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AXIOLOGICAL FOUNDATIONS OF THE ORGANIZATIONAL AND LEGAL MECHANISM FOR THE CONVERGENCE OF EU ACTIVITIES IN THE FIELD OF HEALTH POLICY

Abstract. The article addresses the issues of developing and implementing a unified strategy in the field of health policy and medical law in the European Union. The main focus is on analyzing differences between national legislations, assessing the institutional capacity of member states to adapt European standards, and studying the impact of a unified strategy on pan-European health effectiveness. Particular attention is given to the role of the European Parliament in shaping health policy and the potential of technological innovations to improve the quality of medical services. **The purpose of the research.** The purpose of the research is to determine and summarize the axiological aspects of the convergence of the European Union's activities in the field of health policy. **Methodology.** The methodological basis of the research includes an axiological analysis of national and European legislative acts, a comparative analysis of national approaches to medical standards, and an assessment of the institutional capacity of EU member states to adapt European standards. **Scientific novelty.** The scientific novelty of the work lies in the comprehensive analysis of the convergence of health policy in the EU and the study of the impact of a unified strategy on pan-European health effectiveness, with a focus on the harmonization of medical standards and regulations. **Conclusions.** The effective implementation of the EU's convergence strategy in health policy is a key factor in improving public health, preventing diseases, and eliminating threats to physical and mental health at the pan-European level.

Key words: axiology, convergence, health care policy, medical law, unification of medical standards, health care, organizational and legal mechanism.

АКСІОЛОГІЧНІ ЗАСАДИ ОРГАНІЗАЦІЙНО-ПРАВОВОГО МЕХАНІЗМУ КОНВЕРГЕНЦІЇ ДІЯЛЬНОСТІ ЄС У СФЕРІ ПОЛІТИКИ ОХОРОНИ ЗДОРОВ'Я

Анотація. У статті розглядається проблематика створення та впровадження єдиної стратегії в сфері політики охорони здоров'я та медичного права в Європейському Союзі. Основна увага приділяється аналізу відмінностей між національними законодавствами, оцінці здатності інституцій країн-членів адаптувати європейські стандарти, а також дослідженню впливу

єдиної стратегії на загальноєвропейську ефективність у сфері охорони здоров'я. Особлива увага приділяється ролі Європейського парламенту у формуванні політики охорони здоров'я та можливостям технологічних інновацій для покращення якості медичних послуг. **Мета роботи.** Метою роботи є визначення та узагальнення аксіологічних аспектів конвергенції діяльності Європейського Союзу у сфері політики охорони здоров'я. **Методологія.** Методологічною основою дослідження є аксіологічний аналіз національних та європейських законодавчих актів, порівняльний аналіз національних підходів до медичних стандартів та оцінка інституційної здатності країн-членів ЄС адаптувати європейські стандарти. **Наукова новизна.** Наукова новизна роботи полягає у всебічному аналізі конвергенції політики охорони здоров'я в ЄС та дослідженні впливу єдиної стратегії на загальноєвропейську ефективність у сфері охорони здоров'я з акцентом на гармонізацію медичних стандартів і правил. **Висновки.** Ефективне впровадження стратегії конвергенції діяльності ЄС у сфері політики охорони здоров'я є ключовим фактором покращення громадського здоров'я, запобігання захворюванням та усунення загроз фізичному та психічному здоров'ю на загальноєвропейському рівні.

Ключові слова: аксіологія, конвергенція, сфера охорони здоров'я, медичне право, уніфікація медичних стандартів, охорона здоров'я, організаційно-правовий механізм.

Introduction. The establishment of a unified strategy in the field of health policy and medical law in the European Union is an extremely important task that requires thorough analysis and integration of national approaches. Despite the adoption and implementation of numerous EU initiatives and directives aimed at unifying medical standards and regulations, national health systems of member states remain relatively fragmented and diverse. This issue has become particularly relevant in the context of global challenges, such as pandemics, and requires the development of comprehensive solutions for effectively addressing public health issues at the pan-European level.

The relevance of the problem lies in the need to study the potential benefits and challenges faced by the European Union in the context of implementing a convergent strategy in medical law and health policy. Special attention should be paid to identifying existing discrepancies between national legislations, assessing the institutional capacity of member states to adapt European standards, and examining the impact of a unified strategy on pan-European health effectiveness. This should include highlighting the potential for accessibility and quality of medical services, considering technological innovations and their integration into medical practice, and identifying ways to enhance transparency and rationality in the management of health care resources.

