DOI:10.35774/app2022.03.140

Maika Nataliia,
Candidate of Juridical Sciences,
Associate Professor of the Department of Civil Law and Process,
West Ukrainian National University
ORCID: http://orcid.org/0000-0002-5676-980X

Yulia Trufanova,
Candidate of Juridical Sciences, Associate Professor,
Associate Professor of the Department of Civil Law and Process,
West Ukrainian National University
ORCID: https://orcid.org/0000-0002-1176-7579

Rostyslav Lukashov,
Candidate of Juridical Sciences,
Instructor of the Department of Civil Law and Process,
West Ukrainian National University
ORCID: https://orcid.org/0000-0003-4310-3061

LEGAL REGULATION OF THE MEDICINES REIMBURSEMENT IN UKRAINE: IMPLEMENTATION OF INTERNATIONAL EXPERIENCE

The article is devoted to the problems of legal adjusting of relations concerning the reimbursement of the cost of medical services by the state for the benefit of subjects of the pharmaceutical industry: manufacturers, pharmacies, healthcare institutions, etc. The nature of reimbursement relations was investigated.

Current domestic legislation on reimbursement is fairly new and is the result of implementing the principles of regulatory policy in the field of health care adopted in the EU. It was also developed to implement the provisions of the Association Agreement between Ukraine and the EU. Therefore, it is logical to conclude that the domestic legislation has a number of disadvantages, in particular regarding the extremely narrow list of diseases for the treatment of which medicines can be reimbursed. In addition, the fact that only the NHSU may be party to reimbursement agreements significantly reduces the opportunities for practical implementation of state guarantees in the sphere of public health care. Instead, expanding the scope of subjective relationships at the expense of local governments will significantly increase the effectiveness of public policies on the availability of medicines.

The analysis of foreign experience has made it possible to establish the effectiveness of such principles of the reimbursement system as therapeutic expediency and value for money / treatment. These principles are the foundations of the reimbursement systems in Germany, France, the United Kingdom, the Baltic States, the Czech Republic, Slovakia, etc. The attention is also drawn to the experience of the United Kingdom in maintaining a register of medicinal products which may be subject to reimbursement mechanisms, the inclusion to which is based solely on information about the efficacy of such medicinal products as confirmed by clinical trials. All of this requires further study in order to introduce the legal support of the medicines reimbursement relations into the domestic practice.

Keywords: *reimbursement, medicines, state regulation of pharmaceutical industry, availability of medicines, state guarantees.*

Майка Н., Труфанова Ю., Лукашов Р.
Законне регулювання компенсації медицини в Україні: виконання гравця збірної досвідчені

У статті розглянуто проблеми правового регулювання відносин з приводу реімбурсації лікарських засобів, тобто відшкодування вартості лікарських послуг з боку держави на користь виробників, аптечних мереж, закладів охорони здоров›я тощо. Досліджено природу відносин реімбурсації. Встановлено, що механізм відшкодування вартості лікарських засобів є способом забезпечення державою виконання гарантій загальнодоступності медичного обслуговування та медичних послуг. Доведено, що він поєднує в собі одночасно економічний

зміст, що розкривається через інструменти компенсації за рахунок коштів державного бюджету витрат суб›єктів фармацевтичної діяльності, а також правовий зміст. Останній забезпечується комплексом нормативно- правових актів, основний регуляторний вплив яких спрямовується на формування чітких та прозорих засад реімбурсації. Проведений аналіз сучасного українського законодавства в аналізованій сфері продемонстрував наявність суттєвих недоліків та потребу пошуку нових ефективних механізмів державного регулювання. Основний акцент у цьому контексті спрямовано на вивчення закордонного досвіду, зокрема досвіду країн ЄС. Окремо було досліджено форми та методи державного регулювання доступності лікарських засобів у таких країнах, як Німеччина, Франція, країни Балтії, Польща тощо. Доведено існування двох основних моделей відносин реімбурсації, лише одна з яких передбачає компенсаторні механізми за рахунок державних коштів. Інша модель передбачає збільшення соціальної відповідальності виробників лікарських засобів через механізми здешевлення останніх для соціальних потреб. Вивчення моделей реімбурсації та державної підтримки фармакологічної галузі за кордоном відкриває нові можливості для вдосконалення відповідного напрямку державної політики в Україні. Зроблено висновок щодо необхідності подальшої деталізації законодавчих положень, зокрема шляхом введення в практику господарської діяльності суб›єктів фармацевтичної галузі окремого договору реімбурсації як засобу практичної реалізації державних гарантій у сфері компенсації вартості лікарських засобів.

