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## The Pharmaceutical Industry in New EU Member States: A Statistical Comparison with Germany. Lessons for Ukraine

Pharmaceutical production is a strategic sector of the EU economy. The authorities of Central and Eastern Europe (CEE) countries that became EU members in 2004 have been building up domestic pharmaceutical industries for purposes of production and distribution of medical drugs (MDs) and medical products (MPs), on the one hand, and government assistance to business entities and public procurement, on the other. The article's objective is to assess the change in economic performance of the pharmaceutical industry in Poland, Hungary and Czechia after their accession to EU, to make a comparative statistical analysis with Germany, the leader of pharmaceutical production in EU, and to reveal key problems of this industry development in CEE countries, in order to elaborate recommendations for Ukraine on replication of best practices and avoidance of potential risks.

Results of research show that pharmaceutical producers (group 54 SITC Rev.4) in CEE countries have been focusing mostly on EU market, with Germany being their main partner. The turnover of high tech pharmaceutical goods in CEE countries has significantly grown after the accession to EU, along with the significantly grown imports of these goods and the increasing negative trade balance. Pharmaceutical companies in CEE countries could increase the salaries and the apparent labor productivity, but the gap between them and Germany in salary and productivity terms still remains too wide. In the studied CEE countries there has been significant increase in pharmaceutical R&D spending, but its estimated share remains quite low compared with average figures for EU (16.1%) and Germany (25.6%).

It is substantiated that because the future Agreement between the European Community and Ukraine on conformity assessment and acceptance of industrial products (ACAA agreement, or "Industrial visa-free regime"), which is being negotiated right now, will cover the pharmaceutical industry, the Ukrainian pharmaceuticals will gain benefits only given the consolidated endogenous capacities of the industry and firmly established advantages of localization providing stimuli for European companies to create production facilities and R&D centers in Ukraine (including ones for contract-based R&D and productions). It is demonstrated that the inflow of investment and technologies from European pharmaceutical companies is capable of accelerating production start-up and exports of MDs and MPs (as time need not be lost for setting up all the links of the chain), thus adding up to the assets of Ukrainian producers (through transfer of knowledge and skills), but all the above cannot compensate for domestic efforts aimed at creating tangible and intangible assets in the industry. Given its Eurointegration context, Ukraine needs to pursue the policy of increasing the industry's endogenous capacities and rely on the comprehensive approach (instead of focusing on MDs and MPs) that will cover the following key areas: biological and chemical ingredients, medical equipment, pharmaceutical fillers and packages, equipment and apparatus for pharmaceutical production. This is expected to reduce the dependence of Ukrainian pharmaceuticals on imports and eliminate the problem of "truncated industrialization" that can cause structural imbalances, worsen the balance of payments and weaken the national currency.

**Key words:** *public policy, Eurointegration, pharmaceuticals, innovations, technological development.*

**Introduction.** It was in the earliest years of Ukrainian independence when the Verkhovna Rada of Ukraine ascertained the self-identification of Ukraine as a European country, with the goal of Ukrainian foreign policy determined in 1993 as the membership in European Communities "on

the condition that this will not harm the national interests" [1]. These decisions laid the foundation for the approval of a series of critical legal acts confirming the Eurointegration vector of the national economy development and giving impulse to transformation processes specific to the pharmaceutical industry.

New challenges and threats faced by the Ukrainian economy due to the global COVID-19

pandemic make one seek for effective mechanisms to ensure the stability of pharmaceutical business, health care system, national economy and security, and adjust the priorities of Ukraine-EU partnership by emphasizing “the expansion of interactions in health care and pharmaceuticals” [2]. To grasp the effects of Eurointegration process and EU membership for the pharmaceuticals, it is necessary to explore the experiences of Central and Eastern European (CEE) countries that had to float freely in 90s as they faced new business conditions, just like Ukraine; they could change operative principles of the industry and perform institutional transformations, ending up in 2004 by their accession to EU. It should also be assessed if these countries after accession to EU could successfully catch up with Germany, the irrefutable industry leader in Europe in terms of technology and innovation [3].

**Literature review.** Research works of domestic authors were focused on broader problems and perspectives on the way to EU membership [4–7], minute details of legal support for the implementation of EU law on the circulation of medical drugs, peculiarities of political decisions of leading countries on the expansion of production facilities and output growth. But the effects of EU accession for the pharmaceuticals of CEE countries have been out of focus of Ukrainian researchers, which cannot allow for sound discussions and due consideration of best practices in Ukraine.

The article’s objective is to assess the change in economic performance of the pharmaceutical industry in Poland, Hungary and Czechia after their accession to EU, and to make a comparative statistical analysis with Germany, a pharmaceutical leader in EU. Key problems of this industry in CEE countries will be identified as part of the study, to elaborate recommendations for replicating best practices and formulate warnings for Ukraine.

