону здоров'я та розширення національного ринку медичних препаратів.

Авторами було доведено, що державна стратегія реалізації політики забезпечення населення доступними лікарськими засобами не в повному обсязі відповідає сучасним світовим стандартам та вимогам у зв'язку з тим, що реалізація перспективних планів розвитку відповідної галузі здійснюється не за всіма напрямами, а нормативно-правова база фармацевтичного законодавства містить широке коло неврегульованих питань.

З метою пошуку шляхів удосконалення нормативно-правового регулювання ринку обігу лікарських засобів авторами було проведено аналіз міжнародних правових стандартів сфери обігу лікарських засобів. З'ясовані

умови, що сприяють динамічному розвитку ринку обігу лікарських засобів у розвинутих країнах світу. Визначено характерні рисами нормативно-правового регулювання ринку обігу лікарських засобів в Україні. Дана характеристика тенденцій розвитку нормативної регламентації ринку обігу лікарських засобів.

Сформовано перелік пріоритетних завдань та дій, які сприятимуть конструктивному розвитку нормативно-правового регулювання ринку обігу лікарських засобів в Україні.

Ключові слова: лікарські засоби, ринок обігу лікарських засобів, нормативно-правове регулювання, державна політика.

Introduction. The domestic pharmaceutical market belongs to the segment of relatively low income countries which impacts the purchasing power. Furthermore, medicines of domestic manufacture are inferior in terms of price and quality as compared to their European analogues. This situation can also be explained by the fact that European manufacturers offer innovative drugs that Ukrainian manufacturers cannot afford due to high research costs. All stages of a strategic innovation process are very labor-intensive, require significant investments, are long-drawn-out and come with a large number of risks. Thus, only 40% of innovative drugs succeed in clinical trials, and less than 10% of them enter the market, 50% do not justify their cost and do not pay off, and only a third becomes profitable.

However, developed countries invest money into innovations. Export of medicines is a significant part of export of products with high added-value for developed countries. Export amounts in developed countries are in billions of dollars, while Ukraine exports medicines to the amount of no more than USD 251 million a year. Markets of developed countries have programs to support their own manufacturers, strict requirements for production and registration of medicines, other non-tariff barriers, which makes Ukrainian manufacturers unable to withstand competition.

Thus, the future of pharmaceutical market highly depends on the country's regulatory position.

Problem statement. Production and sale of pharmaceutical products is an economically attractive field. Pharmaceutical products play an important role in the healthcare system. The right to healthcare of the citizens is provided for by the Constitution of Ukraine. Proper legal regulation of the field of turnover of pharmaceutical products is an important factor in issues of provision of the citizens' health. In conditions of implementation of the healthcare reform in Ukraine, the issue of legal regulation of the field of turnover of pharmaceutical products is an urgent one.

Today a social community pays more and more attention to theoretical and practical issues related to creation, production, quality control, transportation, export, import and sale of pharmaceutical products in Ukraine. Such attention is driven by the fact that legal regulation of the turnover of pharmaceutical products in the country is on quite a low level and requires complex, substantial examination and the legislative improvement.

Objective. To make analysis of the condition of turnover of pharmaceutical products in Ukraine. To highlight the trends in legal regulation of the pharmaceutical market. To find the problematic issues of legal provision for the turnover of pharmaceutical products in Ukraine.

Analysis of recent research and publications. The issue of legal regulation of the turnover of pharmaceutical products has been analyzed in works of A. Volkov, B. Hromovyk, N. Hutorova, A. Kotvytska, A. Nemchenko, O. Parovyshnyk, V. Pashkov, M. Ponomarenko.

Problems previously unsolved. Current legislation regarding turnover of pharmaceutical products has got a lot of controversies and omissions related to social-political and economic transformations, which are constantly taking place in global politics as well as in the country. The process of timely updating of the legal base is done not to the fullest extent, and it results in omissions in the legal provision for the turnover of pharmaceutical products and decreases the citizens' quality of life. There is necessity for a research into the existing problems.

Presentation of basic material. The domestic pharmaceutical market belongs to the segment of relatively low income countries which impacts the purchasing power. Furthermore, medicines of domestic manufacture are inferior in terms of price and quality as compared to their European analogues. This situation can also be explained by the fact that European manufacturers offer innovative drugs that Ukrainian manufacturers cannot afford due to high research costs. All stages of a strategic innovation process are very labor-intensive, require significant investments, are long-drawn-out and come with a large number of risks. Thus, only 40% of innovative drugs succeed in clinical trials, and less than 10% of them enter the market, 50% do not justify their cost and do not pay off, and only a third becomes profitable.