Ключові слова: *реімбурсація, лікарські засоби, договір реімбурсації, доступність лікарських засобів, державні гарантії.*

Formulation of the problem. The pharmaceutical sector is simultaneously one of the most attractive and one of the most difficult industries, the former in terms of profitability and the latter in terms of production and economic turnover relations. For business entities, such as manufacturers, pharmacy chains and other actors in the relationship regarding the production and circulation of medicines, the existence of transparent, stable and progressive mechanisms for state regulation of the industry is crucial. In this context, the primary task is to develop regulatory support for the pharmaceutical industry, including the creation of optimal conditions for the implementation of contractual relations. Expanding a modern understanding of the content and subject areas of contractual relations in the Ukrainian pharmaceutical sector is not possible without active and thorough study of foreign experience. The emergence of new models and new forms of activity in the analysed sector of the economy requires increased attention from public authorities. Various forms of state participation, predominantly incentive in nature, are considered inter alia as means of stimulating the economic activity of the pharmaceutical market entities. However, the involvement of the state results not only from the desire to stimulate and develop the pharmaceutical industry, but also because of the social responsibility to citizens to implement state guarantees of medical care accessibility. The latter is achieved through a reimbursement mechanism. The relevance of the legal regulation of reimbursement relations is dual. Firstly, the mechanism of medicines reimbursement in Ukraine needs substantial improvement; secondly, the economic potential of reimbursement can significantly stimulate economic activity of pharmaceutical manufacturers and substantially increase the availability of medical services in Ukraine.

Analysis of recent research and publications. The study of the legal nature and legal support of the reimbursement agreement is based on the modern domestic legislation, as well as on the works of leading scientists in the this area, in particular A. V. Belichenko, T. V. Blashchuk, R. M. Voron, A. A. Kotvitska, I. V. Kubarieva, Yu. Ye. Kurylenko, N. M. Levchenko, A. S. Nemchenko, D. O. Plekhanov, A. S. Poltavtseva, and others.

The aim of the research is to study foreign experience of reimbursement, in particular the experience of EU countries.

Main results of research. The pharmaceutical sector is one of the most important economic areas in terms of social responsibility and social guarantees of the state. Establishing the availability of health care at the level of constitutional guarantees, the state should thus regulate relations concerning the production and distribution of medicines, which will allow reaching the maximum level of guarantees instilled in the law. The medicines reimbursement mechanism is at the forefront in this context, as it is the simplest and most effective means of providing the public buying medicines with social guarantees.

In this context, exemplary is the opinion of D.V. Pinchuk, who in his research concludes that «The complex, multi-level and multidimensional regulation of the pharmaceutical sector and its social significance for the population of the country necessitate an adequate understanding of the essence of the state regulatory policy in the field of medicines trade. It should be considered as a set of state measures aimed at improving the legal regulation of economic relations on the pharmaceutical market and administrative relations between regulatory authorities. Unlike other spheres of regulation, it aims to ensure the physical availability of quality

medicines through the establishment of rules for public procurement of medicines, regulation of their wholesale and retail trade, control over the quality of medicines, as well as the economic availability of medicines to the end consumer through reimbursement» [1, P.15]. This posit of the scientist gives us an understanding that the mechanism of reimbursement has a dual nature: legal and economic. In terms of economics, it is considered as a means of stimulating the economic activity of pharmaceutical manufacturers. In terms of law, the reimbursement mechanism is a means of providing state guarantees in the field of the medicines market regulation.