**Results and discussion.** It was in 1994 (at the beginning of Eurointegration process in CEE countries) that EU authorities formulated the guidelines for industrial policy in the pharmaceutical sector, with highlighting that the industry [8]:

- belongs to the most effective high tech sectors, generates more than 1% GDP and grows by more than 6% in a year (in the period of 1982–1992);
- creates great many jobs, including ones in related activities;
- plays a key role in the health care and social security system, apart from the innovation and industrial contribution in the EU economy and competitiveness.

A series of official EU documents approved at early 90s laid the foundation for the European industrial policy for the pharmaceutical sector [8; 9]. As highlighted by EU authorities, the industry has to be a priority which implementation will call

for the involvement of stimulatory mechanisms [10]. These guidelines had implications for the countries undergoing the phase of Eurointegration.

It was in 1996 that the EU Council approved the Council Resolution designed to implement the outlines of an industrial policy in the pharmaceutical sector in the European Union [11].

Once the active process of Eurointegration of CEE countries began, the Council pointed out that each member country had to define the measures with the highest effect for competitiveness enhancement in view of its system specificities, in parallel with support to utilization of the capacities available with the pharmaceutical sector, to develop technologies, economy, and employment; and to set up industrial cooperation with third countries, e. g. to seek for improvements of terms for access to third countries’ markets for medical drugs invented and developed by the European pharmaceutical industry. The Resolution highlighted the importance of [11]:

- proper preparation in this sector, started in the period prior to the accession of CEE countries and other candidate countries, especially with respect to the adaptation of their law to *acquis communautaire*, creation of the appropriate infrastructure for authorization and control of medical drugs, protection of industrial and commercial ownership and fostering of free market environment;
- third countries’ markets, for expanding the pharmaceutical industry of EU that is the main global center of manufacturing and exports of medical drugs.

Privatization of pharmaceutical enterprises in CEE countries, launched in 90s along with the Eurointegration process, helped attract foreign investors and technologies of Western companies and adapt to international standards as a required condition for entry of local manufacturers into the EU market. When the privatization process was going on, the emphasis was made on preservation on the overall profile of pharmaceutical enterprises, with establishing a set of investment obligations for new owners, including the following ones: the involvement of privatized companies in research and development (R&D); technology and know-how transfer; allocation of a part of profit in the privatized company development; terms of joint access to distribution channels; use of resources, materials and packages of local origin; penetration to external markets. Thus, upon request of the Polish Ministry of Health Protection and Social Security, investors were obliged to transfer a number of technologies and set up the manufacturing of drugs that were new for Polish factories (including currently existing generics) [12].

The authorities of CEE countries that are new members of EU, by relying on European norms and regulations on manufacturing and distribution of medical drugs (MDs) and medical products (MPs), on the one hand, and government assistance to

business entities, on the other hand, have implemented mechanisms for regional and horizontal assistance (which included the assistance for SMEs, rescue and restructuring of ailing enterprises, professional development of staff, environmental protection, R&D and innovation, etc. [10]. As shown by Polish, Hungarian and Czech practices, this assistance is provided with reference to specified domestic priorities relating to technology, innovation and industry [13–15].

Upon EU accession, governments of the CEE countries launched operational programs for economy and innovation development, which had essential impact on the pharmaceuticals performance and became national manifestations of the implementation of EU cohesion policy in R&D and innovation given generous funding from the European Regional Development Fund (ERDF). One example is the Polish program “Innovative Economy 2007–2013” (Program Operacyjny Innowacyjna Gospodarka, PO IG) with the total funding of 9.7 billion euro [16], of which 85% was covered by ERDF and the rest – by the public budget of Poland; 1.3 billion euro was allocated in the projects by the following priorities: intensification of R&D in the advanced technology field; building up infrastructures for business enterprise R&D; increasing the capital for innovations; expanding of presence of Polish innovative goods on the international market, etc. When this program was finished, the Polish government approved the next operative program “Smart Development for 2014–2020” (Program Operacyjny Inteligentny Rozwój – PO IR) with the budget of 8 614.1 million euro, which was also implemented with ERDF funds [17]. The author’s review of more than 11,000 projects (as of January, 3, 2021) co-financed by EU on the PO IR line [18], revealed that companies involved in manufacturing of MDs and MPs and in related activities (packaging, protection from forgeries, etc.) received in this period the total of 1.5 billion zlotys in form of ERDF grants for projects focused on the pharmaceuticals development. Also, the mechanisms were defined, by which these projects would receive the largest assistance from ERDF on the PO IR line, including:

- support to R&D performed by industrial companies (industrial R&D), Action 1.1;
- sectoral R&D programs, Action 1.2;
- support to investment in company R&D infrastructures, to enhance R&D capacities, Action 3.2.