Such Ukrainian scientists as I. Biletska, A. Fal-kovskyi, Z. Gladun, V. Hlukhovskiy, V. Kutsik, R. Lupak, V. Matsik, V. Moskalenko, S. Nazarko, N. Nyzhnyk, O. Petrukh, Yu. Safonov, Yu. Samoilik, T. Semigina, V. Sidel, V. Spivak, M. Spivak, A. Vyalkova.

The works of such foreign authors as: D. Bach-Goletska, M. Becker, L. Bosek, K. Kovalyuk-Banchyk, A. Kraevska, M. Marshevska, E. Sobchak and others were also devoted to this issue. At the same time, revealing the convergence strategy of EU activities in the field of health care policy and medical law is such a significant and multifaceted problem that there is an urgent need for research in this area.

The axiological principles of the organizational and legal mechanism of convergence of the European Union's activities in the field of health policy play a crucial role in ensuring high standards of life and health for EU citizens. These principles include fundamental values such as the right to health, access to quality medical care, equality, and solidarity. European integration in this area contributes to the harmonization of national health policies, the reduction of disparities between member states, and the overall improvement of health-care systems' efficiency.

Harmonization of National Health Policies. At the EU level, the organizational and legal mechanism of convergence includes the creation of common regulatory standards, the harmonization of legislation, and the implementation of unified approaches to healthcare financing and management. An important tool is the programs and projects funded by the European Union aimed at strengthening national healthcare systems, particularly through the development of infrastructure, training of medical personnel, and support for scientific research in the field of medicine. These measures help create a stable and efficient health-care system that meets the needs of all EU citizens.

The convergence of health policy in the EU is also based on the principles of transparency and

accountability. Regular monitoring and evaluation of implemented measures allow for the adjustment of policies and approaches according to new challenges and needs. This process also involves active participation from the public and professional communities, ensuring democratic decision-making and considering the interests of various population groups. Thus, the axiological principles of the organizational and legal mechanism of convergence of the EU's activities in the field of health policy ensure the creation of a unified, effective, and fair system that promotes the improvement of public health and enhances the quality of life.

Regarding the relevance of convergence experience in this field for Ukraine, it is appropriate to agree with the opinion that after the signing of the Association Agreement with the EU, the Euro-integration intentions were confirmed, and the implementation of public policy in the field of public health should follow this vector. Therefore, it is recommended to implement the following measures: adaptation of the sanitary and medical regulations of European countries; development of Euro-integration cooperation in the field of public health; acquisition and dissemination of scientific knowledge in this field; monitoring the implementation of international sanitary rules; implementation of recommendations of European organizations in the field of public health; creation of new sources of funding for the public health system (Мацик, В., 2023, p. 361).

The provisions of the Treaty on the Functioning of the European Union confirm that health care is a shared competence between the EU and its member states, and that the EU has the authority to support, coordinate, or supplement national health policies to protect and improve human health. The main regulatory acts in this matter include Articles 9 and 168 of the Treaty on the Functioning of the European Union. Article 9 states that in defining and implementing its policies and activities, the Union shall take into account requirements aimed at promoting a high level of employment, guaranteeing adequate social protection, and combating social exclusion. Article 168 emphasizes that in defining and implementing all Union policies and activities, a high level of human health protection shall be ensured, which complements national policies aimed at improving public health, preventing illness and human diseases, and eliminating sources of danger to physical and mental health (Pro funktsionuvannia Yevropeiskoho Soiuzu).

This includes combating epidemics by supporting research into their causes, ways of spreading and prevention, as well as monitoring, early warning of,

and response to serious health threats. The Union complements Member States' actions to reduce the harmful effects of drug addiction on health, including information and prevention. The following paragraphs set out the EU's powers to act in the field of public health, thus setting out the EU's objectives for achieving a high level of health protection. As E. Sobchak rightly points out, the competence of the EU in the field of health care has an auxiliary nature of ensuring, coordinating and supplementing the actions of member states (Sobczak, J., 2020).

Therefore, it is possible to distinguish at least four key elements that are interconnected and determine the main strategy of convergence of EU activities in the field of health care and efforts to unify EU medical law. The first of them is content coherence, which determines the scope of competences. The second element concerns the attempt to institutionalize the integration of powers in the field of health care through the Directorate General of the European Commission (DG SANCO, known since 2015 as DG SANTE). The third is strengthening the democratic legitimacy of EU medical law. Finally, the fourth element covers the recognition and development of relevant powers at EU and Member State level.

Thus, the importance of EU legislative and political measures in the field of health care for European society is emphasized by the obligations of the European Parliament, which, as a democratic representative of European voters, initiates policy in this area. In particular, the parliament is gradually expanding its opportunities to influence the management of citizens' health care (Public health).

