SPER Publications and Solutions Pvt. Ltd.

Original Article

Legal regulation of the EU pharmaceutical market and the possibility of implementing the European experience in Ukraine

Ruslan S. Fyl[1], Svitlana P. Fyl[2]*, Iryna V. Alekseenko[3], Maryna P. Kobets[4], Iryna H. Lubenets[5]

[1] Research Laboratory for Forensic and Specialist Technique, State Research Institute of the Ministry of Internal Affairs of Ukraine, [2] Scientific-Organizational Department, State Research Institute of the Ministry of Internal Affairs of Ukraine, [3] Department of International Relations and Tourism, Faculty of Social Psychological Education and Management, Dnipropetrovsk State University of Internal Affairs, [4] Department of Scientific Information, Editorial and Publishing Activities, State Research Institute of the Ministry of Internal Affairs of Ukraine, [5] Research Laboratory of Criminological Research and Problems Crime Prevention, State Research Institute of the Ministry of Internal Affairs of Ukraine.

Correspondence: Svitlana P. Fyl, 4a, Y. Gutsalo Lane, Kyiv, 01011, Ukraine. E-mail: 1981phd@gmail.com.

ABSTRACT

The study deals with the analysis of the EU legislation provisions in the field of pharmaceutical market regulation. The main focus is laid on the analysis of the provisions of the EU founding acts as well as of the secondary legislation. The features of the legal regulation of the EU pharmaceutical market are distinguished based on the analysis of Directive 2001/83 provisions, including for the purpose of implementing certain legal regulation mechanisms in the legislation of Ukraine. A special focus is made on the study of EU pricing instruments in the pharmaceutical sector. In particular, the mechanisms of regulating the price of pharmaceuticals by means of reverse payments are studied. The procedure for admission of pharmaceuticals to the EU market is addressed, and other mechanisms of non-price regulation of the pharmaceutical sector are explored. The necessity to implement the EU experience in the field of pharmaceutical market regulation into Ukrainian legislation has been proved, taking into account the interests of national manufacturers. The principles and the key foundations of combining the objectives are revealed for providing the EU citizens with high-quality and affordable medicines while protecting European pharmaceutical manufacturers and enhancing their competitive advantages through state regulation over the non-European manufacturers. Such findings demonstrate the need to integrate the abovementioned objectives in order to achieve the goal of ensuring the development of the Ukrainian pharmaceutical market.

Keywords: state regulation, pharmaceutical market, secondary EU legislation, EU law, implementation of EU law

Introduction

The development of the EU pharmaceutical industry is closely linked to two systems of regulators: the system of economic regulators and the system of state-legal regulators. Considering the pharmaceutical market as a solely economic category, we agree that its functioning fully complies with the principles of the market economy, free competition, and freedom of choice of forms in the way of conducting business. However, we also agree that this market is subject to state regulation, which necessitates the subordination of all economic processes to certain rules that are uniform throughout the EU. Such rules are shaped by a system of organizational and legal support, which includes legal, institutional, organizational, and other mechanisms of governmental influence on the functioning of the pharmaceutical market. Legal and regulatory support has an objectively leading place since it defines the basic principles of the economic activity of all its participants, as well as all the forms of such an activity, from the development of medicines and ending up with their sale. Considering Ukraine's European integration aspirations, it is quite reasonable to look into the most powerful legal regulation methods of the analyzed market

Access this article online	
Website: www.japer.in	**E-ISSN:** 2249-3379

How to cite this article: Ruslan S. Fyl, Svitlana P. Fyl, Iryna V. Alekseenko, Maryna P. Kobets, Iryna H. Lubenets. Legal regulation of the EU pharmaceutical market and the possibility of implementing the European experience in Ukraine. J Adv Pharm Edu Res 2019;9(4):1-8.
Source of Support: Nil, Conflict of Interest: None declared.

within the EU in order to further implement them in Ukrainian legislation.

Thus, the purpose of this study, apart from analyzing the EU legislation on the pharmaceutical market regulation, is to identify its most essential regulators for the purposes of national legislation in Ukraine. To achieve these goals, it is necessary to:

- analyze the EU legislation on fixed assets and vectors of legal regulation of the EU pharmaceutical market;
- identify the most effective mechanisms for the legal regulation of the pan-European market for medicines;
- define the specific instruments of legal regulation of the pharmaceutical market that are feasible for implementation in the national legislation of Ukraine.