On line of Action 3.2, to accelerate technological development of pharmaceuticals and intensify commercialization of R&D in the neuromedical field, the Polish government launched the industry program InnoNeuroPharm till 2026. Apart from the abovementioned mechanisms, pharmaceutical capacity building in CEE countries had essential benefits from the cluster policy [19], by which the government grants companies assistance for purchase of fixed assets and intangible assets, when it requires new investment, as well as tax preferences on R&D. This enables companies

to deduct the part of the expenditure on industrial R&D, allocated in developments of new products, processed and services, or in essential improvements in existing ones, or in creating prototypes and pilot lines, from the taxed amount of company profit [20]. At the same time, governments of CEE countries do not confine the financial support to R&D and innovation projects of pharmaceutical companies, extending it, in case of need, on other aspects of company operation. For example, in 2008 Poland received the European Commission agreement for a preferential loan (with 7.42% interest) meant for the rescue of the firm Tarchominskie Zakłady Farmaceutyczne Polfa (Polfa Tarchomin) that was in a predicament. The government assistance in form of a loan amounting to 20.5 million zlotys (nearly 3.6 million euro) was recognized by the European Commission as one commensurable with the domestic market [21]. The assistance can also be given through recapitalization. In 2019, Polfa Tarchomin received the capital injection from the State Treasury through repurchase of its shares worth 200 million zlotys [22], which allowed the company to invest in the construction of a new production site and improve its R&D laboratory.

Ukraine has failed to implement any kind of mechanism for government support of R&D and innovation in the business sector, as was the case in CEE countries. An elaborated mechanism for government support of technological innovations in industry, which framework is presented in [23], has not been launched, and the draft directive of the Cabinet of Ministries of Ukraine, created on its basis and agreed by the Antimonopoly Committee of Ukraine (the resolution No 572-p from 03.09.2020) is yet to be approved.

Due to the political actions aiming to increase the technological capacities and enhance the competitiveness of pharmaceuticals, implemented by CEE governments with EU sponsorships, this industry could become an effective actor on the overall EU market. According to data for 2020, Poland, Hungary, Czechia and other CEE countries were highly integrated in the foreign trade with the other EU countries by the commodity category “Medical and pharmaceutical products” (group 54 SITC Rev. 4) (Figure 1, constructed by data from [24]).

As shown in Figure 1, in 2020 the smallest share of pharmaceutical exports among CEE countries was in Latvia (51%), whereas the strongest export orientation on the EU market was demonstrated by the Czech pharmaceuticals (84.4%). The pharmaceutical exports and imports of CEE countries grew several fold over 15 years. This growth was largely due to Germany with its significant contribution in the industry’s exports (Table 1, constructed by data from [24]). It can be argued with reference to the regional dimension of K. Akamatsu’s paradigm of “flying geese” that Germany could become “the leading goose” of Eurointegration, for Poland in particular, in which wake the catching-up of the pharmaceutical industry was being on. By implementing this strategy Poland could enhance the competitiveness

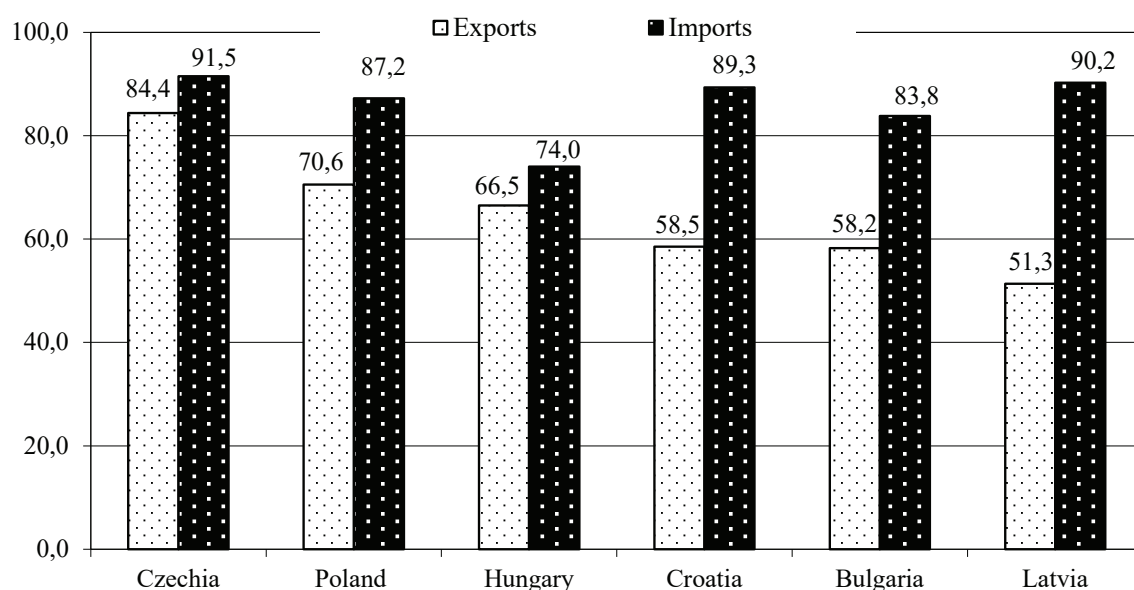


Figure 1. Exports and imports of pharmaceuticals in selected CEE countries within the European Community (Intra-EU27), 2020

of domestic manufacturers of MDs and MPs, but they (like Hungarian or Czech ones) have remained far behind

the German ones by technological level, innovation activity, productivity and salary.

