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CHALLENGES OF THE COVID-19 PANDEMIC TO PHARMACEUTICAL MANUFACTURING: THE EU AND UKRAINE'S RESPONSE

The global COVID-19 pandemic, which caused a shortage of medicines and medical products, as well as pharmaceutical products, especially active pharmaceutical ingredients, demonstrated Ukraine's unpreparedness to face such challenges and threats. This encourages the search for effective mechanisms to reduce vulnerability, ensure stability and develop pharmaceutical activities. The purpose of the article is to draw on the experience of the European Union to justify the need to introduce measures of the policy of stimulating the development of pharmaceuticals in Ukraine in order to reduce the dependence of the sector and the healthcare system on imports. To achieve the goal of the article, the authors used analysis and synthesis, logic-dialectic and comparative analysis methods. The article shows the nature and extent of existing dependencies of pharmaceutical production; and identifies features of the EU policy. The EU was found to have a long history of prioritizing and promoting pharmaceutical industry. It is shown that the new EU strategic documents adopted in response to the COVID-19 crisis laid the foundation for the elimination of the industry's vulnerabilities and external trade dependencies. For the first time, a conceptual approach to the formation of a dualist state policy and strategy for the development of Ukraine's high-tech pharmaceutical production was proposed, which is based on synergies and complementary policies between drug policy and industrial policy. This approach is aimed both at stimulating the development and production of new pharmaceuticals based on advanced technologies and reducing the dependence of this country's healthcare system on imports. Also, the approach aims at enhancing the competitiveness of pharmaceutical production, increased localization through the use of locally produced products, intensifying related activities, ensuring stability of supply of pharmaceutical products and transforming the industry into a strategic asset of growth of the economy, employment, and national security. The

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authors propose a conceptual approach to defining the priorities and programme tasks of the policy for the development of Ukrainian high-technology pharmaceutical production based on the principles of multi-dimensionality and comprehensiveness, and covering the development and production not only of medicines and medical products, but also of pharmaceutical ingredients (chemical and biotechnological), fillers and packaging materials, equipment and apparatus for pharmaceutical production. The principles of the formation of a strategy for the development of the high-tech pharmaceutical production of Ukraine are justified based on the balance of interests of consumers and producers of pharmaceutical goods with the interests of the State, based on its following goals: to care for the health of the nation, ensure an efficient economic system and social stability; promote the emergence of new effective drugs based on advanced technologies; and reduce dependence on imports and threats to national security.

Keywords: *Eurointegration, pharmaceutical industry, pharmaceutical policy, industrial policy, technological dependence, high-tech manufacturing*

Problem Statement. The global COVID-19 pandemic hit the pharmaceutical industry harder than any other economic shock in modern economic history, including the financial crises of 1997-98 and 2008-09, causing supply disruption and blockages. The negative impact was particularly severe for national health systems - with the inability of local producers to meet needs for essential medicines and medical products. The EU leadership, assessing the reasons for this situation, pointed to the dependence of EU member states' pharmaceutical production on imports from third countries of active pharmaceutical ingredients (APIs), some drugs and commodities related to COVID-19 [1]. The Ukrainian pharmaceutical industry had a similar impact but on a larger scale due to operating predominantly on imported substances [2]. The closure of foreign plants supplying APIs due to strict quarantine through COVID-19, the introduction of a ban in certain countries, particularly India, to export certain types of APIs, and the inaccessibility of air and sea transportation resulted in market shortages of both intermediate and finished products (medicines) and medical products, prompting the leadership of both the EU and its member states and Ukraine to look for ways out of the crisis situation, and reduce vulnerability and dependence of pharmaceutical production [3]. The **purpose** of the article is to reveal features of the public policy of pharmaceutical development in the EU and Ukraine; to identify changes in public administration mechanisms in response to the challenges of COVID-19 pandemic; to substantiate recommendations on the basis of development of high-tech pharmaceutical industry of Ukraine, based on national innovation achievements, and to identify strategic priorities and actions, taking into account current threats, as well as experience and recent changes in EU policy. We need to solve the following tasks: 1) identify the main cause of dependence of pharmaceutical industry and show the EU management's strategic decisions taken in response to the challenges of the COVID-19 pandemic; and 2) assess the features of formation and implementation of pharmaceutical policy in Ukraine, and to identify gaps in the approaches and justify the necessary changes.

The analysis of recent studies and publications. Ukraine's scientists drew attention to the problems of pharmaceutical activities since Ukraine's independence [4-5]. They outlined the features and strategic guidelines for the development of Ukrainian pharmaceuticals [6-8], the problems and prospects of the course towards EU membership, the priority of the pharmaceutical industry to accelerate high-tech growth [9], and possible effects of European integration on pharmaceuticals [10]. They also justified the role of government regulation in counteracting and overcoming the global coronary crisis triggered by the SARS-CoV-2 virus [11], outlining a vision for its causes and solutions in EU countries [12], and proposed a toolkit for assessing the value-added benefits of pharmaceuticals and emergence of new players [13].

Research methodology. To achieve the goals and to solve the tasks set for this research, the authors used the methods of analysis and synthesis, comparison and grouping (to study the regulatory framework in the sphere of pharmaceutical regulations), tools to stimulate the development of the industry through the provision of state aid; the logical dialectical method and the method of comparative analysis. In particular, comparative historical analysis was used to study the experience of EU countries in terms of pharmaceutical development in order to reveal the evolution of policy mechanisms, and to assess the role of the state; functional analysis was used to characterize initiatives for the development of pharmaceutics and the adopted legal and regulatory acts in terms of their impact on the industry's development; structural analysis was used to identify the limitations of high-tech pharmaceutical manufacturing development in Ukraine and the development of public policy and strategy framework based on a holistic approach.

Presenting main material.

The scale and nature of the existing dependencies of the EU pharmaceutical production

Assessing the impact of the pandemic on the EU economy, EU policymakers called the situation "external trade dependency" [14], noting that the COVID-19 pandemic crisis raised the issue of dependency of EU industrial ecosystems (including pharmaceuticals) on key technologies that affect industry competitiveness. The European Council in 2020 recommended that the Commission identify strategic dependencies[3], especially in the most vulnerable industrial ecosystems, in particular, to ensure the functioning of the health system, and propose measures to reduce these dependencies [15].

The problem of the external dependence of pharmaceutical production and development is not new [16, 17]. In the past, however, it was unique to developing countries[4]. UN specialists noted the problem of technological dependency when *a*

[3] Strategic dependencies are defined as those that affect the main interests of the EU. In particular, these include areas relating to security, health and care, access to goods, services, and technology.

[4] In [2] it was noted that this issue was raised by supporters of the theory of dependent development, pointing to the dependence on foreign technological resources as a key obstacle. T. Santos drew attention to TNCs, which are holders of advanced technologies, as the reason for the formation of *technological-industrial dependence* due to their impact on the internal structure and orientation of production in recipient countries.

major source of technology is abroad; if a country's industry imports this technology, it has a very high degree of technological dependency while building local production capacity. In their view, dependence on imports of critical resources and means of production as carriers of technology is a form of technological dependence [18].

But international trade disruptions and shortages in a number of EU countries (which were caused by the COVID-19 pandemic) revealed another form of dependency. Experts from the European company Pro Generika analyzed the global production of Active Pharmaceutical Ingredients (APIs) and, in particular, the issuance, over the past 20 years, of Certificates of Suitability to the Monographs of the European Pharmacopoeia (CEP), which show that the quality of the substance meets EU requirements [19], and drew the following conclusions:

Europe is losing (and lost on certain items) its strong position in API production; taking into account the trends in new CEPs between 2000 and 2020, Asia is already well ahead of Europe: Asian producers increased their CEPs from 183 to 2369, while European producers - from 348 to 1260 CEPs (Figure 1).