Materials and Methods

The principal materials underpinning this study are based are the EU legal acts such as the EU Establishment Agreement and the EU Functioning Agreement, as well as EU Directive 89/105;[1] EU Directive 2001/83;[2] EU Directive 65/65;[3] as well as EU Council Regulations. At the core of the research lies the work of leading experts in the field of EU pharmaceutical law, both European and Ukrainian. Thus, of the utmost importance are the works, which are devoted to the main aspects of state regulation.[4, 5] Some scholarly contributions are devoted to the analysis of the EU pricing policy.[6, 7] The work[8] addresses the regulation features of such components as the release and distribution in the pharmaceutical market.

A thorough study of the legal regulation problem of the EU pharmaceutical market from the standpoint of the possibility to implement some of its provisions in the Ukrainian legislation was carried out in the scholarly works.[9-13]

In order to accomplish the goal of this research and to more comprehensively study the underpinning material base, a synthesis of various scientific methods was used. Of particular importance are the following methods: system analysis, dialectics and synthesis methods, which were gradually providing insight into the legal regulations of the EU pharmaceutical market. First analyzing the EU Directives and then examining the provisions of the EU Regulations, the main tools and instruments for state regulation of pharmaceutical market development were identified. The formal logical method and the structural analysis tools revealed major weaknesses in the legal regulation of the EU pharmaceutical market, as well as the issues of addressing the means of regulating the pharmaceutical segment in Ukraine. Overall, it was the combination of several research methods that gave insight into the main content of EU policy in the field of regulating the EU pharmaceutical market.

Results

Legal regulation of the pharmaceutical market in the EU, likewise any other market, has a threefold nature, which is explained by the complex character of building socio-economic relations. The threefold nature is explained by the existence of the founding legal acts, which are the basis of EU law; the presence of the legal and regulatory acts of the EU institutions; and the availability of the national legislation of the EU member states.

Another starting point for analyzing the legal foundations of regulating the EU pharmaceutical market is the understanding that the EU goals include ensuring a free, integrated and at that a secure market, including in the field of the pharmaceutical industry, and ensuring a high standard of healthcare by means of new, advanced, effective and maximally efficacious medicines, which is not always possible only at the expense of the EU inner expertise.

For instance, Article 2 of the Treaty establishing the European Community claims that "The Community's task is to promote a harmonious, balanced and consistent development of economic activity, a high employment level by introducing a common market, an economic and monetary union, and by pursuing throughout the Community the common policies as well as the social protection and equality between women and men, the stable and non-inflationary growth, the high level of competitiveness and convergence of economic indicators, high level of protecting and improving the environment, raising the level and enhancing the quality of life, economic and social cohesion and solidarity among the member states".[14] However, part 4 of Art. 152 of the Treaty establishing the European Community sets out that the EU Council envisages one of its main objectives in the implementation of the pan-European policy aimed at achieving the goals of high-level health care, medical and pharmaceutical standards, high quality of life of the EU citizens, for which purpose it directs its activities to the adoption of the common European legal acts and the harmonization of national laws.[14]

"The legal structure of the EU internal market encompasses, in addition to the interests of this market specifically, other legal interests, including those that underpin national health care systems. On the other hand, health care interests may ultimately be more clearly articulated through the interests of the EU internal market. Consequently, the EU internal market law and health care law will mostly act as the so-called "mutual enhancers" and, as regards the EU pharmaceutical law, it is an integral product of these industries in the EU law system".[12] In other words, speaking of the pharmaceutical law as a separate area of the EU law is inappropriate, and therefore the analysis of "the secondary EU legislation" in the field of pharmaceutical market regulation should be narrowed to the analysis of the EU Council Directives and the EU Council Recommendations governing three separate aspects of any market: production process, placing products on the market and/or market access, overseeing the overall pharmaceutical activity by the EU member states and the EU institutions.

The key position in this framework is taken by Directive 65/65 of January 26, 1965, under the title "On the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products". This

Directive belongs to the class of legal acts, which provide for the state regulation of the pharmaceutical market. Pursuant to Article 3 of this Directive, it is required that no pharmaceutical product can be marketed within the community/region/country without the prior authorization of the competent authority of at least one member state. It is noted that a medicinal product manufactured in an EU member state is defined as "any ready-prepared medicinal product marketed under a special name and in a special pack".[3] Another important document is Directive 2001/83 of November 6, 2001 "On the Community code relating to medicinal products for human use", according to which "the production, distribution and use of medicinal products must be to safeguard public health. However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community".[2] This Directive regulates both the manufacturing and marketing procedures of placing pharmaceuticals on the EU market. It is specification is carried out through the regulatory mechanisms of the EU Council Regulations as follows:

