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WORLD MARKET OF BIOLOGICAL MEDICINES

The advantages and disadvantages of globalization in the medicines market are identified. It is proved that harmonization of standards, provision of the regulatory mechanism of state cooperation in the pharmaceutical sector helps to avoid significant differences in the requirements for registration of medicinal products, reduce duplication of national procedures for the registration of medicinal products, which may affect the access of medicinal products to the global market for biological drugs.

Keywords: globalization, drug market, competitiveness, biological medicinal product, trade, international cooperation, harmonization of standards.

Шкребтиенко А. Мировой рынок биологических лекарственных средств. *Определены преимущества и недостатки глобализации на рынке лекарственных средств. Доказано, что гармонизация стандартов, обеспечение нормативно-правового механизма сотрудничества государств в секторе лекарственных средств помогает избежать значительных различий в требованиях регистрации лекарственных средств, уменьшить дублирование национальных процедур регистрации, которые могут повлиять на доступ на мировой рынок биологических лекарственных средств.*

Ключевые слова: глобализация, рынок лекарственных средств, конкурентоспособность, биологический препарат, торговля, международное сотрудничество, гармонизация стандартов.

Background. To date, the concept of «globalization» is widely used, which includes the process of economic, political and cultural convergence of states on the world level. So, the more integrated the national economy in international economic relations, the more it is influenced by the processes taking place in the world economy.

The consequence of globalization is the strengthening of international harmonization of the rules for regulating the safety, quality and circulation of biological medicinal products, as well as assessing the registration dossier when developing and examining biological medicinal products and biosimilars. The indicator above is that the global market for biologic drugs is influenced by globalization and its impact studies on the market point to urgency.

Analysis of recent research and publications. This problem has led to many studies, among which it is worthwhile to highlight the work of such scholars as D. P. Fidler, J. L. Calamaras [1], Ye. M. Belousov [2],

V. M. Pashkov [3], L. M. Deshko [4]. However, despite the close attention of scholars, it is premature to argue for a thorough study of the globalization impact of the global drug market, given the diversity of approaches, the rapid pace of globalization and the lack of a firm stand on issues that require a proper revision.

The **aim** of the article is to study the process of globalization of the market of biological medicines and its impact on the market at the present stage. To substantiate that globalization is a major factor contributing to the development of cooperation between states to ensure the safety, quality and efficacy of biological medicinal products, and the accuracy and reliability of information on medicines.

Materials and methods. The information base of the study was the work of national and foreign scientists and the current norms of international law in the complex. Methodological basis of the research are general scientific methods: dialectical, analysis, deduction, induction, abstraction, system approach, theoretical generalization and comparison.

Results. Health issues in the modern world go well beyond national boundaries and determine the safety and quality of medicines in the world market.

According to O. V. Maroshishina, the peculiarity of the pharmaceutical market as a part of the market for consumer goods and services is the tendency towards global globalization, the main reasons of which are: the unity of all mankind, the need to preserve food and natural desire to increase the longevity; the similarity in many different countries in the dynamics and prevalence of major diseases; search for the most effective pharmacotherapeutic agents; the high cost of developing and implementing new libraries, requiring the integration of efforts on an international scale; the aspiration of pharmaceutical companies as much as possible to expand the boundaries of business and win a larger market share [5, p. 160]. Globalization has an impact on the development of the listed trends and causes quantitative and qualitative changes that are expressed in increasing the risk of diseases, the emergence of new health threats and the need to develop modern methods of confronting them.

Effective counter to existing challenges is an integrated approach at the national, regional and global levels.

The main idea of global health management is to provide a more effective redistribution of available resources at the disposal of the world to increase the health of the world's population. The role of healthcare management implies «the use of official and informal institutions, rules and processes by states, intergovernmental organizations and non-state actors to effectively address health-related issues that require cross-border collective action» [1, p. 33].

Thus, global health governance is the process of integrated leadership through joint action by international health organizations, governments, civil society to achieve goals and provide leadership directions to address

global challenges. The main features of global healthcare management are complexity, dynamism, coordination of actions and the ability to affect the interests of the international community.