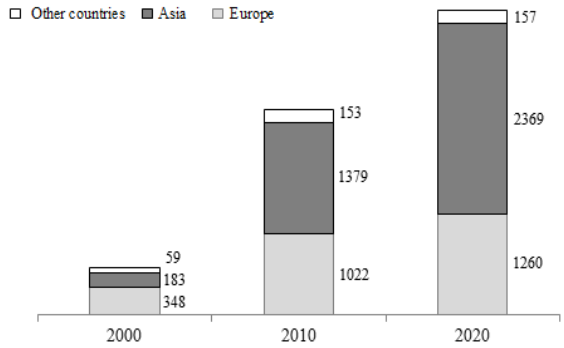

Figure 1. The dynamics of issuing CEP in global regions (2000-2020)

Source: Woher kommen unsere Wirkstoffe? Eine Weltkarte der API-Produktion. (September 2020). Kurzreport. Pro Generika. Berlin. 16 p.

The supply of APIs to Europe is quite vulnerable and has significant risks, as 2/3 of the current CEPs for APIs belong to Asian manufacturers, among which Indian and Chinese companies dominate, which are localized in several provinces[5] (Figure 2, 3). At the same time there are no European drug analogues for 1/6 of APIs; there are between 1 to 5 CEPs for more than half of APIs. In other words, their manufacturers worldwide are very few. European companies focus on certain high-tech APIs with complex manufacturing processes that are produced in low quantities[6].

[5] Chinese API exports increased by 14% annually, together with its market share in more than 70 countries and regions in North America, Europe, Latin America and Asia. Pharmaceutical production is concentrated in China's eastern and southern regions. East China, covering the provinces of Shanghai, Zhejiang, Fujian, Anhui and Jiangxi, has long been known as a pharmaceutical hub because a number of low-molecular-weight API manufacturers are localized there, while the southern region specializes in biologics. Hubei Province, the epicenter of the COVID-19 pandemic outbreak in China, is adjacent to these provinces and has a number of large pharmaceutical companies.

[6] European manufacturers retain their key position for specific high-tech APIs with small output and complex production processes. The member countries with the highest number of registered production sites include

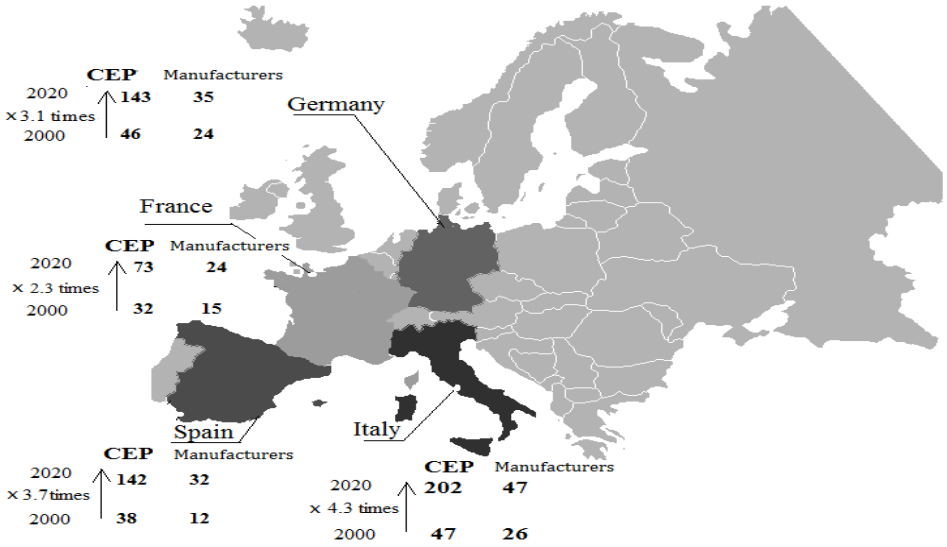

Figure 2. The dynamics of issuing CEP to manufacturers by European countries (2000-2020)

Source: compiled based on: Woher kommen unsere Wirkstoffe? Eine Weltkarte der API-Produktion (September 2020). Kurzreport. Pro Generika. Berlin.. 16 p.

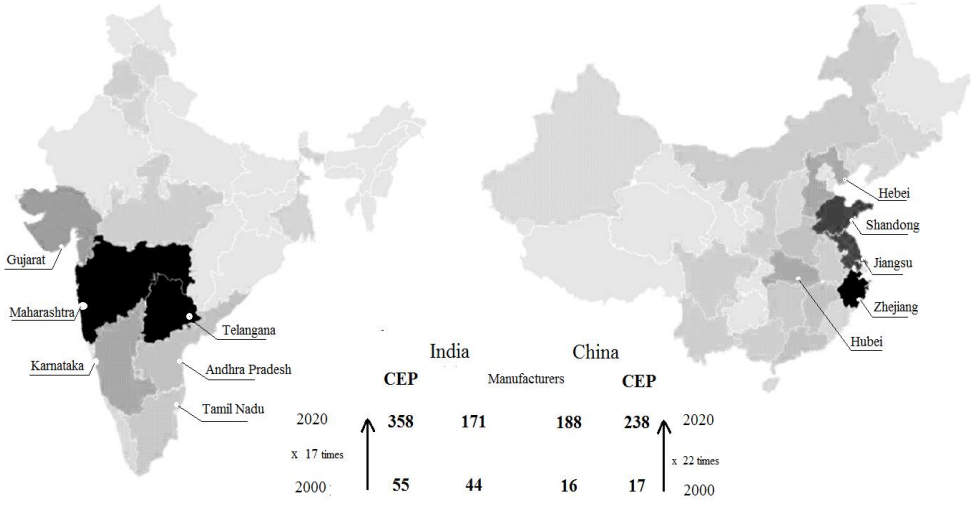

Figure 3. The dynamics of issuing CEP to manufacturers in India and China (2000-2020)

Source: compiled based on: Woher kommen unsere Wirkstoffe? Eine Weltkarte der API-Produktion (September 2020). Kurzreport. Pro Generika. Berlin. 16 p.

The difference between pharmaceutical standards and regulations in Asia and Europe, together with pricing pressures[7], are the main reasons for the development,

Italy (185), France (149), Germany (92), Spain (87) and Poland (84). European API manufacturers have a reputation for the highest quality and have an important share in the world market for high-tech APIs.

[7] As noted in [12, 13] with the reference to primary sources, lower production costs in India and China were the driving force behind the transfer of API production to these countries, as the costs of developing, testing, producing and marketing the generics here are 20-40% of the corresponding cost

which resulted in the fact that India and even China are now dominating in the API market [20] (Figure 4) making the pharmaceutical industry in developed and developing countries strategically trade dependent on a number of important factors.