No. 726/2004 setting out the authorization and surveillance procedures for medicinal and veterinary medicinal products № 726/2004;[15]

No. 1901/2006, which regulates relations concerning the production and distribution of pharmaceutical and medicinal products for pediatric purposes;[16]

No. 1394/2007, which regulates relations concerning the placement of medicinal products used for therapeutic purposes.[17]

An important document in the system of the EU legal acts in the field of the pharmaceutical market is Council Directive No. 98/34/EC, which lays down a procedure for the provision of information in the field of technical standards and regulations, as well as the rules on the information society services. This Directive sets out the list of the EU institutions in the field of standardization and certification of medicinal products and defines national standards and rules for correlating the medicinal products.[18]

An important aspect of the EU regulation of the pharmaceutical market is pricing regulation. In this context, authors[19] note that "pricing regulation in this sector of economy aims at eliminating the price competition between pharmacies by setting uniform retail prices, which causes them to increase the service level, to diversify the product range. However, the pharmaceutical pricing in the EU countries is mainly regulated at the national level". A comprehensive analysis of the EU legal acts shows that in most EU member states, the pharmaceutical pricing is based on the compulsory co-financing of their costs through compulsory or voluntary health insurance.

But despite the limitations of legal regulation of pricing by means of pan-European nature, it is still necessary to draw attention to the presence of a large number of court rulings which have shaped a certain demand and a certain legal regime in regulating the most controversial aspects of the tariff system and setting prices for pharmaceutical products.[20-22] The case law has demonstrated the need to adopt a number of legal acts of the EU Council. For example, Directive 89/195, "which lays down the procedure by which the decisions must be made by the authorities within a specific timeframe of 90 days after receiving the relevant information and negative decisions must be communicated to the applicant and contain a statement of reasons based on objective and verifiable criteria".[12] Besides, the due attention should be paid to the provisions of Directive 89/105 on the transparency of measures established by EU countries to control the pricing of medicinal products for human use and their inclusion in the scope of public health insurance systems. In particular, this Directive specifies that member states have adopted economic measures to market medicinal products in order to manage the consumption of medicines, regulate their prices or establish the conditions of their public funding. These measures include either direct or indirect control of the prices of medicinal products as a result of the inadequacy or absence of competition in the pharmaceutical market and the restriction on the range of products covered by national health insurance systems. Such measures mainly aim at promoting public health by ensuring the availability of an adequate supply of medicinal products at a reasonable cost. However, these measures should also be aimed at improving the efficiency in the manufacturing of medicinal products and encouraging the research and development of new medicines.[1]

In addition to Directive 2001/83, the regulation of certain aspects of pharmaceutical manufacturing in the EU is also addressed by specific legal acts such as:

Directive 2001/20/EC of the Council of the European Union "On the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use", which lays down the relationship between clinical trials of medicinal products and clinical practice, with the exception of studies that exclude interference into the human body. The main objective of this Directive was to systematize the legal rules to safeguard and protect the rights of patients who are participating in clinical trials. But subsequently, there was a need to expand its regulatory influence toward strengthening the requirements for laboratories and research centres to conduct research, as well as expanding their obligations to report on the progress of the tests and their results, including the adverse reactions.[23]

The EU Council and the European Parliament Directive No. 2003/94/EC "On the establishment of principles of good manufacturing practice for medicinal products for human use", which improved the system of principles and requirements for good manufacturing practice for medicinal products for human use, the production of which is limited and subject to certain provisions of Directive 2001/83/EC.[24]

Another important aspect of the pharmaceutical market regulation is the procedure for the pharmaceutical products admission within the EU market and to the markets of individual EU member states, which is regulated by various

means of legal support, including Directive 2001/83/EC (Fig. 1).

A schematic view of the procedures different in content gives the idea that not all admission procedures are governed by the EU law, even with regard to the EU member states. This is due to the fact that national economic interests are protected under EU law and this is one of the paramount implications for Ukraine since the unification of Ukraine's legislation with that of the EU should occur strictly within the scope of pharmaceutical manufacturers and their distribution networks.