However, some scholars, in particular, Ye. Bilousov, in the processes of globalization from the point of view of each individual state distinguish both positive and negative factors. To negative factors, as Ye. Bilousov considers, firstly, the «servicing» by state institutions of the interests of international corporations may be attributed, which in practice leads to the weakening of the interests of the national commodity producer, removing it from external markets. Secondly, it may be the usurpation by economically developed states of «economic power». Thirdly, it may be the weakening of the sovereignty of the state by limiting opportunities for choosing activities in foreign markets. Fourthly, it may be an increase in the requirements of normative documents of interstate entities in relation to the national legislation of a particular state [2, p. 32]. The mentioned negative factors can be considered on the example of the market of medical products of Ukraine.

An example of this in Ukraine is the introduction of certain international institutions, in particular the Pharmaceutical Inspection Cooperation System (PIC/S), and the introduction of GMP (Good Manufacturing Practice) international standards. It is believed that membership in PIC/S for Ukraine is recognition of the compliance of the domestic regulatory system with world standards. However, according to the slogans of the struggle for the quality of pharmaceutical products, due to these steps in Ukraine, virtually all pharmaceutical factories were destroyed, with a few exceptions; the number of pharmaceutical manufacturers has decreased significantly. However, if it is true that Ukrainian citizens are now receiving high-quality pharmaceutical products, it is unknown, especially in conditions of total corruption in the field of public procurement, in particular in the field of health care. An example of this is the loud scandals and consequences of vaccination by the population of questionable quality drugs [3, p. 155]. L. Deshko believes that the regulatory body, in the process of licensing, has taken measures that give grounds for judging him about the reliability of the new participant, thus minimizing the risk of admittance to the health care market of potentially dangerous professional participants. Solving such tasks involves not only studying, but also checking the documents provided [4]. So checking documents will help protect private and public interests.

Ye. Bilousov refers to the positive aspects of globalization in terms of ensuring the sovereignty of a particular state by improving the economic situation by attracting investments, bank capital, a single monetary currency, mutual funds, etc. In general, the analysis of modern interstate cooperation allows us to state that the regulatory mechanisms that have developed as a result of such cooperation demonstrate different effectiveness depending on its scope [2, p. 32]. In our opinion, the main purpose of creating a powerful and competitive market for biological medicines in Ukraine is to attract investments for market development, to establish new technologies

for the production of biological medicines, to adequately finance research programs for the development and production of new biological medicines, to develop anti-crisis and warranty programs.

Globalization also affects the manufacturing and circulation of medicines around the world. In order to reduce the cost of producing medicines and meet the needs of the population, companies are forced to make components of drugs in the less developed regions of the world.

Thus, India and China are on the first and second place among countries seeking to overcome the West's superiority in the global drug market in the coming years; in the third, South Korea, a group of emerging markets is closing – Brazil, Mexico, Russia, Turkey [8]. Low levels of drug control in developing countries can lead to increased production and import of counterfeit and low-quality medicines, and may lead to corrupt activities and unethical clinical trials of medicinal products.

Even organizations with sufficient technical and material resources, such as the Food and Drug Administration, do not have the capacity to carry out their activities without proper legal regulation and the implementation of high quality standards and the safety of the entire spectrum of medicines, including biologic ones, in developing countries. Differences in legal regulation are a problem for large corporations, which are forced to re-examine and registration procedures for the circulation of medicines on a global scale.

The globalization of the pharmaceutical market, supported by research, the development of the creation, production and enhancement of the needs of medicines, requires the development of international cooperation and harmonization of standards. Thus, harmonization of standards, provision of a normative legal mechanism of cooperation of the states in the sector of medicines helps to avoid significant differences in requirements, to reduce the process of duplication of procedures during registration of medicines, which may affect the access of medicines to the market.

An example of the process of globalization of the economy is the World Trade Organization. It is advisable to distinguish the advantages and disadvantages for countries participating in the World Trade Organization on the pharmaceutical market.