The main responsibility for health care and, in particular, for health care systems rests with the Member States, but the EU plays a key role in improving public health, preventing diseases, reducing health risks and unifying health care strategies between member countries. The EU effectively implemented its policy through the Health for Growth strategy and the corresponding Action Program (2014-2020) and a number of regulatory acts. The European Social Fund Plus (ESF+) continues funding within the 2021-2027 program period. The European Parliament specifies the legal basis for its actions in Art. 168 and Art. 114 of the Treaty on the Functioning of the European Union" (Pro funktsionuvannia Yevropeiskoho Soiuzu).

The importance of EU health legislation and policy for European society was underlined by the obligation of the European Parliament (as a democratic representative of the European electorate) to take initiatives in the field of health. The European Parliament has gradually developed its

capacity to respond from a health perspective to various legislative proposals, in particular through other parliamentary committees. As we can see on the official website of the European Parliament: «The Treaty of Lisbon reinforced the importance of health policy, stating that «a high level of protection of human health must be ensured in the definition and implementation of all Community policies and measures». The main responsibility for health care, and in particular health care systems, remains with the member states. However, the EU plays an important role in improving public health, preventing and treating diseases, mitigating the sources of threats to people's health and harmonization of health care strategies between Member States. The EU has successfully implemented a comprehensive policy through the Health for Growth strategy and its Action Program (2014-2020) and a number of subordinate acts. European Social Fund plus (ESF+) will continue to provide funding during the 2021-2022 program period made a decision on how the EU can achieve its goals in the end of health care through the integration of the internal market, recalling Article 114 as a legal basis (Pro funktsionuvannia Yevropeiskoho Soiuzu).

The Treaty of Lisbon, referring to the democratic legitimization of EU medical legislation, clearly defines: member states are responsible for health care policy, its organization, management and provision of medical services. They are also responsible for the allocation of resources in this field. This clarification makes it possible to clearly delineate the national spheres of competence and the sphere of action of the EU. It helps to define the limits of European competence, to create a health policy and to develop a concrete strategy. This strategy is implemented through directives, in particular through Directive 2002/98/EC. It concerns the standards of quality and safety of blood and its components, defines the requirements for collection, testing, processing, storage and distribution of blood. These actions are carried out only in specialized, authorized institutions with qualified personnel. Moreover, member states are obliged to implement special quality systems in blood donation institutions, which must conduct audits at least once every two years. Member States and their institutions should encourage voluntary and free blood donation.

According to the provisions of Directive 2002/98/EC, the collected data, including genetic information, are stored anonymously, which excludes the possibility of identifying the donor. In addition, blood donation facilities are required to perform thorough donor evaluations and check

each batch of donated blood for the presence of, for example, hepatitis B or C. They must also ensure proper storage, transportation and distribution of blood. The EU directive is aimed at ensuring a high level of quality and safety of blood and its components, which strengthens regulatory oversight in the field of blood transfusions. The integration of this directive into the national legal systems of the Member States has also had a significant impact on plasma collection and testing processes. Through the legal provisions of Directive 2002/98/EC, the European Commission, with the support of the Committee, established mandatory minimum requirements, which are taken into account in subsequent directives. This gave Member States the opportunity to adapt the regulatory mechanisms for the implementation of this directive, taking into account national specificities.

The importance of the unification of medical standards within the EU cannot be overestimated, especially in the context of globalization and increased population mobility. Standardization of procedures for evaluating the quality and safety of medical services, including blood transfusions and the use of medical devices, can ensure not only a higher level of health care, but also reduce the administrative burden on medical institutions. Measures such as Directive 2002/98/EC serve as an example of effective harmonization that can be extended to other aspects of healthcare.

Expanding cooperation between member states is also critical to developing a unified strategy for responding to medical emergencies. The EU can use existing mechanisms, such as the European Center for Disease Control (ECDC), to coordinate actions in the event of health crises, including epidemics. This will not only improve the responsiveness of response to threats to public health, but also ensure more efficient use of resources at the continental level.

Technological Innovations and Resource Management. In the context of globalization and technological progress, the integration of medical data across national borders is becoming important. The European Union has the opportunity to use the combined databases to improve the quality of medical research and improve the effectiveness of treatment. Standardization of data collection and subsequent anonymization can contribute to greater transparency and ensure the protection of patients' personal data (European Centre for Disease Prevention and Control). The EU has all the prerequisites to become a leader in the field of medical innovation. Funding startups developing the latest technologies in medicine, in particular those that

use artificial intelligence for diagnosis and treatment, can significantly strengthen the EU's role on the global stage of medical innovation. This will also contribute to the faster integration of the latest solutions into the practice of European medicine (European Institute of Innovation & Technology).