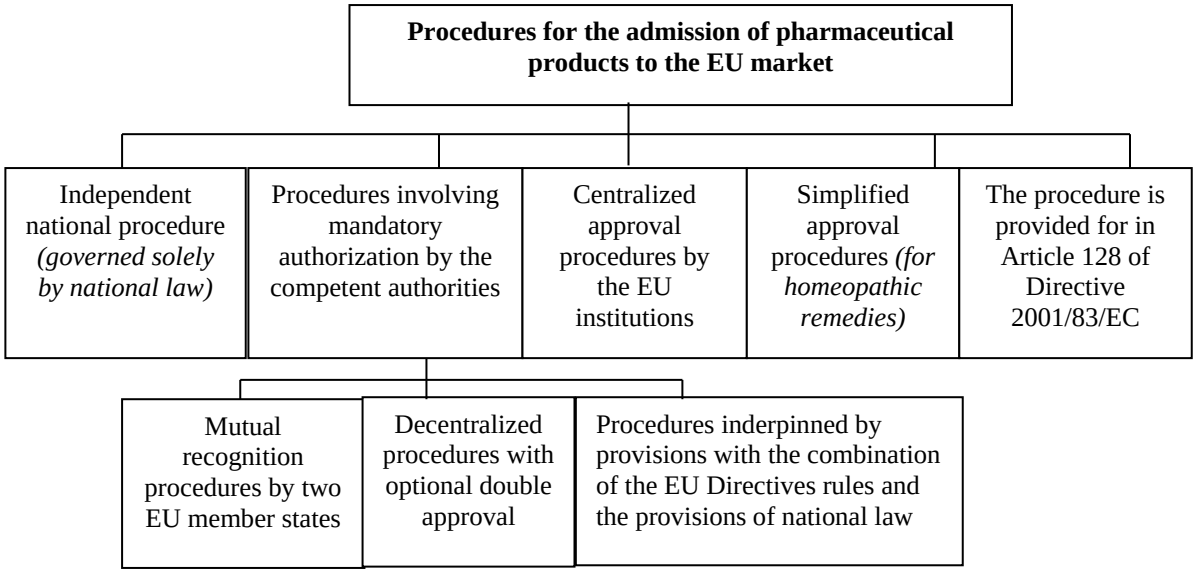

Figure 1. The procedure for the admission of pharmaceutical products to the EU market

Thus, the main regulatory impact of the abovementioned EU Directives is traced through the constitutive mechanisms that regulate the conditions, requirements and lay out the basic principles of the economic entities' activity in the pharmaceutical market, as well as determine the set of tools and limits of state regulation of the said market. The constitutive effect means that the minimum scope of pharmaceutical market regulation is fixed specifically by the directives and this scope should be introduced at the national level. Furthermore, at the pan-European level, the limits of permissible freedom of the market actors' economic activity are set. The European law has also become rather widespread, stimulating the development of the pharmaceutical market and its agents, but incentives and compensatory measures are limited to empowering national governments to adopt relevant programs. At the EU level common standards, trends and vectors for the industry development are set, reflecting both the content of the EU health policy at large as well as the nature of the regulatory acts adopted by the EU member states.

In view of the above, it should be noted that the legal support for the EU pharmaceutical industry has the following important features:

first, it is implemented at the pan-European level and underpins the basic principles and grounds of possible state regulation based on the priorities of pan-European development that is the priorities of the single market, the reduction of intra-European restrictions and barriers, as well as compliance with the standards of health care quality;

second, it is both binding and advisory in nature, enabling the EU member states to have a larger degree of freedom to manoeuvre in the field of establishing national regulators;

third, the EU Directives in the pharmaceutical sector need updating in the face of new challenges and new realities of the pan-European integration, especially when the UK as one of the key market players leaves the EU.

Discussion

Despite the existence of a quite extensive but codified legal coverage for the development of the pharmaceutical market in the EU, only certain aspects of state regulation and legal support for the functioning of the said market though are of considerable scientific interest. In this regard, it was noted that the EU set up the European Medicines Agency (EMEA), which exercises broad legislative powers in the field of defining and interpreting the "ways of regulating" the pharmaceutical market. These comprise the permits to sell new products; advanced quality standards and requirements for the manufacturing environment of pharmaceutical products, etc. At the same time, the role of the member states in the field of price regulation is being constantly enhanced by means of introducing the price minimization tools".[25]

In a fundamental study[8] on EU competition law in the pharmaceutical market was pointed out, that price regulation is one of the most effective mechanisms for public administration in the pharmaceutical sector on the whole. However, the pricing and tariff mechanisms differ depending not only on national legislation but also on the national policy of the pharmaceutical market entity itself and the competition level achieved in the market. The nature of the instruments used to regulate the pharmaceuticals' prices is significant, and the

calculation of the reverse payments is one of the instruments having a certain uniqueness and peculiarity. Authors associate them with the period of patents validity for new pharmaceuticals (under the EU law, the duration of patent exclusivity comprises only 25 years), during which companies producing generics (that is using the patented formulas or parts thereof) shall partially pay the funds to the patent recipients.[8] The essence of reverse payments is that the main benefit is obtained in one way or another, only by the patent holders, but they maximize their profits through minimizing the costs by receiving not the proceeds of pharmaceutical sales but the cash flows from the return payments of the entities that sell products similar or partially compliant to the patented medicines on the market (Fig. 2).