According to O. Mironishina the apparent advantage of free trade for the consumer is to reduce the cost of living by reducing protectionist trade barriers. As a result, the reduction of barriers is reduced not only ready-made imported goods and services, but also domestic products, the production of which uses imported components. Import competition stimulates effective domestic production, reduces prices and improves the quality of manufactured products. Also, as a result of active commodity exchange, new technologies are developing. The increase in exports of domestic products also increases producer revenues, competitiveness and tax deductions to the budget. The development of trade leads in the long run to increasing employment. The application of the principles of the WTO

can improve the efficiency of foreign economic activity [5, p. 161–162]. Consequently, the principle of non-discrimination, transparency, trade-offs and simplification procedures are an integrated approach to creating a supportive environment for trade and investment in the pharmaceutical market.

In the short term, job losses as a result of competition between domestic enterprises and foreign producers are inevitable. Despite the fact that the country's economy wins, some industries may lose. Therefore, it is necessary to distinguish between national and sectoral interests. Industry interest is to have access to the foreign market, to imported components and raw materials, while protecting the domestic market from the importers of competing products. Industry interests are often controversial. Even in countries with a developed civil society, when discussing the problems of international trade, the advantage (for obvious reasons) is given to large businesses, while the interests of the population and small businesses are not fully accounted for. In Ukraine, this is accompanied by the underdevelopment of civil society institutions and the fact that some industries that will emerge as a result of embedding into the global economy, as yet absent or embryonic. The main argument of protectionism, the so-called infant industry argument: if the industry is almost competitive in the global economy, it should be protected (by tariffs, quotas) for some time until it reaches the level of competitiveness, and then open the market [6, p. 11]. This approach is relevant, as most states have tried to apply it, but they are faced with the following phenomenon: a particular industry declares itself to be almost competitive and needs protection (in this case, not only new and growing industries are successful).

The TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) is of great importance for the development of the pharmaceutical market.

The TRIPS agreement protects not only the technological process by which the drug is produced, but also the preparation itself. It is therefore impossible to produce and sell an analogue of a proprietary medicinal product obtained by a new technological process. Some countries (India, China, Brazil, Malaysia, Thailand, Mexico, Argentina, Egypt and Canada) signed an agreement on TRIPS or excluded medicines from the scope of their patent system, or provided patents only to the technological process. Without patent for the drug, local companies could develop drugs using processes that differ from those that were patented, and thus produce cheaper local versions of the drug.

Ukraine, alike many other countries, applies increased requirements for the protection of intellectual property, which makes it possible to apply the «flexible elements» of the TRIPS Agreement. Their application would ensure the innovative development of the domestic pharmaceutical industry; remove barriers to access of patients to innovative medicines, ensure balance between the rights of patent holders and health of the population, reducing the burden on the budget [7, p. 163]. It is worth

agreeing that the TRIPS agreement is an important step in the development of the market for medicines in Ukraine and ensuring accessibility to them.

There is a significant impact of the TRIPS Agreement on the cost and availability of medicines: the granting of exclusive rights to a drug for a period of 20 years will allow the patent holder to maintain high prices for a patented product; it will be prohibited to place on the market copies of a patented patent medicinal product, which were either previously carried out internally or imported [7]. Based on the foregoing, the TRIPS Agreement had a mixed impact on the world market for medicines.

The World Health Organization has expressed its views on the TRIPS Agreement.

Firstly, patent protection is a necessary and effective incentive for research and development of new drugs. Since essential medicines do not belong to ordinary consumer goods, patent issues should be dealt with on an equitable basis, in the interests of both patent holders and society. Protectionism has never been to the benefit of public health. The World Health Organization supports the government in adopting national legislation that will help win a more open trade system and a better regulated system of international relations. Secondly, the World Health Organization strongly supports the development of mechanisms to establish preferential low prices for essential medicines in low-income countries. Finally, trade agreements should not create barriers to trade. An important principle of the WTO is the following: technical rules, standards and procedures should be based on international standards, guidelines and recommendations. In the field of medicines, such an international consensus is reflected in World Health Organization standards, standards and guidelines. World Health Organization will actively promote these guides [8, p. 20].