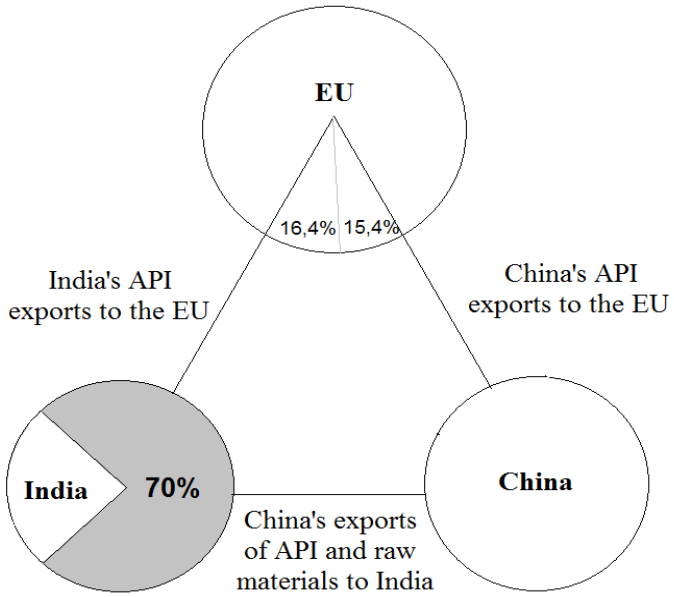

Figure 4. Key suppliers of generic APIs to the EU

Source: compiled based on: The EU's API supply chain under focus. Special Report (2021, June 8). *Chemical Weekly*, 161.

Everything mentioned above shows that the increase in the production of intermediates (raw materials and processed products) for the manufacture of medicines (mainly generics), together with the simultaneous decline of these industries in Europe led to a concentration of the production of strategic commodities in China and India, turning these countries into a major source of pharmaceutical ingredients for both developed and developing countries. The technological, human and manufacturing resources available in the EU are capable of expanding API production and therefore do not have a technological dependency. We can say that with globalization and offshoring, as well as the active policies of the Chinese and Indian governments, another form of industry dependency developed, which can be called "**component dependency**"[8]. It began to take shape in the 2000s and emerged

in the West. The main advantages of India and China were lower labor, infrastructure, transportation and equipment costs. While an average Western API company has an average wage index 100, an average Indian API company has 10, and an average Chinese API company – 8. Even the higher productivity of Western companies (due to increased automation of production processes) cannot offset the difference in labor costs. In addition, India and China have lower costs for electricity, coal and water. Firms in these two countries often use cheaper equipment, resulting in lower depreciation costs. These countries are also attractive to foreign investors because of their low environmental requirements.

[8] Pharmaceutical production in developed countries depends on pharmaceutical intermediates (ingredients) of foreign origin, affecting the competitiveness of the final product, while increasing the production of medicines (mainly generics). Transferring the production of some components from Asia to Europe is considered technically feasible, but not profitable. As noted in [12], German experts investigating the prospects of localizing the production of antibiotics (cephalosporins) in Germany

due to disruptions in the importation of pharmaceutical starting products in the face of the COVID-19 pandemic.

Key aspects of the EU policy that determine the industry's development and their changes in response to the challenges of the COVID-19 pandemic

For the EU leadership, the pharmaceutical industry is a strategic priority[9]. A number of official EU documents, dating back to the 1990s, laid the foundation for modern policies in the field. In particular, in the Council Resolution of 23 April 1996 aimed at implementing the basic principles of industrial policy for the EU pharmaceutical sector EU [22], set out in the 1994 Commission Communication [21], the EU leadership drew attention of the member states to the importance of the link between policies to control costs in the health sector and measures to ensure the competitiveness of national pharmaceutical industries [21][10]. 20 years ago, the document ***"Pharmaceutical industry: a strategic sector in the European economy"*** [23] outlined the industry development priorities to be implemented during 2014-2020 in the framework of "Horizon 2020"[11] and the EU Structural Funds for 2014-2020. However, despite the strong position of European producers on the global market, the COVID-19 pandemic hit the sector harder than any other economic shock in EU history.

In order to maintain the competitiveness, innovation potential and sustainability of the EU pharmaceutical industry, a new ***"Pharmaceutical Strategy for Europe"***, created as a result of a social dialogue, was adopted in 2020 [24]. In order to implement it, the EU is introducing measures to ensure an enabling environment for the pharmaceutical industry. As the sector's traditional companies increasingly outsource production processes and focus investment in a limited number of therapeutic areas (the most commercially needed ones), while abandoning investment in other important areas, more government regulation is needed, according to the strategists. Namely, a pharmaceutical strategy for Europe based on the mechanisms of the ***"New industrial strategy for Europe"*** [25].

concluded that this is important but not economically feasible due to higher production costs and low prices. However, given the strategic importance of antibiotics, launching their production requires: government intervention in market mechanisms to raise final prices, government subsidies for production costs, and government compensation for creating the capability to minimize supply risks.

[9] In the European Commission Communication on Industrial Policy Principles for the EU Pharmaceutical Sector 1994 [21], it was noted that the industry is among the most efficient high-tech sectors in Europe; it generates a huge number of jobs in the economy; and plays a key role in the health care system as well as in the social security system (as the ability to finance consumption of pharmaceutical products has a direct impact on national social security budgets). The European Commission has determined that since the pharmaceutical sector is an important asset for the economy (in terms of both growth and employment), its underlying economic strength and competitiveness need to be supported through industrial policy.

[10] The basic principles of industrial policy on pharmaceuticals were identified as: encouraging innovation through a competitive market and changes in the regulatory framework; protecting new medicines by intellectual property rights, both in the EU and in third countries; ensuring the availability of medicines that provide better health protection for European citizens; promoting research on innovative therapies of particular relevance to public health and encouraging research on rare diseases and the development of appropriate medicines.

[11] The Innovative Medicines Initiative (IMI) has become one of the flagships of Horizon 2020 health research, a public-private partnership in the life sciences between the EU and the European pharmaceutical industry.

The implementation of the priorities of the Pharmaceutical Strategy for Europe is supported by a number of EU programs. In particular, in 2020, the European Commission announced the allocation of over €1 billion from the EU's Horizon 2020 research and innovation program to tackle the challenges of the pandemic. As of February 2021, €781 million of the planned €1 billion was mobilized, including €602.3 million to support R&D and innovation projects in many aspects of the pandemic: diagnostic tools, treatments, vaccines, epidemiology, outbreak preparedness and rehabilitation, socio-economic aspects, mental health, pharmaceutical production and digital technologies, and the infrastructure and databases that make these projects possible [26] (Figure 5).

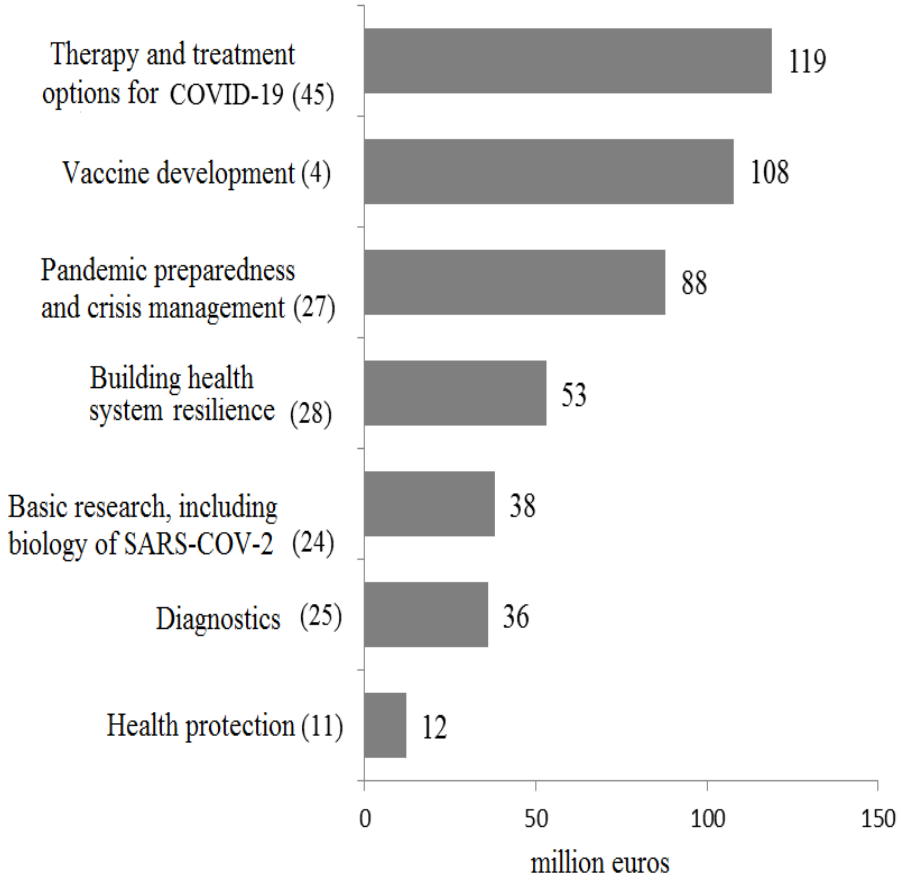

Figure 5. Financial assistance for projects addressing pandemic challenges (by thematic area), *number of projects*