As is evident, the price of pharmaceutical products by business entities that did not incur costs associated with R&D and market promotion is lower than the price of the patent holders for such products. However, by receiving reverse payments by the latter, it is the patent owners who maximize their profits because they do not pay income taxes or retail sales taxes. Such an instrument is typical of countries with a high level of market freedom and competitive development of economic relations and is desirable for Ukraine, but it requires considerable research as it is regulated at the level of the EU legislation by setting priorities for minimizing the prices of medicinal products. This method of minimization is traditional for the national laws of the member states for it is permitted and promoted by European law.

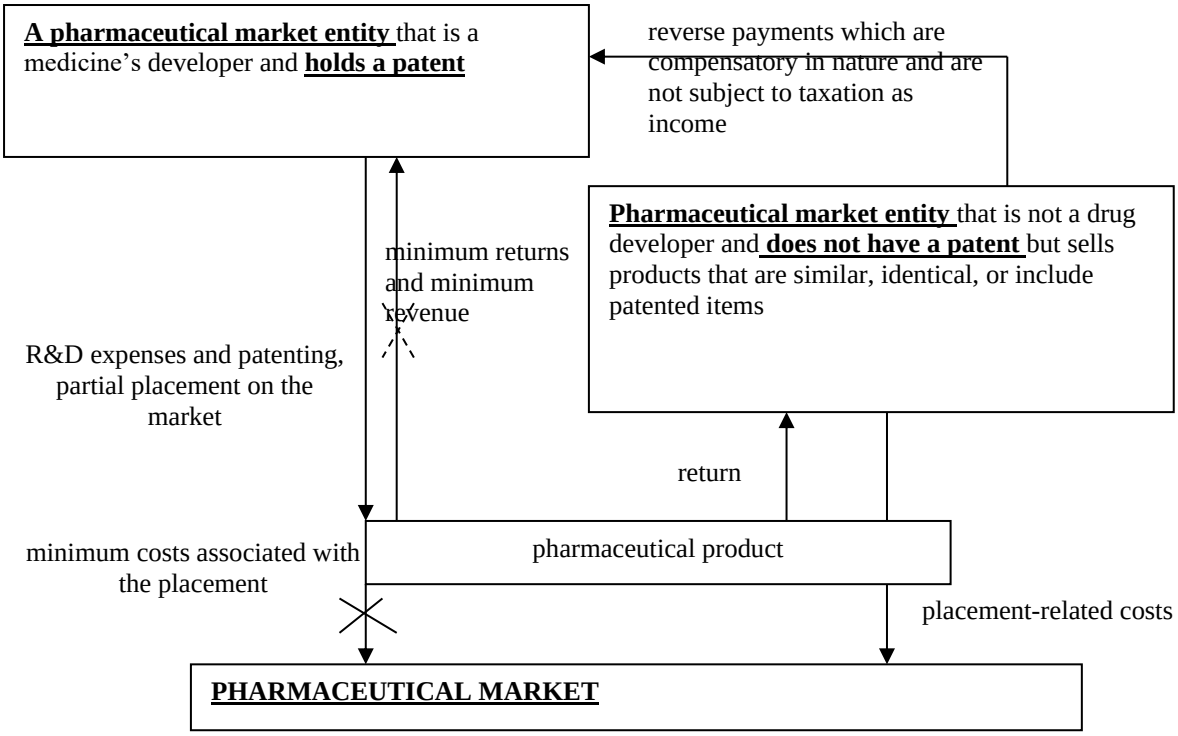

Figure 2. The mechanism of price regulation of pharmaceuticals by means of reverse payments.