Table 1

Change in exports and imports (in monetary units) of the pharmaceuticals in CEE countries within the European Community (Intra-EU27), 2005–2020, and the contribution of Germany in the total exports and imports

Country	Rate of growth, 2020/2005, times		Share of Germany, 2020, %	
	Exports	Imports	Exports	Imports
Czechia	6.6	3.7	24.2	33.6
Hungary	10.4	4.2	30.2	24.4
Poland	12.1	3.2	23.5	37.4

Key indicators for CEE countries are given with reference to Eurostat data [26; 27] for the industry “Manufacturing of main pharmaceutical products and

pharmaceutical drugs” (C 21 by NACE Rev. 2), with providing data on Ukraine for illustrative purposes (Table 2, constructed by data from [25–28]).

Table 2

Performance indicators of the industry “Manufacturing of main pharmaceutical products and pharmaceutical drugs” (C 21 by NACE Rev. 2) for CEE countries and Ukraine, 2018

Indicator	Country							
	Germany	Bulgaria	Czechia	Croatia	Latvia	Hungary	Poland	Ukraine
Enterprises, number	534	51	93	48	36	88	384	112
Persons employed, number	157 773	8 895	10 769	4 985	2 232	19 514	25 305	24 000
Value added at factor cost, VA, million euro	20 431.2	189.3	461.0	288.0	80.9	1 412.7	1 139.3	731.4
Apparent labor productivity: Gross value added per person employed, thousand euro	129.5	21.3	42.8	57.8	36.2	72.4	45.0	30.5
Wages and Salaries, million euro	11 364.8	72.6	186.4	115.5	39.8	487.7	482.6	150.1
Business enterprise R&D expenditure, million euro	5 226.4	7.5	53.7	47.4	4.5	242.0	124.5	18.5
Share of the business enterprise R&D expenditure in value added, %	25.6	4.0	11.7	16.5	5.6	17.1	10.9	3.4

As shown in Table 2, the largest pharmaceutical industry by employment and value added is in Poland, Hungary and Czechia. But if even taken together, these countries will be far behind Germany by key pharmaceutical figures. The structure of foreign trade of CEE countries with EU is dominated by high tech

pharmaceutical goods (HTPGs). The shares of HTPGs in the Polish imports and exports grew from 25% to 39% and from 14% to 36% in 2007–2018. The similar growth in the share of HTPGs in the foreign trade, with its essential increase in the exports, was recorded in Hungary (Table 3, constructed by data from [24; 29]).

Table 3

High tech pharmaceutical goods in the foreign trade of pharmaceutics in Central and Eastern European countries

Country	Imports, %		Exports, %		HTPGs turnover, million euro		HTPGs balance, million euro	
	2007	2018	2007	2018	2007	2018	2007	2018
Czechia	27.1	28.7	22.4	21.7	766	1 828	-410	-726
Hungary	23.0	50.4	7.1	35.3	511	4 082	-249	-332
Poland	25.5	37.8	16.8	31.3	1010	3 530	-738	-1 464

According to data in Table 3, although the HTPGs turnover in CEE countries with the rest of the world grew considerably in 2007–2018, the trade balance had a negative trend. The negative balance in Poland increased twofold: from 738 million euro in 2007 to 1464 million euro in 2018, being a result of the rapidly increasing rates of HTPG imports.

The increasing imports were also recorded for finished MDs and MPs, and intermediate goods for their manufacturing. The problems caused by large shares of high tech pharmaceutical intermediate goods (HTPIGs) in the imports of pharmaceutical goods were explored by the author’s tools constructed by use of the methodology proposed by O. Salikhova. She combined the UN Classification by Broad Economic Categories and the high-tech aggregation OECD/Eurostat, and aggregated high tech goods by functional purpose (production assets, intermediate and consumer goods), to come out with a radically new statistical tool for analysis of the high tech industries’ performance [30; 31]. She extended these tools and defined the range of goods that were inputs in MDs and MPs manufacturing [32], introduced the notion “high-tech pharmaceutical intermediate good” into scientific parlance and formed the Nomenclature of High Tech Medical and Pharmaceutical Goods, classified by end use: intermediate goods and consumer goods by SITC Rev.4 and the Ukrainian Classification of Goods for Foreign Trade Activities [33]. These were innovative statistical tools enabling to assess the dependence of high tech pharmaceutical manufacturing on foreign trade by estimating the new indicators which formulas are given in [33]:

1) the ratio of import dependence of the pharmaceutical manufacturing, showing the concentration of imported pharmaceutical components in the industry’s output ( $D_{HTph}$ );

2) “cleansed” exports of HTPGs, showing the profitability of exports with account to the imported component ( $X_{HTph}^w$ );

3) the ratio of coverage of HTPIG imports by HTPG exports, measuring the capability of pharmaceuticals to get a profit on foreign markets, sufficient for purchasing imported pharmaceutical components required for HTPGs ( $COV_{HTph}$ ).