Source: EU research and innovation in action against the coronavirus: funding, results and impact. URL: https://ec.europa.eu/info/sites/default/files/research_and_innovation/research_by_area/docu-ments/ec_rtd_eu-research-innovation-against-covid.pdf

As vaccine development is a complex and time-consuming process, in order to accelerate it and get results in 12–18 months (or earlier) in June 2020, the European Commission adopted the **"EU Strategy for COVID-19 vaccines" (hereinafter referred to as the vaccine strategy)** [28]. Its key objectives are to ensure EU production and sufficient supplies of vaccines to member states through *advance*

purchase agreements with vaccine manufacturers[12] through *an emergency support mechanism*[13]; and to adapt the EU regulatory framework to the current challenges, using existing regulatory flexibility to speed up vaccine development, authorization and availability while maintaining vaccine quality, safety and efficacy standards.

As part of the implementation of the vaccine strategy, the European Commission started negotiations with developers and manufacturers on a diversified portfolio of vaccines for EU citizens at fair prices. Contracts have been concluded with six companies, bringing the portfolio to 4.4 billion doses. The supply of vaccines to the EU are increasing since December 2020. The Commission issued four marketing authorizations for vaccines developed by BioNTech and Pfizer, Moderna, AstraZeneca and Janssen Pharmaceutica NV, following a positive assessment by the European Medicines Agency on their safety and efficacy [29].

The next step on the part of the EU leadership was the adoption of the **"EU Strategy on COVID-19 Therapeutics"** (hereinafter referred to as the treatment strategy) on 6 May 2021 [30]. The aim of the treatment strategy is to have three new therapeutic products available by October 2021 and possibly two more by the end of the year.

The process of selecting these drugs for inclusion in the EU portfolio will be based on scientific criteria, a list of which will be agreed upon with member states. The selected drugs will receive a full package of scientific and financial support – from R&D to production launch and supply to consumers. As in the early 1990s, the development of pharmaceuticals is not only a health policy but also an industrial policy. In the **"New Industrial Strategy for Europe"**, presented on 10 March 2020, the European Commission noted that the creation of key enabling technologies, among them biotechnology and pharmaceuticals, is of strategic importance for Europe's future industry. The document states that access to medicines and medical products is important for Europe's security and independence in today's world.

On 5 May 2021, the EU authorities presented a revised "New Industrial Strategy for Europe" [25] under the circumstances of the COVID-19 pandemic, among its objectives to ensure industrial sustainability and reduce dependency on industrial ecosystems, among them the industrial ecosystem "Health" covering pharmaceutical and medical products, personal protective equipment, and health services. The aim of the strategy is to facilitate stakeholder engagement and help policymakers and

[12] *Advance purchase agreements (APAs)* are an important incentive tool for pharmaceutical companies. To accelerate vaccine development and production, the European Commission enters into agreements with individual vaccine manufacturers on behalf of the Member States. In exchange for the right to buy a certain number of doses of vaccine within a set period of time, the Commission funds a portion of the initial costs incurred by vaccine manufacturers. This takes the form of advance purchase agreements. The funding provided is considered as an advance payment for vaccines that will actually be procured by Member States. The associated funding is largely delivered through the Emergency Support Mechanism.

[13] The Emergency Support Mechanism consists of EU activities to mobilize resources within Europe when an emergency crisis affects one or more EU Member States. In the context of the pandemic, the EU allocated €2.7 billion to support Member States in the immediate response, exit and recovery phases of the pandemic. The emergency support mechanism allows funds to be channeled to: research and production of medicines and vaccines; development, purchase and distribution of diagnostic and testing consumables; transportation of patients and medical staff in EU member states; and procurement of essential medicines.

investors identify the most important players in each ecosystem when preparing national and regional recovery plans and investment projects in pharmaceuticals and medicine. Among the priorities: a diversified international partnership (ensuring an enabling environment for trade and investment to continue to play a key role in strengthening EU economic sustainability); industrial alliances (launching platforms that accelerate activity in industrial ecosystems, help attract private investors, and integrate start-ups and SMEs into common projects); and the monitoring of strategic dependencies (detecting the EU's strategic dependencies on supply from foreign sources of products in the most vulnerable industrial ecosystems, pharmaceuticals among them).

The aforementioned policy documents demonstrate the active policy of the EU leadership to stimulate pharmaceutical development. During the COVID-19 crisis, the European Commission approved numerous measures compatible with the internal market, in particular: assistance to promote certain sectors or industries (Articles 107 (3) with TFEU). The EU leadership has introduced an investment aid mechanism for the production of items to help in the fight against COVID-19 [28]. The intensity of the aid is up to 80% of the project costs. A number of countries received approval from the European Commission for such aid, including Poland, Ireland, Germany, Hungary, the Czech Republic, etc.

Key guidelines of Ukrainian policy on the industry's development and their change in response to the challenges of the COVID-19 pandemic

After gaining independence in the early 1990s, Ukraine was left with pharmaceutical factories specializing mainly in the production of finished medicines, while the synthesis of chemical substances and production of excipients and raw materials was virtually non-existent – 80% of suppliers of intermediate pharmaceutical products remained outside Ukraine, which led to the cessation of production of more than 50 essential medicines. At that time, the country's pharmaceutical industry was "totally dependent on imported substances and raw materials" [4, p. 3]. Industry experts noted that such a situation in the pharmaceutical market could pose a threat to the national security of Ukraine [5, p. 159].

In the paper *"Threats to pharmaceutical production in Ukraine in the context of foreign trade analysis of high tech goods"* [31], in 2016, one of the authors, D. Honcharenko, noted a number of obstacles to the development of the industry, first and foremost, a high dependence on imported ingredients. Taking into account the identified threats, the paper presents proposals to improve methodological approaches to the analysis of foreign trade in high-tech pharmaceutical products and justifies the appropriateness of using authoring tools, which are based on List of high-tech pharmaceutical goods according to the Ukrainian Classification of Goods for Foreign Economic Activity (according the Standard International Trade Classification (SITC – Rev. 4), with a separation of final goods, namely: intermediate goods – outputs for industrial production and consumer goods – for the public health system. The author noted that "it is appropriate to construct balances and make projections of dynamic shifts in its components (imports, Ukraine's consumption, exports) based on this list. Tracking changes in the balance structure of certain

commodities will minimize threats to the high-tech sector of the economy and facilitate timely managerial decisions to prevent shortages in the raw and processed items that are the inputs to pharmaceutical production. On the other hand, it will stimulate increased output and exports of Ukraine's high-tech goods" [31, p. 32].