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The analysis done on the field of legal regulation of the turnover of pharmaceutical products in Ukraine made it possible to define that the system of legal provisions, which regulate the domestic market of medicines, at the same time create conditions for enforcement of the citizens' right to affordable and qualitative provision with pharmaceutical products.

The Constitution of Ukraine is the main source and is the basis for laws and regulations, which govern social relations of the field of turnover of pharmaceutical products. Constitutional provisions make the legal basis for the turnover of pharmaceutical products. It includes securing of not just the relevant right but also the means of its enforcement, which the state has at its disposal and which are built into political and economic systems and also its social basis [1].

The citizens' right to life, medical aid and healthcare is a constitutional one. Analyzing contents of the legislative acts, which form the legal and regulatory basis of the pharmaceutical field, we make a conclusion that the principle of supremacy of constitutional provisions is in general observed during development and approval of main legislative acts of the field. The law of Ukraine "On Medicinal Products" confirms responsibility of the state to make the most demanded pharmaceutical products available, to protect the citizens in case their health is damaged as a result of use of pharmaceutical products according to medical use and also provision of benefits and guarantees to separate groups of population and categories of citizens concerning their provision with medicinal products in case of disease [2]. Also, the law confirms the right to healthcare, secures guarantees on the part of the state for financing of the guaranteed amount of medical services and pharmaceutical products for the citizens, describes special aspects of use of pharmaceutical products.

The law "On Narcotic Drugs, Psychotropic Substances and Precursors" is aimed at regulation of social relations arising during the turnover of (narcotic) controlled substances.

The concept of development of the pharmaceutical sector in Ukraine (2011–2022) defines the prospects and tasks of the pharmaceutical field and is aimed at creation of the relevant legal and regulation basis, which governs the pharmaceutical activity [3]. Confirms the fact that the valid system of state regulation in the field of turnover of pharmaceutical products does not meet current requirements, since enforcement of legislation of Ukraine is done not in all directions and monitoring is not systematic. Such system requires improvement through harmonization of the legislation of Ukraine with legislation of the European Union (EU) and the World Health Organization (WHO).

Legislation of the European Union is an independent legal system, which has a priority over provisions of the national legislation of the Member States. The European legislation, which regulates turnover of the pharmaceutical products, is mainly based on directives of the European Union Council (namely on the Directive 2001/83/EC of the European Parliament and Council of the European Union dated November 6, 2001 "On the Community Code Related to Medicinal Products for Human Use" [4].

The regulations have a general character and concern the systems and structures but not separate individuals and legal entities. All elements of the regulations are obligatory for execution. The regulations are applied in each country, they are automatically transferred into the national legislation and enter into force simultaneously in all countries of the European Union.

Thus, article 12 of Directive of the European Union Council "On laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency" (EEC) defines special aspects of authorization and supervision of the medicinal products and determines that a notification about issue of the trade license (in Ukraine – the registration certificate) is subject to obligatory publication in the "Official journal of the European Communities", in which, in particular, the date of issue of the license and the number according to the register of the European Union shall be stated.

Directives of the European Union bind every country to achieve the goals stated in the document but reserve for governments of the countries of the European Union the absolute right to choose the form and means of their achievement. Directives are the main mechanism for creation of a single market. The European legislation, which regulates the turnover of pharmaceutical products, is mainly formed using the Directives of the European Union Council. The following directives of the European Union are the main ones: "On approximation of the legislative provisions, rules and administrative measures concerning medicinal products" [6], which defines the concept of medicinal products as any substance or combination of substances intended for treatment or prevention of the disease;

"The Falsified Medicines Directive (FMD)" [7], "On determination of categories of the medicinal products for human use" [8], "The Community Code related to medicinal products for human use and also the state and international standards on good manufacturing, clinical and laboratory practices" [9], "On approximation of laws, by-laws and administrative provisions of the Member States concerning imple-

mentation of good clinical practice in clinical trials of the pharmaceutical products for human use" [10], "On approximation of laws, by-laws and administrative provisions concerning application of principles of good laboratory practice and control of their application in trials for detection of chemical substances (codified revision)" [11].

Ukraine is not a member of the EC, so it has no right to apply the norms of the EC without previous introduction of them into the national legislation. The legislator implements measures for adaptation of the Ukrainian and European legislations according to provisions of the Association Agreement between Ukraine and the European Union.

Conclusions. Legal regulation of the turnover of medicinal products in Ukraine is done through application of a number of legal measures and regulation of social relations arising during turnover of the pharmaceutical products and groups of goods common with them. Main features of legal regulation of the turnover of medicinal products in Ukraine is that it is done by the state, is of a regulatory character, aimed at provision of specific rights and freedoms of citizens, regulation of social relations in relevant social-economic fields and that it requires improvement through implementation of the EU standards into national legislation.

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