Based on the author’s tools, a set of indicators were estimated for CEE countries using the following data:

- for  $I_{HTph\_in}$  (imports of HTPIGs): data of UN Comtrade by the author’s Nomenclature of HTPIGs;
- for  $P_{HTph}$  (pharmaceutical output): data of Eurostat for the indicator “Production value”, section 21 “Output of main pharmaceutical products and pharmaceutical drugs”;
- for  $X_{HTph}$  (exports of HTPGs): data of UN Comtrade by nomenclature positions of the category “Pharmaceutics”, the high-tech aggregation of Eurostat.

As shown in Table 4 (constructed by the author by data from [34; 35]), Poland had the highest ratio of import dependence of the pharmaceutical manufacturing (0.346); Czechia and Hungary demonstrate nearly similar figures (0.137 and 0.139, respectively), which may be attributed to a smaller share of HTPGs in the production structure in Czechia, and to more extensive use of local resources

Table 4

Indicators of foreign trade in high tech pharmaceutical goods, 2018

Country	$I_{HTph\_in}$ , million euro	$D_{HTph}$	$X_{HTph} / P_{HTph}$ , %	$X_{HTph}$ , million euro	$X_{HTph}^w$ , million euro	$COV_{HTph}$
Czechia	204.3	0.137	37.0	551.0	475.4	2.33
Hungary	361.3	0.139	72.0	1875.0	1615.0	4.47
Poland	1013.8	0.346	35.2	1033.0	676.0	0.67



for HTPG manufacturing in Hungary. The Hungarian pharmaceuticals is the most export-oriented one among the studied countries, with 72% of the industry output supplied to foreign markets.

Estimations show that while “cleansed” HTPG exports of Czechia and Hungary were 13% lower than the nominal ones, this variation reached 35% for Poland due to the high imported component. As regards the ratio of coverage of HTPIG exports by HTPG exports, it was the lowest in Poland (0.67), as most part of the manufactured HTPGs were distributed on the domestic market, with the exports covering the imported HTPIGs only by 67%. Hence, the Polish pharmaceuticals operating with imported components manufactures the products mostly for the domestic market, thus being incapable to have

the earnings required to cover the costs on purchases of necessary components. The similar situation was revealed in Ukraine [36]. In spite that Czechia has nearly the same share of exports in the output as Poland (37% against 35%), Czech pharmaceuticals earns much higher profit on external markets (the cover ratio is 2.33), to purchase imported pharmaceutical components for HTPGs.

Eurointegration and accession to EU had the overall positive effects for the dynamics of efficiency in the pharmaceutical industry of CEE countries: industry companies could increase “apparent labor productivity” indicator (defined by Eurostat as the factor cost value added divided by the number of employed) since 2008. Data for 2018 show that in Czechia it grew by 4.4%, in Hungary – by 19%, whereas in Poland it fell by 18% (Figure 2, constructed by data from [25]).

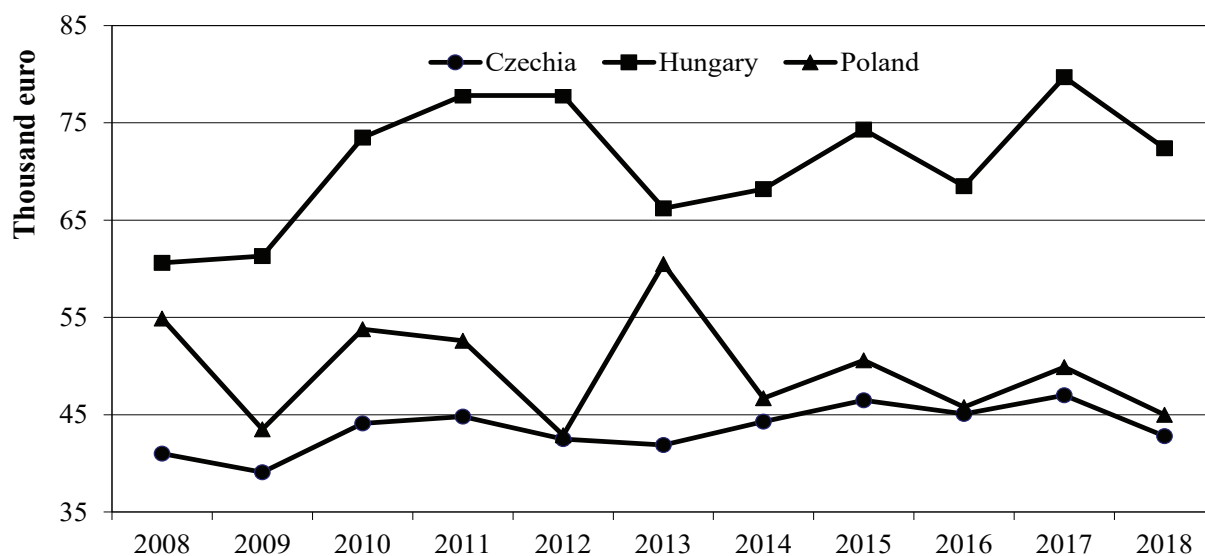


Figure 2. The dynamics of apparent labor productivity of pharmaceuticals in Central and Eastern European countries