As R.A. Maidanyk notes «Reimbursement is the common name used in international healthcare practice for the process by which the health care system influences the availability of medicines and medical services to the public. The basic principle of pharmaceutical assistance is to ensure the economic (price) and physical (availability on the market of the country) accessibility of medicines for all segments of the population, achieved through the mechanism of state pricing regulation» [2, P. 168-169].

All this gives grounds to argue that reimbursement is possible only in the conditions of public-partner relations, since both state and private sector entities are parties to these relations, which, based on their legal nature, must be formalized by contract.

Thus, it seems quite reasonable to use the definition of reimbursement proposed by A. S. Poltavtseva, who understands this phenomenon as «a means of state regulation of economic activity in the pharmaceutical field, which entails partial compensation of the medicinal product costs at the level of the reference price, taking into account marginal supply and marketing (retail) allowances in favour of the economic entity. It is aimed at establishing a socially oriented level of prices for medicines and medical products for certain categories of individuals and is used in combination with state regulation of prices for medicines to rationalize the state budget expenditures» [3, P. 226-232.]. This approach reveals another important feature of reimbursement as a mechanism for public-private relations - the rationalization of public spending.

Summarizing the above, we can conclude with our own definition. Thus, reimbursement is a system of relations drawn up by means of a special contract built on the principles of public-private partnership between state bodies and manufacturers of medicinal products. It provides for making the medicinal products available to the population in the amount necessary to ensure the implementation of the system of state guarantees for the availability of health care, and at the same time ensuring high economic performance of the pharmaceutical market actors through instruments of medicines cost compensation, or promoting their activities in another way – by creating a competitive environment on this market.

Current Ukrainian legislation in this field is based on a number of state guarantees, reflected in particular in the Constitution of Ukraine, Fundamentals of the legislation of Ukraine on health care, the Law of Ukraine «On Medicines», etc.

Thus, according to Article 49 of the Constitution of Ukraine «Everyone has the right to health care, medical care and health insurance. Health care is provided by state funding of relevant socio-economic, health and wellness, and prevention programmes. The state creates conditions for effective and accessible health care for all citizens» [4]. This norm is the starting point and it is also crucial for the whole legal support of reimbursement relations in Ukraine. It is detailed, and its content is expanded in other legal acts, and in fact it is this state guarantee regarding the accessibility of health care that serves as a benchmark for the development of the whole range of state policy instruments in the sphere of regulation for the pharmaceutical market and activities of the pharmaceutical industry.

The above provision of the Constitution of Ukraine is best revealed in the system of health care principles, which are established in Article 4 of the Fundamentals of the legislation of Ukraine on health care. Some of the main principles are: «Recognition of health care as a priority activity of society and the state, one of the main factors of survival and development of the Ukrainian people; respect for the human and citizen rights and freedoms in the field of health care and the provision of related state guarantees; citizens' equality, democracy and public access to health care and other health care services, etc. » [5]. The outlined principles reflect the organizational and legal aspects of the medicines market regulation, and form the boundaries of state influence on the health care sector, setting indicators whose achievements will demonstrate the completeness and effectiveness of public administration in the specified field.

This is most clearly defined in the provisions of Art. 8 and Art. 54-55 of Fundamentals of the legislation of Ukraine on health care, which define the basic principles of state protection of the right to health care, as well as the mechanisms, procedures and limits of medicines provision.

In addition, the availability of medicines and medicinal products is guaranteed by the Law of Ukraine «On Medicines», which does not directly indicate the existence of a reimbursement mechanism, but does declare that

the availability of medicines shall meet the needs of citizens and the minimum state standard of medical care. Thus, according to Part 2 of Art. 3 of the said Law «for the purpose of exercising the right of citizens of Ukraine to health care, the state ensures the availability of essential medicines, protection of citizens in the event of harm to their health due to the use of medicines for medical purposes, and provides benefits and guarantees to certain groups of the population and categories of citizens by providing them with medicines in case of illness» [6]. Therefore, the state understands the reimbursement mechanism as a way of ensuring citizens' access to medicines and creating appropriate state regulation mechanisms aimed at securing the interests of both manufacturers and consumers.