This proposal was the basis of the Recommendations of the hearings of the Verkhovna Rada Committee on Science and Education: "Legislative support for the development of the National Innovation System: status and solutions" (15 June 2016) [32][14], but it was never implemented. However, **measures that authorities could have taken following the identification of strategic commodities on which Ukraine's pharmaceutical production depends could have prevented shortages of inputs to pharmaceutical production that occurred during the COVID-19 pandemic**. As the 2020 calculations showed, Ukraine's pharmaceutical production increased its external dependence on imports of high-tech pharmaceutical intermediates. They account for up to 82% of the industry's consumption structure.

V. Khomenko noted that during the years of independence in Ukraine, significant problems emerged in public administration, while the governance "vertical" was lost, which had a negative impact on the organization of pharmaceutical activities and provision of medicines to the population. In Khomenko's opinion, one of the main reasons for this state of affairs is the lack of a systematic approach to justifying the principles and mechanisms of state management of the industry's development [6].

The author's research showed that the practice of the Ministry of Health's initiatives over the last 10 years confirms the above statement. A retrospective analysis of the adopted laws and regulations showed that in order to combat socially significant diseases in Ukraine, since the early 2000s the government adopted and implemented a number of programs that provided for the annual purchase of medicines and medical devices with public funds. As the industry's experts pointed out 10 years ago, "the bulk of public funds is spent on the purchase of imported medicines and only a small amount on the purchase of medicines produced by Ukrainian pharmaceutical companies" [33]. The Ministry of Health of Ukraine submitted draft policy documents on the creation of domestic medicines and import substitution for public discussion, but they either were not adopted or not implemented [34]. What are the key initiatives and legally regulated measures on pharmaceutical activities in Ukraine?

In March 2010, the Ministry of Health of Ukraine submitted for public discussion the **Draft Concept of the State Target Program for the Creation of Domestic Immunobiological Preparations "Ukrainian Vaccine" for 2011–2015**, justifying the necessity of this normative legal act as follows:

- Ukraine does not have a single powerful modern biotechnology center capable of rapidly addressing the urgent needs of medicine and pharmacology;
- the country hardly ever has any scientific and laboratory base for the development of modern domestic vaccines, genetic diagnostics and new-generation antibiotics.

[14] In particular, the instructions to the Ministry of Health of Ukraine include: "24.2) provide regulatory support and annual analysis of imports of pharmaceutical products that are the source for pharmaceutical production in Ukraine, constructing balances, in the context of these strategic goods, and forecasting changes in its components (imports, domestic consumption, exports)".

The only possible way out of this situation was identified as the urgent organization of domestic production of immunobiological preparations, which are massively used in this country. This draft was developed in response to the decision of the NSDCU of 18 January 2006 "On measures to enhance the effectiveness of the fight against dangerous infectious diseases", approved by Presidential Decree No. 132/2006 of 14 February 2006; and the decision of the National Security and Defense Council of Ukraine of 27 February 2009 entitled "On biological security of Ukraine", approved by Presidential Decree No. 220/2009 of 6 April 2009. **But despite its importance and relevance, the Ukrainian Vaccine Program, initiated in 2010, was not launched.**

In 2011 the Ministry of Health of Ukraine submitted another document – a draft concept of the State Target Program **"Development of Import Substitution Production in Ukraine and Replacement of Imported Medicines with Domestic Medicines, including Biotech Medicines and Vaccines for 2011-2021"** (hereinafter - the Program for Import Substitution), which envisaged concrete steps related to the development and production of new medicines, in particular to ensure a full cycle of production of vital medicines in Ukraine: from the synthesis (biosynthesis) of a substance to the finished dosage form, where possible, and reducing dependence on imported substances; state-financed procurement of licenses for the production of innovative medicines with subsequent mastering of their production at leading pharmaceutical companies in Ukraine; as well as the introduction of preferences in production and public procurement.

Despite the relevance and strong arguments for Ukraine's need for such a program and concrete proposals for its implementation, a number of associations active in Ukraine, and in particular the European Business Association (EBA), called on the government to prevent the adoption of the Import Substitution Program. EBA pointed out that Ukraine is concluding negotiations on a free trade area with certain obligations and therefore the EBA *"draws attention to the risk of creating unequal competitive conditions for domestic and foreign producers in Ukraine if the draft Concept is approved by the government. In addition, since 2008 Ukraine is a full member of the WTO, and the proposed draft Concept on "Import Substitution" may cast doubt on the country's compliance with WTO principles and standards because of the possibility of discrimination against imported goods"* [35]. Unfortunately, this "argument" played a more important role than the problems of the healthcare system, domestic producers and threats to Ukraine's national security. **Under pressure from lobbyists of foreign pharmaceutical companies, the Import Substitution Program was not adopted.** Five years later, the Ministry of Health of Ukraine tried to launch the program again, but without result.

In 2010, the Ministry of Health of Ukraine introduced a concept for a program to create and conduct preclinical trials of domestic medicines. In June 2011 (a month after its adoption), the Decree of the Cabinet of Ministers of Ukraine On Approval of **the State Target Scientific and Technical Program for Development of New Technologies to Create Domestic Medicinal Products** No. 725 of 22.06.2011 was made public, with planned funding of UAH 2.7 billion, including UAH 1.2 billion from the state budget, including UAH 300 million to be spent on research related to

the development of molecular and cellular technologies to create Ukraine's medicines and biologically active substances. However, after the first year of implementation, it became clear that the program was not a priority for the government - it was funded only at UAH 7.3 million [36]. **After two years, both the concept and the program became invalid by the Decree of the Cabinet of Ministers of Ukraine No. 71 of 05.03.2014.**

The document that systematically determined the principles of the industry's development policy was Order of the Ministry of Health of Ukraine No. 769 of 13.09.2010, which approved **the Concept of Pharmaceutical Sector Development in the Health Sector of Ukraine for 2011-2020** (in accordance with the Ministry of Health Order of 27.03.2010 No. 242) (hereinafter referred to as Pharmaceutical Development Concept). This document established prospective guidelines and tasks for the pharmaceutical sector and was aimed at creating an appropriate legal framework to regulate pharmaceutical activities and evelop a national policy in the pharmaceutical sector. Among the tasks set were:

- development and production of essential medicines and supporting exports of medicines, including by working out additional mechanisms for financing Ukraine's developments;
- development of an optimal strategy for import substitution of medicines, and providing for its implementation in the national target program for industrial development for the period up to 2020;
-introduction of new preferences for domestic producers of medicines when developing the production of competitive, innovative and import-substituting generic medicines, as well as for state procurement of Ukraine's medicines;
- priority public procurement of Ukraine's produced medicines developed at public expense;
- granting Ukraine's pharmaceutical enterprises a preference in the system of medicine procurement with public funds and providing the most favorable government's treatment for eligible pharmaceutical companies.

In the Action Plan adopted in pursuance of the of Pharmaceutical Development Concept, out of 80 items, there was not a single one to provide state support for business projects to develop new medicines and put them into production, to provide preferences, or to use of the public procurement system in the interests of national manufacturers. Thus, the objectives of the Pharmaceutical Development Concept remained largely on paper.

The deterioration of the economy due to COVID-19 prompted the Cabinet of Ministers of Ukraine to adopt regulations to stimulate the economy, identifying among key activities the production of essential pharmaceutical products and preparations [2]. Among the short-term initiatives, it is among the following measures are indicated: *"Financing research, development and innovation projects aimed at preventing the emergence and spread of COVID-19"* with a planned

allocation for 2020 of UAH 500 thousand[15], or USD *17.58 thousand* (at the NBU official exchange rate on 01.11.2020). But the problem is not only the small amounts, but also, as pointed out in [37], the administration of the COVID-19 fund, which in 2020 was not very effective, raising questions about the responsibility of the officials and ministries working in areas critical to the well-being of the population in times of crisis.