The globalization processes affected the World Health Organization, which resulted in the introduction of World Health Organization guidelines for biological products, including the 2017 Bio-Related State Health Center, the Ministry of Health of Ukraine.

The World Health Organization experts formulated four options for responding to the presence of bio-like substances on the market by regulatory authorities that have been granted permission to meet the current requirements for these drugs:

- to leave the biological/biotechnological medicinal product on the market and to strengthen its supervision after the issuance of the registration certificate in order to identify possible side effects associated with its use;
- immediately remove the drug from the market;
- to withdraw a medicinal product only if one or another problem is detected related to its safety or efficacy;
- to leave the drug on the market for a period of time, during which it is compulsory manufacturers to submit missing data and a «risk management plan» for regulatory review in order to support the extension of the license [9].

The main objective of the guidelines is the expediency of improving processes

and methods for controlling the safety and efficacy of biological medicines and biosimilars to reduce the risk of their medical use.

The analysis of the above shows that the globalization of the market of medicines at all stages of the creation of these products – from research to implementation and regulatory regulation – requires the development of international cooperation. Therefore, international law is a regulator of cooperation between regulatory authorities of the countries of the world and the approximation of technical standards.

Conclusion. The results of the study showed that the global market for biological medicines is affected by globalization, which has several advantages and disadvantages, and results in quantitative and qualitative changes that are expressed in the need to develop new biological medicinal products. Thus, an effective response to existing challenges is a comprehensive approach at the national level, within the framework of the World Trade Organization and the World Health Organization.

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Шкребтієнко А. Світовий ринок біологічних лікарських засобів.

Постановка проблеми. *Міжнародне право є базою співпраці між регуляторними органами різних держав світу і зближення технічних стандартів. Основним чинником, що впливає на світовий ринок біологічних лікарських засобів, є глобалізація, а дослідження її впливу на ринок свідчать про актуальність вивчення цієї проблематики.*

Мета *статті – дослідити вплив глобалізації на ринок біологічних лікарських засобів на сучасному етапі; обґрунтувати, що саме глобалізація є основним чинником, який сприяє розвитку співробітництва держав для забезпечення безпеки, якості та ефективності біологічних лікарських засобів, а також точності та достовірності інформації про лікарські засоби.*

Матеріали та методи. *Інформаційною базою дослідження стали праці вітчизняних та зарубіжних науковців та комплекс чинних норм міжнародного права. Методологічну основу дослідження становлять загальнонаукові методи: діалектичний, аналіз, дедукція, індукція, абстрагування, системного підходу, теоретичного узагальнення та порівняння.*

Результати дослідження. *Питання охорони здоров'я у сучасному світі виходить далеко за рамки державних кордонів, зокрема, визначаючи безпеку та якість лікарських засобів на світовому ринку. Глобалізація ринку лікарських засобів на всіх етапах створення цієї продукції – від науково-дослідних робіт до реалізації і нормативного регулювання – потребує розвитку міжнародного співробітництва і гармонізації. Гармонізація стандартів, нормативної бази в секторі лікарських засобів допомагає уникнути значних відмінностей у вимогах, мінімізувати дублювання національних процедур реєстрації лікарських засобів, які можуть вплинути на доступ біологічних лікарських засобів на світовий ринок.*

Висновки. *Доведено факт впливу глобалізації на світовий ринок біологічних лікарських засобів. Виявлено як переваги, так і недоліки цього процесу. Встановлено, що саме глобалізація зумовлює кількісні й якісні зміни, що потребує розробки нових біологічних лікарських засобів. Аргументовано, що єдиними структурами, які сприяють ефективному правовому регулюванню світового ринку лікарських засобів, є Світова організація торгівлі та Всесвітня організація охорони здоров'я.*

Ключові слова: глобалізація, ринок лікарських засобів, конкурентоспроможність, біологічний лікарський засіб, торгівля, міжнародне співробітництво, гармонізація стандартів.