It should be noted that the implementation of the reimbursement mechanism in the domestic legislation was made possible by the implementation of the provisions of the Association Agreement between the EU and Ukraine as a prerequisite for sustainable development and economic growth [7]. However, as noted by T. Skaskiv, as well as A.A. Kotvitska and I.V. Kubarieva, Law of Ukraine «On Medicines», does not meet the requirements of EU law, has a huge number of blanket norms, and is devoid of direct mechanisms for regulating many relationships in the medical field. This, among other reasons, can explain the low efficiency of the practical implementation of the reimbursement mechanism. That is why it is important to continue exploring the foreign experience, and in particular the EU experience, to enhance the capacity of the domestic legal support for reimbursement relations [8],. Overcoming the shortcomings of the domestic reimbursement system is possible, first of all, through widespread implementation of certain provisions of 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; 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.

In the above-mentioned EU Directives, the states' obligation to ensure the availability of health care services is linked with mechanisms of economic incentive and economic cooperation between national governments of EU Member States and pharmaceutical market participants to optimize the costs associated with reimbursement of the partial cost of medicines to not only pharmacy chains, but also health care facilities and even to manufacturers of medical drugs directly.

In general, as noted by R.M. Voron, all models of reimbursement relations that exist in different countries of the world, may be divided them into two systems: state - purely social in nature and private - dominated by private pharmaceutical assistance[9, P. 105-109]. The first model is of more interest as it involves active participation of the state in the processes of reimbursement of medicines.

According to A. S. Poltavtseva, the most striking example of the practical implementation of this model is the German reimbursement model, «which is based on the principles humanism and taking into account the generally recognized level of achievements in medicine. This follows from § 70 of the Social Code of Germany (hereinafter referred to as the SCG), which states that insured persons are guaranteed the provision of medical services that are proportionate to their needs and meet the generally recognized level of achievement in medicine» [10, p. 228-230].

We can conclude that the principle of therapeutic expediency of medicines is the basis for the reimbursement system in Germany, which is not the case in Ukraine. This means that the reimbursement is not for the benefit of a particular pharmacy institution or network, but for the benefit of a particular medicine, the use of which is most appropriate to the needs of the protocol of treatment for a particular disease. In addition, the application of this principle opens the possibility to apply a reimbursement mechanism even in the case of non-prescription drugs.

The UK's experience is indicative of the existence of a separate register of medicines in this country - the British National Formulary, in which entries are based solely on «information confirmed by evidence from clinical trials. In this case, the reimbursement is based on the principle of correlation of the «efficiency / cost» indicators. That is, a medicine must be no less effective and safe than a formulation with the same indications and have a similar or better «efficiency / cost» indicator to be subject to the reimbursement mechanism.» [9, p.107-108].

Indeed, the existence of such a National Formulary is a logical practice for improving the efficiency of state regulation of the pharmaceutical industry as a whole. However, it should be noted that the introduction of a medicinal product into such a Formulary is only one of the conditions for applying the reimbursement mechanism.

A.V. Bielichenko notes that in the «old» EU countries (Great Britain, France, Italy, Germany, Austria, Belgium, Norway, Portugal, Finland) the mechanisms of state regulation for providing the population with medicines are based on the principle of centralization of state codes. In some European countries (Denmark, Sweden and Switzerland), appropriate mechanisms, mainly based on decentralization, are in place. In many EU countries, there is a furthering decentralization in the state regulation of providing medicines to the public [11, p. 9].

Nevertheless, decentralization of public management of medicines cost compensation means only expanding the possibilities for public funds allocated to these needs. This also means granting such powers to local self-government bodies, which confirms the expediency of introducing relevant foreign experience in the domestic practice of reimbursement relations. However, most EU countries have strict conditions and criteria for entering medicinal products on such national formularies or registers.