In December 2020, the Ministry of Health put up for discussion another draft regulatory act - **the Concept of State target program for the creation and development of domestic production of high quality medicines for the prevention and treatment of especially dangerous infectious and other diseases for the state needs of Ukraine for 2021-2026** [38], which is essentially the same as the previously discussed "Ukrainian Vaccine" of 2010. In the explanatory note to the draft regulatory act, the relevant ministry states: *"Due to the loss of domestic production of immunobiological drugs and the country's almost complete dependence on imports of such drugs, and given the worsening epidemic situation in Ukraine, there is a question of national security in general".* So, **10 years after the launch of the Pharmaceutical Development Concept, it is not the creation, but the loss of own production that is stated!** At the meeting of the Presidium of NAS of Ukraine, dedicated to the participation of the Academy's scientists in counteracting COVID-19, the Minister of Health of Ukraine in his speech noted that the country's leadership intends to resume in Ukraine own pharmaceutical production of immunobiological preparations, stressing that the priority is the creation of pharmaceutical independence of our country, which should start with the production of own immunobiological preparations [39]. Despite these declarations, as of 17.09.2021, the document was not adopted.

Despite a number of initiatives by the Ministry of Health to draft regulations on targeted measures to develop pharmaceutical production and reduce dependence on imports, as well as the adopted regulations serving as the basis for the development of production of medicines and medical products in Ukraine, **the Pharmaceutical Development Concept to 2020 was the key document defining the national policy on pharmaceutical activities. Today there is no such document in the country.** Other legal acts in Ukraine regulate the legal relations in the pharmaceutical sector in the context of European integration processes, but they do not define priorities for the sector and measures to achieve them.

The adopted National Economic Strategy for the period up to 2030 has among its objectives "ensuring a high level of health and high rates of life expectancy and longevity of healthy life". One of the ways to achieve it, as stated in the document, is to "implement *pharmaceutical policies* and ensure access to quality, effective and safe medicines", in particular [40].

This strategic government document confirms that the government of Ukraine implements only pharmaceutical (medical) policy, leaving out the industrial policy in the pharmaceutical sector. Pharmaceutical policy refers to the development,

[15] From the state budget (the COVID-19 Acute Respiratory Disease Response Fund to fight the SARS-CoV-2, and its consequences).

provision and use of medicines in the health care system and to government efforts to provide medicines to the public in the context of public health policy; while the objectives of the industrial policy for the pharmaceutical sector as an asset of the national economy, starting from the general principles of EU industrial policy, are somewhat different: they aim to improve the industry's competitiveness of, making it an engine of sustainable growth and employment.

The development of pharmacy in Ukraine, as noted in [2], has a number of obstacles. It is revealed that the small amount of the government request for training pharmacists at public expense and the low admission rates to training in the specialties of "pharmacy" and "industrial pharmacy" cause a shortage of specialists and personnel shortage in the sector. Limited public funding for scientific and technological activities; imperfect research infrastructure; weak correlation between R&D activities of academic institutions and the innovation strategies of pharmaceutical companies result in low effectiveness of the rapid-return R&D efforts.

The above is a consequence of the lack of public policy for the development of pharmaceuticals based on national innovation assets, which has led to shortages of medicines, medical devices and pharmaceutical inputs, (especially the active pharmaceutical ingredients), during the COVID-19 pandemic, which demonstrates Ukraine's unpreparedness to such challenges. A. Myronenko, a virologist, Doctor of Medicine, Professor, Head of the department of viral infections at L.V. Gromashevsky Institute of Epidemiology and Infectious Diseases of the NAMS of Ukraine, says: "Ukraine not only lacks laboratories with the required level of biosafety[16] - the country also lacks appropriate scientific personnel who could develop such medicines. The medical doctor has strong doubts that Ukraine is capable of developing and producing an anti-covid vaccine because it did not have its own vaccine production since 1996 [42][17].

Counteracting these obstacles requires the introduction of a targeted public policy to develop "technology champions" in the pharmaceutical and related industries based on national innovation achievements. For this purpose, not only a proper pharmaceutical policy should be implemented, but also an industrial policy in relation to pharmaceuticals (following the EU example) and mechanisms for revival and interaction of all elements of the ecosystem of high-tech pharmaceutical production in Ukraine should be launched.

In order to accelerate the development of Ukraine's high-tech pharmaceutical industries, it is necessary to strengthen the role of the state in administering the process; to create a quality resource for scientific, innovative and productive

[16] In particular, there is no biosafety Level 4 laboratory in Ukraine. However, there are two Level 3 laboratories at the Ukrainian I.I. Mechnikov Research Anti-Plague Institute of Ministry of Health of Ukraine (Odesa) and a laboratory of the Center for Public Health of the Ministry of Health of Ukraine [41].

[17] Ukrainian scientists also urge "not to spread false information about the development of a domestic vaccine against coronavirus" [42], as Ukraine has neither the appropriate level of laboratories nor adequate funding for such work. However, there are a number of innovative companies ("Indar", "Farmak", "Arterium", "Iuriia-Farm", etc.) that have the capacity to produce the vaccine. Ukrainian pharmaceutical companies are currently working to find partners for technology transfer to master the production of COVID-19 vaccines at their production sites. Among the partners considered are companies with late-stage developments, including those in the phase III clinical trials.

activities; to increase cooperation between the state, the academic, educational, and production sectors, on the one hand, and the public on the other; to launch budgetary state aid programs for common projects focused on technological innovation in the pharmaceutical industry; to establish stable sources of funding based on public-private partnerships; and to establish priority for Ukraine's goods in public procurement. The conditions of global economic governance (in particular the WTO agreements on subsidies and countervailing measures and trade-related investment measures) significantly reduce the range of instruments that can stimulate the development of the pharmaceutical industry. The Association Agreement with the EU and the relevant legislation and regulations adopted in Ukraine have also imposed certain restrictions on permissible policy mechanisms. At the same time, taking into account the decision of the WTO panel, which confirmed the existence of the state of emergency in international relations between Russia and Ukraine, **the Ukrainian government can take measures necessary to ensure national security, in particular, to introduce preferences to national pharmaceutical manufacturers in public procurement or other currently prohibitive mechanisms clearly defining the main security interests of Ukraine** [43, p. 81].

Taking into account the Sustainable Development Goals of Ukraine 2030, in particular the provision of healthy lifestyles and well-being for all at all ages, and the promotion of inclusive and sustainable industrialization and innovation, in the research [44] D. Honcharenko argued for the necessity to form a dual state policy and strategy for the development of high-tech pharmaceutical production in Ukraine. This strategy must be based on synergy and complementary actions of the policy of the provision of population with pharmaceutical products and the industrial policy, aimed at stimulating the development and production of new pharmaceutical products based on advanced technology and reducing dependence on imports. Such a strategy should be also aimed at increasing the competitiveness of Ukraine's pharmaceutical production, reducing its dependence on foreign goods and technologies, reviving cooperative activities, and ensuring the stability of the supply of pharmaceutical products and making the industry an environmentally friendly strategic asset for economic growth, employment and national security.

In order to implement this approach, pharmaceuticals should be defined as a strategic area in terms of national economic development priorities. This requires amendments to **the National Economic Strategy for the period until 2030, as well as the development of High-Tech Pharmaceutical Production Strategy of Ukraine** (hereinafter - the Strategy) [45], which represents a set of goals, tools and measures clearly aligned with each other, as well as with the nation's economic priorities, among which is the European economic integration.