The convergence strategy of the EU's activities in the field of health care and medical law involves the integration of political and economic measures aimed at the harmonization of medical costs among member countries. The study of health care costs in EU countries shows that the convergence process is complex and differs depending on the country, which requires a careful approach to the regulation and adaptation of national health care systems (Kerem, K., Puss, T., Viies, M., & Maldre, R., 2008).

Convergence in the field of medical law in the EU also occurs through the development of uniform standards regulating clinical research, the circulation of medicinal products and the protection of patients' rights, including the right to receive medical care within the EU. These measures are aimed at increasing the availability and quality of medical services (Hervey T.K, McHale J.V., 2004). Convergence in EU medical legislation is largely determined by national policies and characteristics of countries. Legislative harmonization and convergence are key tasks for the EU, especially in the area of consumer protection, including health and safety. Understanding the impact of domestic political factors is important for evaluating the effectiveness of these processes (Goanta C, Siems M., 2019).

There is a significant unevenness in the levels of health care spending between EU countries, which requires additional efforts to achieve convergence. Studies indicate mixed results in the process of convergence between countries, depending on the methodologies and economic conditions in each country. In particular, the results indicate the stationarity of cost differences in some countries, while in others they remain unchanged (Albulescu, C., 2022).

Further expansion of European integration in the field of public health also requires a focus on the exchange of best practices between member countries. Experience-sharing initiatives can contribute not only to improved health outcomes, but also to the efficient use of limited resources. In particular, it is important to ensure that less developed health care systems can use knowledge and technologies that are already successfully applied in more developed EU countries.

Taking into account the cultural and regional characteristics of the member countries is another critical aspect in the formation of an effective health

care policy. Policies and programs must be flexible to adapt to different social, economic and cultural contexts within Europe. This will allow not only to achieve a higher level of general health care, but also to ensure fairness in access to medical services for all EU citizens.

Increasing funding in the field of public health and research should become a priority for the EU to effectively respond to future medical challenges and pandemics. Investments in medical research and development can bring significant benefits, including faster implementation of the latest treatment methods and vaccines. Strengthening efforts in this area can significantly enhance the EU's readiness for challenges and improve public health in the long term.

In conclusion, integrating innovative technologies into medical practice has enormous potential to transform healthcare in the EU. The implementation of digital technologies in medicine, such as electronic medical records and remote patient monitoring systems, can significantly improve the accessibility and quality of medical services. However, to achieve these goals, it is necessary to ensure a high level of data protection and privacy, as well as to establish unified European standards for the protection and processing of medical information.

Conclusions. Effective management of healthcare in the European Union requires the integration and unification of national health systems to create common standards and practices. Despite significant challenges in coordinating various national legislations, the EU must continue working towards forming a unified strategy that considers the needs of individual member states and promotes overall health improvement across the continent.

A central element of this strategy should be increasing transparency and accountability in EU-level decision-making processes related to health. Strengthening the role of the European Parliament in shaping health policy can help ensure more open and representative governance capable of addressing contemporary challenges. Furthermore, enhancing scientific research and implementing innovative technologies should become a key factor in improving the efficiency of medical services and ensuring a high level of public health.

Engaging member states in developing unified patient care protocols, diagnostic and treatment standards will allow the EU not only to harmonize medical practices but also to respond more effectively to public health threats such as pandemics. At the same time, it is essential to ensure that these standards are flexible enough to adapt to the specific medical and socio-cultural needs of all member states.

In this context, the EU should consider increasing funding for programs aimed at supporting citizens' health through the European Social Fund Plus and other initiatives, thereby ensuring a more sustainable and integrated healthcare system in Europe. Thus, the convergence strategy can become a decisive factor in improving the overall health of the EU population and enhancing its resilience to future challenges.