The pharmaceutical sector requires close scrutiny of competition laws, and the registered antitrust and merger cases provide a number of examples of how the competition law specifically helps to ensure that EU patients have access to affordable and innovative medicines. High drug prices place a heavy burden on national health care systems, where pharmaceuticals already account for a significant proportion of costs. Therefore, a generics company earns part of the profits from artificially set high prices, but the high prices do not mean their relative value in monetary terms but only a staggering part of the profits by minimizing the production costs.[26]

In other words, today the pricing tools are needed to determine the minimum and maximum price base, which in its turn will regulate the revenue level of pharmaceutical corporations in a certain way.[27]

Currently, reverse payments are an alternative to such methods of price regulation as parallel trade, where pharmaceutical manufacturers of two EU member states compete with each other in the markets of their countries, using both the potential of domestic purchasing power and the tools for reducing the price of pharmaceutical products imported by them.[28] In this regard, authors[29] point out that the parallel trade mechanism is a protectionist measure against the EU member states when they enter the markets of non-EU countries. This warning is crucial for Ukraine since in signing the Association Agreement with the EU, Ukraine actually commits itself to implement the provisions of the EU law into the national law, which most often relate to the free export, but in the case of high-quality pharmaceutical products manufactured by the EU member states, the Ukrainian market is too vulnerable.

In this context, it was concluded that "parallel imports reduce the prices of the patented drugs by 11%, but in fact, they do not affect the prices of the generic drugs".[30] This means an increase in the excess demand and maximization of the profit of

pharmaceutical producers through an increase in the volume of deliveries.[30] But according to a study,[6] the parallel imports substantially threaten to increase R&D expenditure in the pharmaceutical field, which is a major drawback for strategic perspective. Thus, the parallel imports can be considered a means to rapidly stimulate the pharmaceutical market in the EU member states experiencing stagnation in this area.[6]

It was pointed out that the demand for pharmaceutical products is largely unusual.[31] As a rule, patients do not pay for health care costs or pay only a part of the costs, since medical costs are covered by national health insurance schemes, which usually cover the risk of the disease. However, in most European countries, the price of pharmaceuticals is the result of some consensus between the national regulator and pharmaceutical companies.[31] Thus, the state regulation of pricing takes place at the level regulating the activities of market agents, that is the pharmaceutical networks. Authors[32] argue that such a centralized policy of the EU countries is based on a state-level minimum margin that is reimbursed by the state to a pharmaceutical manufacturer. " European legislation only applies to the authorization and marketing of pharmaceutical products. Pricing for pharmaceutical products is the exclusive jurisdiction of the EU member states".[33] This view is fully in line with the findings of the abovementioned studies, but there is still a view that pharmaceutical pricing in EU member states is the result of Member States policy, but not a coordinated policy aimed at regulating the competitive conditions of the pharmaceutical market products, but not the operating conditions of the manufacturers themselves.[34]

For example, in a study[4] it was stated that Council Directive 2001/20/EC has been the subject of intense debate and criticism and is generally considered to have failed to achieve the stated objectives. The monitoring of the potential adverse impact of this Directive on the regulation of the pharmaceutical market shows that its purpose was only to regulate the conditions of issue and manufacturing, not the price formation and market mechanism. That is why the researcher[35] believes that the main instrument for regulating the EU pharmaceutical market is patent regulatory instruments, which simultaneously lay down the conditions and rules for the release of pharmaceutical products and also create the prerequisites for regulating reverse payments, that is, in any case, the pricing issues, such as a major element of market regulation in the pharmaceutical market are touched in EU Directives. This position is supported by studies[5, 28], where it was noted that the EU policy is derived from the synthesis of national policies of the EU member states, where the main element of pharmaceutical regulation the market is just price regulators.

We support this idea in part, but we also note that price regulation is not a central element of EU pharmaceutical policy. Most directives and legal acts refer to so-called soft regulation, which defines the limits and the means recommended by the EU political institutions to national governments. The exceptions, however, are those legal provisions and norms, which lay down the pan-European requirements and standards regarding the production and marketing of pharmaceutical products, their form, labelling, packaging and the like in a more imperative, rigid form. That is, those are the aspects of market regulation that refer to standards related to ensuring the rights of the EU citizens to quality medicines and access to them.

The confirmation of this can be found in work,[7] but this research is more about the correlation of different EU policies and their synthesized impact on the pharmaceutical market, and it is, therefore, difficult to distinguish any elements of this policy regarding the competing regulatory instruments.

According to Ukrainian researchers,[12, 13] the price regulation of the pharmaceutical market in the EU is important in the legal regulation of the latter. This is substantiated by the fact that all the emphasis of regulating this market by the EU institutions is to ensure that the end consumer (the patient) pays only a part of the price of the product. The rest of the cost is provided either through taxation, or in the systems where health care is provided, or through compulsory insurance, the insurer, or both. The states intervene in establishing the controls on profits or prices and in regulating the general consumption of medicines, in particular by fixing the prices for medicines. But a researcher[36] underlines the need to revise the approaches to the legal provision of the EU pharmaceutical market by reviewing the existing regulations and creating a single codified act.