However, pharmaceutical manufacturers in CEE countries are still far behind Germany in the production effectiveness: while in Germany it reached 129.5 thousand euro in 2018, in Czechia, Hungary and Poland it amounted 42.8, 72.4, and 45.0 thousand euro, respectively. Hence, the factor cost value added

per employee in Czechia, Hungary and Poland makes only 33%, 56% and 35% of the German’s one. While in Czechia and Hungary this gap could be slightly reduced, its trend Poland continued to be upward (Table 5, constructed by data from [24]).

Table 5

Ratios of apparent labor productivity in the pharmaceuticals of Central and Eastern European countries and Germany

Country \ Year	Year					
	2008	2010	2012	2014	2016	2018
Czechia	31.54	32.76	32.37	33.08	33.24	33.05
Hungary	46.62	54.61	59.25	50.93	50.48	55.91
Poland	42.23	39.97	32.67	34.88	33.75	34.75

The period of 2008–2018 was marked by considerable growth in the business enterprise

R&D expenditure of pharmaceuticals (Figure 3, constructed by data from [26]).

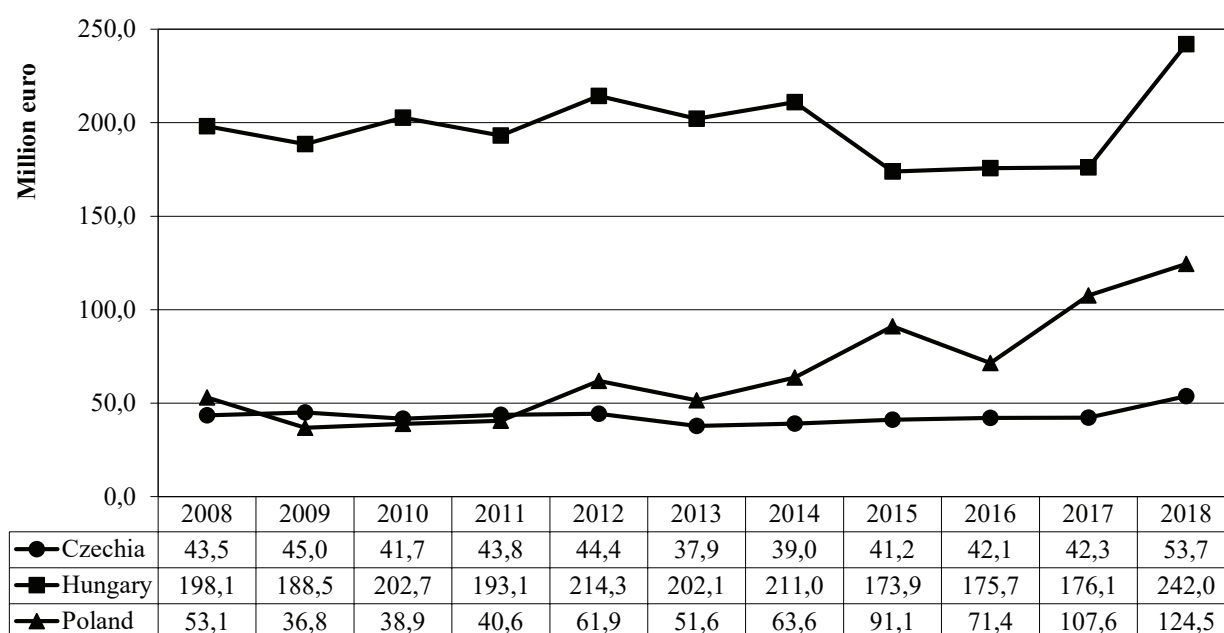


Figure 3. R&D expenditure in the pharmaceutical industry of Central and Eastern European countries

In Czechia R&D expenditures in the pharmaceuticals grew in the analyzed period by 23%, to reach 53.7 million euro, in Hungary – by 22%, to reach 242 million euro, in Poland – by 135%, up to 124.5 million euro. At industry level, the pharmaceutical industry in these countries had the highest innovation activity.

But the study shows that R&D expenditure in the pharmaceuticals of these countries remained too low compared with Germany. In 2018, business enterprise R&D expenditure in pharmaceuticals per inhabitant in Poland, Czechia and Hungary made nearly 5%, 8% and 39% of the German one (Table 6, constructed by data from [24]).