BIBLIOGRAPHY:

1. Мацик, В. Публічна політика охорони громадського здоров'я України в умовах євроінтеграційних викликів. *Вісник Хмельницького національного університету. Серія: економічні науки*, (2), 316. URL: <http://journals.khnu.km.ua/vestnik/wp-content/uploads/2023/11/2023-316-56.pdf>.
2. Консолідовані версії Договору про Європейський Союз та Договору про функціонування Європейського Союзу з протоколами та деклараціями : Договір Європейського Союзу від 07.02.1992 р.: станом на 25 берез. 1957 р. URL: https://zakon.rada.gov.ua/laws/show/994_b06#Text.
3. Sobczak J. Regulacje unijne w zakresie szczepień jako środek zwalczania chorób zakaźnych w obliczu pandemii COVID-19/SARS-CoV-2. *Ius Novum*, 14(3), 17–37. URL: <https://doi.org/10.26399/iusnovum.v14.3.2020.23/j.sobczak>.
4. Public health. URL: <https://www.europarl.europa.eu/factsheets/en/sheet/49/public-health>.
5. European Centre for Disease Prevention and Control. URL: <https://www.ecdc.europa.eu/en> (date of access: 23.04.2024).
6. European Institute of Innovation & Technology (EIT). URL: <https://eit.europa.eu/>.
7. Kerem K., Puss T., Viies M., Maldre R. Health and Convergence of Health Care Expenditure in EU. *International Business & Economics Research Journal (IBER)*, 7(3). URL: <https://doi.org/10.19030/iber.v7i3.3232>.
8. Hervey T. K., McHale J. V. Data protection and health information privacy. In: *Health Law and the European Union. Law in Context*. Cambridge University Press; 2004:159–188.
9. Goanta C., Siems M. What determines national convergence of EU law? Measuring the implementation of consumer sales law. *Legal Studies*, 39(4), 714–734. URL: [doi:10.1017/lst.2019.8](https://doi.org/10.1017/lst.2019.8).
10. Albulescu C. T. Health Care Expenditure in the European Union Countries: New Insights about the Convergence Process. *International Journal of Environmental Research and Public Health*, 19(4), 1991. <https://doi.org/10.3390/ijerph19041991>.

Environmental Research and Public Health, 19(4), 1991. URL: <https://doi.org/10.3390/ijerph19041991>.

REFERENCES:

1. Matsyk, V. (2023). Publiczna polityka okhorony hromadskoho zdorov'ia Ukrainy v umovakh yevrointehratsiinykh vyklykiv [Public Health Policy of Ukraine under Eurointegration Challenges]. *Visnyk Khmelnytskoho Natsionalnoho Universytetu. Seria: ekonomichni nauky*, (2), 316. Retrieved from <http://journals.khnu.km.ua/vestnik/wp-content/uploads/2023/11/2023-316-56.pdf> [in Ukrainian].
2. Konsolidovani versii Dohovoru pro Yevropeyskyi Soiuz ta Dohovoru pro funktsionuvannia Yevropeiskoho Soiuzu z protokolamy ta deklaratsiiamy: Dohovir Yevropeiskoho Soiuzu vid 07.02.1992 r.: stanom na 25 berez. 1957 r. [Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union with protocols and declarations: Treaty of the European Union from February 7, 1992: as of March 25, 1957]. Retrieved from https://zakon.rada.gov.ua/laws/show/994_b06#Text [in Ukrainian].
3. Sobczak, J. (2020). EU Regulations on Vaccinations as a Means to Combat Infectious Diseases in the Face of the COVID-19/SARS-CoV-2 Pandemic. *Ius Novum*, 14(3), 17–37. <https://doi.org/10.26399/iusnovum.v14.3.2020.23/j.sobczak>.
4. Public health. Retrieved from <https://www.europarl.europa.eu/factsheets/en/sheet/49/public-health>.
5. European Centre for Disease Prevention and Control. Retrieved from <https://www.ecdc.europa.eu/en> (date of access: 23.04.2024).
6. European Institute of Innovation & Technology (EIT) | EIT. Retrieved from <https://eit.europa.eu/>.
7. Kerem, K., Puss, T., Viies, M., & Maldre, R. (2008). Health and Convergence of Health Care Expenditure in the EU. *International Business & Economics Research Journal (IBER)*, 7(3). <https://doi.org/10.19030/iber.v7i3.3232>.
8. Hervey, T. K., & McHale, J. V. (2004). Data Protection and Health Information Privacy. In: *Health Law and the European Union. Law in Context*. Cambridge University Press; 2004:159–188.
9. Goanta, C., & Siems, M. (2019). What Determines National Convergence of EU Law? Measuring the Implementation of Consumer Sales Law. *Legal Studies*, 39(4), 714–734. [doi:10.1017/lst.2019.8](https://doi.org/10.1017/lst.2019.8).
10. Albulescu, C. T. (2022). Health Care Expenditure in the European Union Countries: New Insights about the Convergence Process. *International Journal of Environmental Research and Public Health*, 19(4), 1991. <https://doi.org/10.3390/ijerph19041991>.