Researcher[9] emphasizes the codification though at the level of national legislation in the field of regulation of the pharmaceutical market and this is where the researcher focuses her attention, inter alia, on the national legislation of Ukraine, based on EU Directive 2001/83.[9] The harmonization of Ukrainian legislation with EU secondary law acts aims to consolidate a broad list of terms at the level of the law in order to harmonize them with national legislation. It is also necessary to extend the competence of the central executive body responsible for the formulation of state health policy (Ministry of Health of Ukraine) to approve the basic procedures and provisions aimed at implementing the rules of the legislation on the circulation of medicinal products, and to the State Service for Medicinal Products of Ukraine the means as the authority of state control to put the actual implementation of these acts and monitoring over their implementation.[11] In their turn, authors[10] explain the need to develop import substitution incentives for the needs of the Ukrainian pharmaceutical market. On the whole, the practice of import substitution is quite common in the EU, but Directive 2001/83 deals mainly with import substitution in the EU countries of the products manufactured outside the single market.[2] For Ukraine, import substitution is more indispensable because it is crucial to stimulate the national producer.

The majority of Ukrainian researchers of the problem of implementing the greatest legal regulation achievements of the pharmaceutical market from EU practice to the practice of the Ukrainian government, of paramount importance is primarily the safeguarding of the national interests. The pharmaceutical industry in Ukraine has a clearly insufficient level of competitiveness for an active expansion into the EU market, so the introduction of traditional barriers for the entry into Europe will have a negative effect on Ukraine. The unilateral reduction

of the import duty on the EU pharmaceuticals into the EU is considered to be almost inaccessible to the extent that it is stipulated in the Association Agreement with the EU. It is considered feasible and appropriate though to expand the system of trade relations with the countries that have special trade regimes with the EU.

Conclusions

It should be noted that the nature of the EU pharmaceutical market regulation has, in fact, a clear emphasis on seeking to achieve two objectives simultaneously: ensuring access to high-quality pharmaceuticals for citizens and developing the pharmaceutical market with open and reasonable competition rules, excluding national protectionism. Although it turns out that EU law is directly applicable only to the provisions relating to the requirements for the production and marketing of pharmaceutical products.

The EU has quite an extensive legislation governing the pharmaceutical market, but there are also legal acts, in particular, Directive 2001/83, which is characterized by the codification of the provisions in the area under study. This exemplifies a constant transformation of the EU policy towards identifying the most effective means of regulation. Consequently, this draws attention to the features that can be applied in the Ukrainian legislation to consolidate at the national level the means of regulating the pharmaceutical market. Among the main tools, it is expedient to examine the EU experience in the field of reverse payments, as well as the means to develop national legislation to legally secure the preferences for the national producer in the context of implementing the Association Agreement with the EU. In fact, the EU law contains a large number of regulatory mechanisms for the pharmaceutical market that can stimulate specifically the internal market and the domestic producer, but the ramifications and complexity of the EU law also make it difficult for the national policy to select and combine the most effective regulatory mechanisms in the field under study.

Conflicts of Interest

Authors have no conflict of interest to disclose.

References

1. Council of the European Union. Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems; [cited 2019 Nov 9]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31989L0105
2. Council of the European Union. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use; [cited 2019 Nov 9]. Available from: https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32001L0083
3. Council of the European Union. Directive 65/65/EEC On the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products; [cited 2019 Nov 9]. Available from: https://op.europa.eu/en/publication-detail/-/publication/a761f2b9-d398-4fc5-a2fe-f1f7bebdb9b4/language-en
4. Permanand G, Mossialos E, McKee M. Regulating medicines in Europe: the European Medicines Agency, marketing authorisation, transparency and pharmacovigilance. Clinical medicine. 2006 Jan 1;6(1):87-90.
5. den Exter A, Hervey TK, editors. European Union health law: treaties and legislation. Maklu; 2012.
6. Bennato AR, Valletti T. Pharmaceutical innovation and parallel trade. International Journal of Industrial Organization. 2014 Mar 1;33:83-92.
7. Ferreira N, Kostakopoulou D. The Human Face of the European Union. Cambridge: Cambridge University Press; 2018.
8. Figueroa P, Abogados G. EU Law of Competition and Trade in the Pharmaceutical Sector: Elgar Competition Law and Practice series. London: Queen Mary University; 2019.
9. Deynega OO. To the question of defining the concept, characteristics of the drug market and its competition. Medical Law. 2014; 2(14): 28-36.
10. Dorovsky OV, Yaroshenko IV. Comparison of Pharmaceutical Markets of the EU Member Countries and the CIS Countries. Business-Inform. 2014; 12: 47-61.
11. Parshov VM. Legal support for the implementation of EU legislation on the circulation of medicines. Medical Law. 2016; 2(18): 55-64.
12. Pasechnik OV. Integrative regulation of drug circulation in the European Union. PhD thesis abstract. Odesa; 2015.
13. Pasechnik OV. Pharmaceutical legislation and EU internal market law: the issue of correlation. European Studies and Law. 2014; 1: 89-102.
14. The Member States. Consolidated version of the Treaty on the Functioning of the European Union / Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union 2012/C 326/01; [cited 2019 Nov 9]. Available from: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:12012E/TXT
15. Council of the European Union. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency; [cited 2019 Nov 11].