A policy for the development of high-tech pharmaceutical production in Ukraine should take a comprehensive approach (that is, without focusing only on medicines). The strategy should include key areas for the creation and production of goods such as:

1) *biological preparations and intermediates for their production* (antibody-based medicines; recombinant protein-based medicines; vaccines; nucleic acid preparations and products for cell therapy; and biologics development technologies);

2) *chemicals and intermediates for their production* (newly synthesized chemical medicines, generic chemical medicines, high-performance medicines, and chemical development technologies).

3) *medical equipment* (medical imaging equipment, in vitro diagnostic medical devices, health-care equipment, *interventional medical devices* and medical supplies, and mobile medical devices);

4) *pharmaceutical excipients and packaging system* (pharmaceutical auxiliary substances and functional materials; and packaging and drug delivery systems);

5) *equipment and apparatus for pharmaceuticals* (development of modern equipment and production technology).

A separate priority should be to develop and master the production of goods relating to COVID-19, in particular: medicines (including vaccines) and their intermediates (related APIs and raw materials); medical devices, medical equipment (including artificial lungs ventilation machines[18], oxygen concentrators[19], protective clothing and equipment, and diagnostic tools) and their necessary components; disinfectants and their intermediates, the chemical raw materials needed for their production; data collection/processing tools, etc.

Identification and implementation of priorities for the development of high-tech pharmaceutical production in Ukraine under conditions of European integration requires improvement of the relevant institutional and organizational mechanism, in particular, the building of an institutional vertical from the Prime Minister to the relevant structural subdivisions of the central executive authorities, involved in pharmaceutical and industrial policy communication with a governmental advisory body of representatives from the high-tech pharmaceutical manufacturing ecosystem. This will make it possible, through a consensus of interests, to rapidly agree initiatives, develop strategic and policy documents based on social dialogue, and launch budgetary programs to support scientific, innovative and investment business projects funded via public-private partnerships[20].

The pharmaceutical industry should contribute to high rates of economic growth, reduce the budget deficit, reduce strategic dependence on imports, create new well-paid jobs, and make Ukraine a worthy participant in the global market for high-tech

[18] State-owned enterprise "Novator" (part of State Concern "Ukroboronprom") started developing artificial lungs ventilation machines by signing an agreement with a Swiss company and obtaining technology to produce oxygen concentrators.

[19] "Telekart-Prylad" research and production company from Odessa developed and launched production of an oxygen concentrator - the Breath-20 device in 2020. The company received a package of domestic certificates (in particular from the Ministry of Health of Ukraine) where the Ukrainian name "Briz-20" is mentioned.

[20] This proposal is based on the successful experience of France, where back in 2010 the Conférence nationale de l'industrie was established (since 2013 it is the Conseil national de l'industrie (CNI), chaired by the Prime Minister). The CNI is mandated to submit reasoned proposals on the effectiveness of state aid to the industry [46]. Comités strategiques de filières (CSFs) were set up on the CNI platform to establish effective and systematic dialogue between government and business, to identify the range of sectoral problems and propose solutions to them. Today there are 19 CSFs, headed by business representatives with outstanding competences in their respective fields. In particular, *Le Comité Stratégique de Filière Industries et Technologies de santé* (CSF ITS) deals with pharmaceuticals.

pharmaceutical production. One of the authors outlines the ecosystem of high-tech pharmaceutical production in Ukraine (Figure 6).

Therefore, the goal of the Strategy should be the development of a stable operating industry with high added value, which in its development relies on skilled labor force and endogenous innovation as a guarantee of competitiveness of existing and production of new substances and finished pharmaceuticals; has a high level of localization in Ukraine and no critical dependence on imports of pharmaceutical ingredients; and is able to meet Ukraine's needs and expand its share in the global market of high-tech pharmaceutical manufacturing.

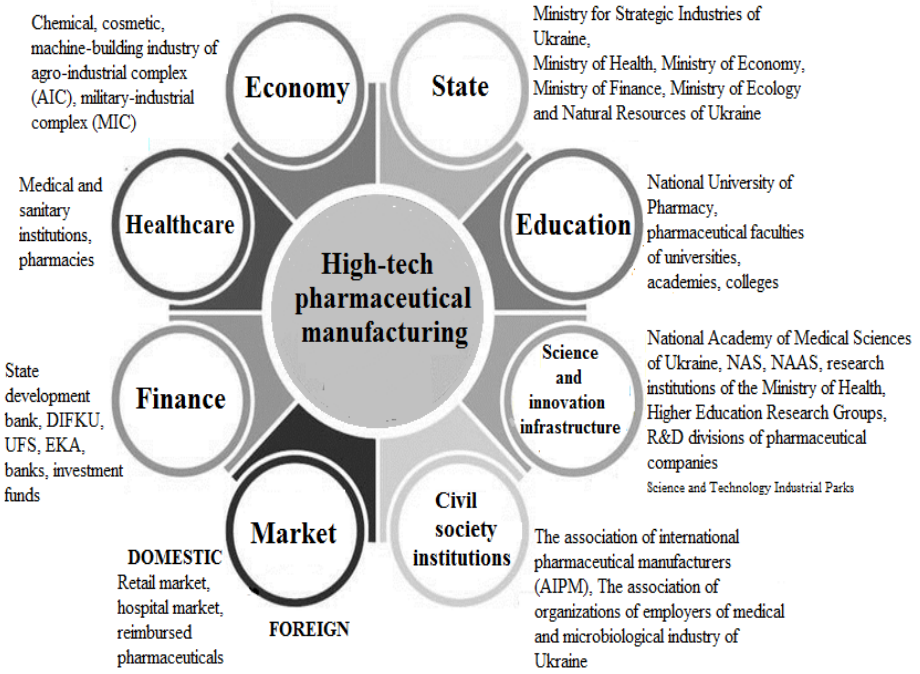

Figure 6. Ecosystem of high-tech pharmaceutical manufacturing in Ukraine

Source: compiled by D.O. Honcharenko.

This objective should be pursued through a focused problem-oriented approach and should focus on such **aspects** as:

- accelerating the modernization and scale-up of high-tech pharmaceutical production by operating companies, and forming national technology champions;
- launching development-based start-ups whose implementation will contribute to technological innovation in pharmaceuticals;
- creating new pharmaceutical companies (especially ones specialized in contract manufacturing with transnational corporations to acquire advanced foreign technology to enhance the endogenous innovation potential of the industry).

Taking this into account, **the key priorities of the strategy** should be:

- *technological innovation* (building the innovation capacity of the industry; accelerating the introduction of new generation information and communication technologies in pharmaceutical production; and promoting new business models for pharmaceutical manufacturers);

- *cooperation and collaboration* (improvement of scientific, technological and innovative cooperation of pharmaceutical companies with the academic and educational sector; and formation (lengthening) of value chains in Ukraine through the establishment (strengthening) of technological and production links between business entities);

- *international cooperation* (expanding scientific and industrial cooperation with the EU to develop technology, human resources, production capacity and capital provision; and creating attractive conditions for foreign companies to establish R&D and industrial sites in Ukraine to carry out clinical trials of new drugs and contract manufacturing);

- *quality and efficacy* (strengthening manufacturers' responsibility for the quality of finished pharmaceutical products; improving the system of quality and safety standards and quality control; and promoting quality and efficacy of chemical and biological intermediates);

- *import substitution, stability of Ukraine's supply* (mastering the production of important substances (intermediate goods) for pharmaceutical production; ensuring the necessary drug stock, improving the drug storage and distribution network; creating conditions for security of supply);

- *access to foreign markets* (improving the international competitiveness of pharmaceutical products, introducing incentives to increase exports and strengthening Ukraine's position on the world market of high-tech goods);

- *ecology, green pharmaceuticals* (preventing and reducing the negative effects of pharmaceutical waste on the human body and the environment; controlling the proper management of pharmaceutical waste and assessing its environmental risk; promotion of circular production systems; reducing energy consumption, CO2 emissions, water consumption, and volatile organic compounds emissions; and improving the environmental performance of chemical compounds for pharmaceuticals);

- *intelligent manufacturing* (increasing automation and digitalization of the pharmaceutical manufacturing process, the use of artificial intelligence and machine learning, augmented reality (AR), virtual reality (VR), digital software, IoT, Blockchain, 3D printing of drugs, and organ-on-chips).