Table 6

Ratios of R&D expenditures in pharmaceuticals per inhabitant in CEE countries and Germany

(%)

Country \ Year	2008	2010	2012	2014	2016	2018
Czechia	10.12	8.75	8.25	7.40	7.27	8.08
Hungary	47.47	44.20	42.44	42.80	32.55	39.14
Poland	3.37	2.19	3.14	3.40	3.45	5.23

However, the share of R&D expenditure in the value added of the Ukrainian pharmaceuticals made only 3.4%, being far lower than in CEE countries. Considering the experiences of CEE countries, the growth in health care spending to 5% of GDP (according to the current law [37]) with no stimuli for the development of the Ukrainian pharmaceuticals and no preferences for domestic manufacturers in public procurement will trigger the continuing growth in imports of finished MDs and MPs.

It means that Ukrainian tax payers will be forced to support the pharmaceuticals in the countries supplying finished MDs and MPs (including EU members) rather than in Ukraine. Further growth in imports of HNPGs (both finished and intermediary ones) will worsen the trade balance, increase the threats of hryvnia devaluation, and cause adverse economic effects.

As regards wages and salaries in the pharmaceutical industry of CEE countries, they were rapidly growing in 2008–2018: the growth made 40% in Czechia (to reach 186.4 million euro), 47% in Hungary (487.7 million euro), 20% in Poland (482.6 million euro) (see Table 1). Average personnel costs (personnel costs per employee) were also increased in Czechia (by 33%), Hungary (14%) and Poland (12%) (Figure 4, constructed by data from [25]).

Estimations show that the salary gap between pharmaceutical companies in CEE countries and Germany still remains very wide, with an upward trend in Poland: while in 2008 the ratio made 29.8%, y 2018 p. – 25.6%; Hungary has the similar trend (38.6% in 2008, and 33.8% in 2018), and only in Czechia the gap could be slightly reduced (26.7% in 2008, and 27.2% in 2018) (Table 7, constructed by data from [24]).

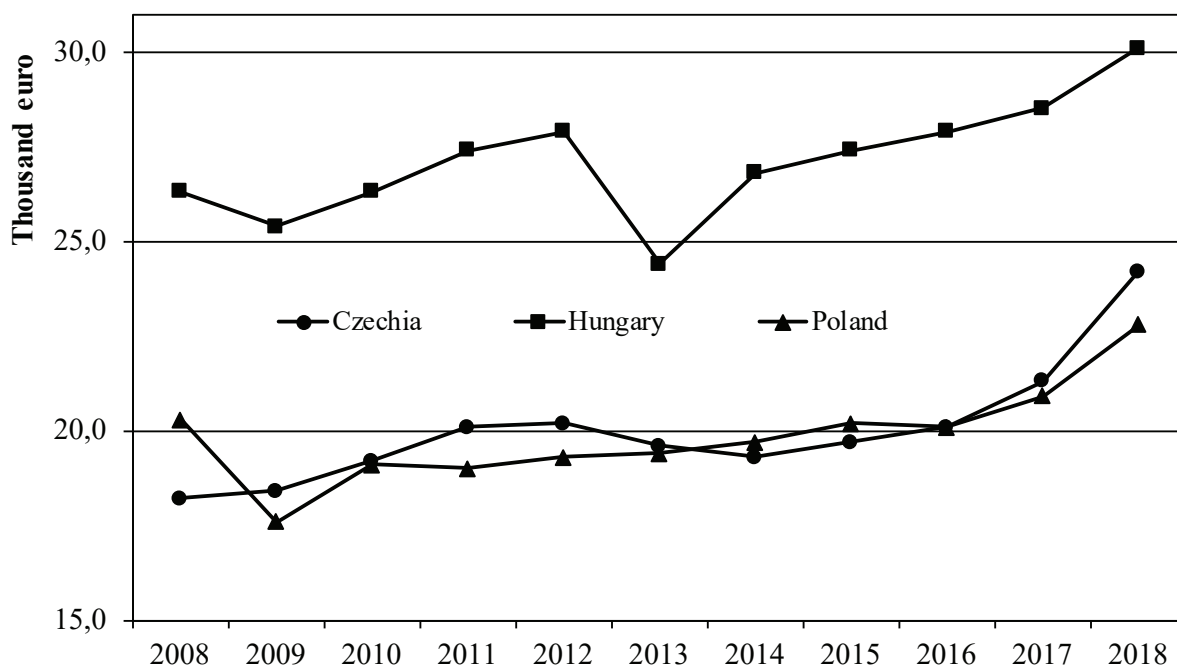


Figure 4. Personnel costs per employee in pharmaceutical companies of CEE countries

Table 7

Ratios of costs per employee in the pharmaceuticals in Central and Eastern European countries and Germany

Country \ Year	Year					
	2008	2010	2012	2014	2016	2018
Czechia	26.73	27.71	29.40	26.08	26.76	27.16
Hungary	38.62	37.95	40.61	36.22	37.15	33.78
Poland	29.81	27.56	28.09	26.62	26.76	25.59

The data for 2018 show that the contribution of pharmaceuticals in the total production value of the manufacturing industry in Poland fell to 0.93% (against 1.29% in 2008); in Czechia it fell to 0.82% (against 0.85% in 2008), and in Hungary it did not change and remained to be 2.52%, without significant

variations throughout the period. Whereas in Germany this industry continued to improve the structural position in the industry, as its contribution increased from 2.31% in 2008 to 2.96 in 2018) (Table 8, constructed by data from [24]).