Available from: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32004R0726

16. Council of the European Union. Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004; [cited 2019 Nov 9]. Available from: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32006R1901
17. Council of the European Union. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004; [cited 2019 Nov 9]. Available from: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32007R1394
18. Legislation of Ukraine. Directive No. 98/34 / EC. The European Parliament and the Council of the EU on the procedure for the provision of information in the field of technical standards and regulations, as well as the rules for the provision of services in the information society; [cited 2019 Nov 9]. Available from: https://zakon.rada.gov.ua/laws/show/994_b11
19. Volkov A, Ryzhkov A. EU Law Influence on Regulating National Pharmaceutical Markets in EU Member States. Journal of the Higer School of Economics. 2013; 2: 116-33.
20. Court of Justice. Judgment of the Court of 24 November 1993. Criminal proceedings against Bernard Keck and Daniel Mithouard; [cited 2019 Nov 12]. Available from: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:61991CJ0267
21. Court of Justice. Judgment of the Court of 29 November 1983. Roussel Laboratoria BV and others v Etat neerlandais; [cited 2019 Nov 12]. Available from: https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:61982CJ0181
22. Judgment of the Court of 26 February 1976. Riccardo Tasca. Case 65-75; [cited 2019 Nov 12]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A61975CJ0065
23. Council of the European Union. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use; [cited 2019 Nov 9]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32001L0020
24. European Commission. Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use; [cited 2019 Nov 9]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1575865337542&uri=CELEX:32003L0094
25. Hancher L. The EU Pharmaceuticals Market: Parameters and Pathways; [cited 2019 Nov 12]. Available from: https://apps.who.int/medicinedocs/documents/s21372en/s21372en.pdf
26. European Commission. Competition Enforcement in the Pharmaceutical Sector (2009-2017. Luxembourg: Publications Office of the European Union; 2019.
27. De Souza N. Competition in Pharmaceuticals: the challenges ahead post AstraZeneca. Competition policy newsletter. 2007(1):39-43.
28. Flear M. Governing Public Health: EU Law, Regulation and Biopolitics. Bloomsbury Publishing; 2015 Jul 30.
29. Kanavos P, Vandoros S. Competition in prescription drug markets: is parallel trade the answer?. Managerial and decision economics. 2010 Jul;31(5):325-38.
30. Duso T, Herr A, Suppliet M. The welfare impact of parallel imports: A structural approach applied to the German market for oral anti-diabetics. Health economics. 2014 Sep;23(9):1036-57.
31. Vogler S, Kilpatrick K, Babar ZU. Analysis of Medicine Prices in New Zealand and 16 European Countries. Value in Health. 2015; 18(4): 484-92.
32. DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: new estimates of R&D costs. Journal of health economics. 2016 May 1;47:20-33.
33. Provost M, Thill-Tayara M. Pharmaceutical antitrust law in European Union Dechert LLP; [cited 2019 Nov 9]. Available from: https://www.lexology.com/library/detail.aspx?g=ad4263c0-d776-4fb8-be02-2bc3464f31a1
34. Pogorzelczyk K, Synoweć J, Robakowska M, Ślęzak D, Holajn P, Robakowski P, Żuratyński P, Nadolny K. Pharmaceutical markets regulation overview of the selected European Union countries. Wiadomosci lekarskie (Warsaw, Poland: 1960). 2018;71(7):1404-8.
35. Bar-Bouyssiere B, Fierens A, Schoefs R. Pharmaceutical IP and competition law in the EU; [cited 2019 Nov 9]. Available from: https://uk.practicallaw.thomsonreuters.com/9-617-0567?transitionType=Default&contextData=(sc.Default)&firstPage=true&bhcp=1
36. Malichenko VS. International legal mechanisms for ensuring the safe circulation of medicines. PhD thesis. Moscow; 2015.