It should also be noted that the principle of reference pricing can be based on the mechanism of reimbursement, as A. S. Nemchenko and Yu. Ye. Kurylenko mention. For example, such practices, according to researchers, are typical of countries such as the Polish Republic, Slovak Republic, Hungary, Serbia, and the Republic of Latvia. They use the method of reference pricing as the main criterion for calculating the prices of medicines subject to reimbursement. This method is also used in Ukraine, but its short period of application thus far makes unambiguous conclusions about effectiveness unfeasible [12, p.17].

On the other hand, the diversity of methods and principles underlying the system of medicines reimbursement in EU countries is offset by the existence of insurance medicine. According to O. Soldatenko «Compulsory health insurance allows for more effective reimbursement mechanisms that can be reduced to two types of compensation: for insured persons and for pharmacy institutions. The use of a mechanism, a list of state-reimbursed drugs or medicines, and the level of reimbursement depend on the peculiarities of the national health care system and the model of health insurance» [13]. For example, in France, reimbursement is applied to pharmacies, but to the maximum extent possible provided for in the state budget. At the same time, verification of the implementation of reimbursement programmes is carried out not only by the state, but also by local self-government bodies and even insurance companies, which are also active participants of the reimbursement program, although not party to the relevant contract.

Conclusions. Summarizing the above, the following conclusions should be drawn. First, an analysis of the doctrinal provisions and studies of leading scientists has made it possible to formulate a definition of reimbursement at theoretical level. Thus, reimbursement is a system of relations drawn up by means of a special contract built on the principles of public-private partnership between state bodies and manufacturers of medicinal products. It provides for making the medicinal products available to the population in the amount necessary to ensure the implementation of the system of state guarantees for the availability of health care, and at the same time ensuring high economic performance of the pharmaceutical market actors through instruments of medicines cost compensation, or promoting their activities in another way – by creating a competitive environment on this market.

Second, current domestic legislation on reimbursement is fairly new and is the result of implementing the principles of regulatory policy in the field of health care adopted in the EU. It was also developed to implement the provisions of the Association Agreement between Ukraine and the EU. Therefore, it is logical to conclude that the domestic legislation has a number of disadvantages, in particular regarding the extremely narrow list of diseases for the treatment of which medicines can be reimbursed. In addition, the fact that only the NHSU may be party to reimbursement agreements significantly reduces the opportunities for practical implementation of state guarantees in the sphere of public health care. Instead, expanding the scope of subjective relationships at the expense of local governments will significantly increase the effectiveness of public policies on the availability of medicines.

Third, the analysis of foreign experience has made it possible to establish the effectiveness of such principles of the reimbursement system as therapeutic expediency and value for money / treatment. These principles are the foundations of the reimbursement systems in Germany, France, the United Kingdom, the Baltic States, the Czech Republic, Slovakia, etc. The attention is also drawn to the experience of the United Kingdom in maintaining a register of medicinal products which may be subject to reimbursement mechanisms, the inclusion to which is based solely on information about the efficacy of such medicinal products as confirmed by clinical trials. All of this requires further study in order to introduce the legal support of the medicines reimbursement relations into the domestic practice.

References

1. Pinchuk, D. V. (2019). *Rehuliatorna polityka u sferi torhivli likarskymy zasobamy [Regulatory policy in the sphere of trade in medicinal products].* Extended abstract of candidate's thesis. Kyiv [in Ukrainian].
2. Maidanyk, R. A. (2014). Dostup do likarskykh zasobiv v ukraini: pryntsyp spivrobitnytstva i yurydychna model farmatsevtychnoho rynku [Access to medicines in Ukraine: the principle of cooperation and the legal model of the pharmaceutical market]. *Pravo i hromadianske suspilstvo – Law and civil society, 1,* 165–176 [in Ukrainian].