The implementation of the author's recommendations on mechanisms for the development of high-tech pharmaceutical production in Ukraine will contribute:

- development of Ukraine's production of chemical and biotechnological medicines, including the creation of new vaccines and serums;

- development of the range of original medicines and innovative generics by Ukraine's manufacturers, reduction of overlapping product ranges, and the growth of the share of domestic products in the pharmaceutical market;

- increasing the physical and economic accessibility of medicines and medical devices through the introduction of new products of high-tech pharmaceutical production in Ukraine; on the one hand, it will increase the capacity to treat illnesses, on the other hand, it will reduce household expenditure (which accounts for more

than 90% of basic expenditure on pharmaceuticals and other short-term medical devices) and improve access to them for the most vulnerable population;

- bringing the structure and consumption of medicines in Ukraine closer to the morbidity indicators; and expanding the range of medicines for children and for the pharmacotherapy of rare diseases;

- reducing the dependence of high-tech pharmaceutical production and health care system of Ukraine on imports of pharmaceutical substances and finished products, and threats in cases of global or local emergencies, such as the COVID-19 pandemic;

- budget savings due to reduced costs for the purchase of imported drugs;

- increasing budget revenues at all levels by increasing the production of medicines and medical devices.

Conclusions

The authors' study, aiming to substantiate the necessary policy measures to reduce vulnerability and dependency of Ukraine's pharmaceutical industry in the light of the EU experience, led to this conclusion: the lack of political will, inconsistency in decision-making, interdepartmental incoherence, and lack of executive discipline in the implementation of already approved mechanisms hinder the development of the pharmaceuticals in Ukraine, which proved to be unprepared for the challenges of the COVID-19 pandemic and are now at the periphery of finding answers to these challenges. Only purposeful action on the part of the state (rather than market forces) can give an impetus to the industry's development based on endogenous innovation, convert European integration processes into competitive Ukrainian products and facilitate their entry into European markets.

Summarizing the key strategic documents guiding EU policy (given its dual nature), it is clear that the EU leadership, adhering to a long-standing position of prioritizing the industry, promotes its development through industrial and health policy. The new EU strategic documents, adopted in response to the COVID-19 crisis, laid the foundation for addressing the industry's vulnerabilities through the expansion of Ukraine's production and the transfer of certain production (primarily active pharmaceutical ingredients) from Asia to Europe to reduce strategic dependencies. In the context of European integration, this opens new opportunities for Ukraine to attract investment, transfer advanced technologies and create new businesses.

The formation and implementation in Ukraine of a dualistic policy for the development of high-tech pharmaceutical production, based on complementary mechanisms of pharmaceutical and industrial policy, will contribute both to providing the public health system with innovative products created on the basis of advanced technology and to turning the industry into an engine of economic growth and employment. In order to focus limited resources on priorities that will have the greatest effect, a strategy for the development of high-tech pharmaceutical production in Ukraine should be developed, based on a comprehensive approach, in particular, focusing not only on the creation and production of new medicines, but also on medical devices and pharmaceutical ingredients (chemical and biological), fillers and packaging, and equipment and devices for pharmaceuticals.

The critical dependence of drug production on imported intermediate goods, the increase in their supply to Ukraine, as well as the importation of finished drugs and medical devices should be an argument for the Ukrainian authorities to show political will and make public decisions on the introduction of mechanisms for pharmaceutical development in the interests of the safety and health of the nation. The EU experience proves: in order to reduce external dependence, the state leadership should resort to a number of measures aimed at: 1) strengthening the scientific, technological and innovation potential of pharmaceuticals; 2) promoting private investment to expand the product range of existing pharmaceutical companies and 3) creating the preconditions for new production facilities in Ukraine. Consequently, the **prospects** for further research lie in the development of mechanisms for the implementation of these measures in Ukraine, taking into account both European attitudes and national interests.

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ВИКЛИКИ COVID-19 ФАРМАЦЕВТИЧНІЙ ПРОМИСЛОВОСТІ: ВІДПОВІДІ ЄС ТА УКРАЇНИ

Глобальна пандемія COVID-19, яка призвела до дефіциту лікарських засобів і медичних виробів, а також вихідних товарів фармацевтичного виробництва, насамперед активних фармацевтичних інгредієнтів, продемонструвала неготовність України до таких викликів і загроз. Це спонукає до пошуку дієвих механізмів зменшення уразливості, забезпечення стабільності та розвитку фармацевтичної діяльності.

Мета статті – спираючись на досвід ЄС, обґрунтувати необхідність запровадження заходів політики стимулювання розвитку фармацевтики України задля зменшення залежності галузі та системи охорони здоров'я від імпорту. Для досягнення зазначеної мети використано методи аналізу та синтезу, логіко-діалектичний метод та метод компаративного аналізу, зокрема порівняльно-історичного.

У статті показано характер та масштаби існуючих залежностей фармацевтичного виробництва; виявлено особливості політики ЄС щодо фармацевтики. Встановлено, що керівництво ЄС, дотримуючись багаторічної позиції щодо пріоритетності галузі, активно сприяє її розвитку; нові стратегічні документи ЄС, ухвалені у відповідь на кризу COVID-19, заклали підґрунтя для усунення вразливості та зовнішньої торговельної залежності галузі. Вперше запропоновано концептуальний підхід до формування дуалістичної державної політики та стратегії розбудови високотехнологічного фармацевтичного виробництва України, що базується на синергії та комплементарних заходах політики забезпечення населення лікарськими засобами та промислової політики, орієнтований як на стимулювання розробки та випуску нових фармацевтичних товарів на базі передових технологій та зменшення залежності системи охорони здоров'я від імпорту; так і на посилення конкурентоспроможності фармацевтичного виробництва, збільшення рівня локалізації через використання продукції місцевого виробництв, активізацію суміжних видів діяльності, забезпечення стабільності постачання фармацевтичних товарів та перетворення галузі на стратегічний актив зростання економіки, зайнятості, національної безпеки. Запропоновано методологічний підхід до визначення пріоритетних

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напрямів та програмних завдань політики розвитку високотехнологічного фармацевтичного виробництва України, який базується на засадах поліаспектності та комплексності, охоплюючи розробку та випуск не лише лікарських засобів та медичних виробів, а й фармацевтичних інгредієнтів (хімічних та біотехнологічних), наповнювачів та пакувальних матеріалів, обладнання та апаратури для фармацевтичного виробництва.

Обґрунтовано засади формування стратегії розвитку високотехнологічного фармацевтичного виробництва України, що базуються на балансі інтересів споживачів та виробників фармацевтичних товарів із інтересами держави, з огляду на її цілі: дбати про здоров'я нації; забезпечити ефективність економічної системи та соціальну стабільність; сприяти появі нових ефективних ліків на базі передових технологій; зменшити залежність від імпорту та загрози національній безпеці.

***Ключові слова**: євроінтеграція, фармацевтична індустрія, фармацевтична політика, промислова політика, технологічна залежність, високотехнологічне виробництво*