3. Poltavtseva, A. S. (2014). Funktsionuvannia systemy reimbursatsii: yevropeiskyi dosvid dlia Ukrainy [Functioning of the reimbursement system: European experience for Ukraine]. *Aktualni problemy derzhavy i prava – Actual problems of the state and law, 71,* 226–232.
4. *Konstytutusiia Ukrainy [Constitution of Ukraine] (1996, July 28).* Retrieved from https://zakon.rada.gov.ua/laws/show/254%D0%BA/96-%D0%B2%D1%80 [in Ukrainian].
5. *Zakon Ukrainy «Osnovy zakonodavstva Ukrainy pro okhoronu zdorovia: pryiniatyi» 19.11.1992. [Law of Ukraine «Basics of Ukrainian legislation on health care» from November 19 1992] (1992, November 19)*. Retrieved from https://zakon.rada.gov.ua/laws/show/2801-12#n18 [in Ukrainian].
6. *Zakon Ukrainy «Pro likarski zasoby pryiniatyi» 04.04.1996. [Law of Ukraine* «About medicines» from April 04 1996] (1996, April 04, No. 123/96-VR.) Retrieved from https://zakon.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80 [in Ukrainian].
7. *Uhoda pro asotsiatsiiu mizh Ukrainoiu, z odniiei storony, ta Yevropeiskym Soiuzom, Yevropeiskym spivtovarystvom z atomnoi enerhii i yikhnimy derzhavamy-chlenamy, z inshoi storony [Association Agreement between Ukraine, on the one hand, and the European Union, the European Atomic Energy Community and other member states, on the other hand] (2014).* Retrieved from https://zakon.rada.gov.ua/laws/show/984_011#n2574 [in Ukrainian].
8. Skaskiv, T. (2017). Vidpovidnist medychnoi reformy vymoham Uhody pro asotsiatsiiu Ukrainy z YeS: pohliad yurysta [Compliance of the medical reform with the requirements of the Association Agreement of Ukraine with the European Union: a lawyer's view]. *Ukrainskyi medychnyi chasopys – Ukrainian medical journal.* Retrieved from https://www.umj.com.ua/wp/wp-content/uploads/2017/10/UkraineEU-1.pdf?upload [in Ukrainian].
9. Voron, R. M. (2010). Reimbursatsiia yak zasib hospodarsko-pravovoho rehuliuvannia tsinoutvorennia farmatsevtychnoi produktsii [Reimbursement as a means of economic and legal rehuliovannya tsinutvorennia pharmaceutic products]. *Pravo i suspilstvo – Law and society, 5,* 105–109 [in Ukrainian].
10. Poltavtseva, A. S. (2014). Funktsionuvannia systemy reimbursatsii: yevropeiskyi dosvid dlia Ukrainy [Functioning of the reimbursement system: European experience for Ukraine]. *Aktualni problemy derzhavy i prava – Actual problems of the state and law, 71,* 226–232 [in Ukrainian].
11. Bielichenko. A. V. (2010). *Derzhavne rehuliuvannia zabezpechennia naselennia likarskymy zasobamy [State regulation of providing the population with medicinal products].* Extended abstract of candidate's thesis. Kharkiv [in Ukrainian].
12. Nemchenko, A. S. & Kurylenko, Yu. Ye. (2017). Analiz normatyvno-pravovykh aktiv shchodo derzhavnoho rehuliuvannia tsin na likarski zasoby dlia likuvannia sertsevo-sudynnykh zakhvoriuvan [Analysis of legal acts regarding the state regulation of prices for drugs for the treatment of cardiovascular diseases] *Sotsialna farmatsiia v okhoroni zdorovia - Social pharmacy in health care, 3 (3).* 12–20 [in Ukrainian].
13. Soldatenko, O. (2010). Reimbursatsiia yak odyn iz vydiv finansuvannia vydatkiv na okhoronu zdorovia [Reimbursement as one of the types of financing of health care expenses]. *Viche – Viche.* Retrieved from http://veche.kiev.ua/journal/1963/ [in Ukrainian].

Стаття надійшла до редакції 12.09.2022.