Table 8

The share of pharmaceuticals in the total production value of the manufacturing industry in Central and Eastern European countries and Germany

Country \ Year	Year					
	2008	2010	2012	2014	2016	2018
Czechia	0.85	0.98	0.89	0.86	0.84	0.82
Hungary	2.52	3.23	3.51	3.13	3.16	2.52
Poland	1.29	1.50	1.18	1.29	1.34	0.93
Germany	2.31	2.29	2.27	2.45	2.55	2.96

It can be concluded that after EU accession the Polish pharmaceuticals had slower development rates than other manufacturing industries, and was gradually losing its positions. Of the CEE countries, pharmaceuticals determines the industrial specialization only in Hungary. As shown by the

study [38], the comparative advantage in value added activity ( $CAVA_{ih}$ ) for Hungary was 1.32 in 2018, with the performance of pharmaceutical industry found to be more effective than the other domestic manufacturing industries.



Ukraine demonstrated the increasing advantage in the value added activity of the pharmaceuticals amidst the slacking performance of the other industries: it was in 2014 that *CAVA* exceeded 1 [38].

However, considering scanty HTPG exports of Ukraine and its narrow geography [37], the inclusion of the pharmaceutical industry in the future Agreement between the European Community and Ukraine on conformity assessment and acceptance of industrial products (“industrial visa-free regime”) will be beneficial for the Ukrainian pharmaceuticals only given the consolidated industry’s capacities and creating competitive products on the basis of endogenous innovations, on the one hand, and the increased advantages of localization and the improved business environment, on the other hand. More favorable terms of business will encourage European companies to create R&D centers and production facilities (including ones for contract R&D and manufacturing) on the Ukrainian territory in view of reshoring tendencies in EU.

The pandemic of COVID-19 highlighted the problems related with the export-import dependence of the EU industry on critical supplies, mainly due to disruptions of imports of active pharmaceutical components. The European Council indicated the need to determine strategic dependencies [39], first of all in the most vulnerable industrial ecosystems such as health protection system with its heavy reliance on the pharmaceutical industry.

Considering the weak R&D and innovation activity in the Ukrainian pharmaceuticals and its heavy dependence on foreign technologies, capacity building in the pharmaceutical industry and its current advantages are conditional on global tendencies and global market conjunctures rather than national science & technology and innovation priorities.

**Conclusions.** The study demonstrates that CEE countries, once becoming new EU members, were building up the pharmaceuticals by relying on European norms and regulations. This helped the industry enhance the competitiveness, improve considerably the economic performance and enter EU markets. But these positive processes were accompanied by the adverse tendencies: the growing pharmaceutical imports, including high tech ones, and the increasing trade imbalance.

The innovation-driven development of the Ukrainian pharmaceuticals is hampered by a number of problems: lack of staff, lack of science and technology developments ready to commercialization, lack of loans and low level of capital accumulation in pharmaceutical companies, e. g. due to their small size (compared with transnational pharmaceutical corporations), making them incapable to implement

large-scale investment and innovation projects on creation and commercialization of original MDs.

CEE countries receive financing support from EU funds in implementing innovation and investment projects and related activities at company level. Ukraine, like CEE countries, has brought the pharmaceutical business into compliance with EU requirements (with enforcing appropriate international standards, including GMP, GLP, GCP, GSP, GDP, which led to the industry modernization and removal of technical barriers in trade). However, unlike CEE countries, Ukraine does not have access to vast EU funds that cover a part of pharmaceutical companies’ costs on R&D infrastructures and science & technology and innovation projects. This makes domestic companies incapable to compete with CEE manufacturers for whom the Ukrainian market has become a targeted one.

Practices show that transfers of technological resources from European pharmaceutical companies are capable of accelerating production start-up and exports of MDs and MPs (as time need not be lost for setting up all the links of the chain), thus adding up to Ukrainian manufacturers’ assets through transfer of knowledge and skills, but they cannot compensate for domestic efforts aimed at creating tangible and intangible assets in the industry. The implementation of a targeted policy for building up “technological champions” in the pharmaceuticals and related industries with reliance on domestic innovations will help convert Eurointegration processes into competitive Ukrainian products and introduce them on European markets.

Given the new EU regulations, the tools for assessing the import dependence of pharmaceuticals, proposed by the author, need to be extended and supplemented by other indicators. Further studies will, therefore, be focused on creating statistical tools for analysis of active pharmaceutical components supplies as part of the international trade. It is, however, necessary to update the tools for assessment of the absorption capacity of national systems to innovations and rapid launch of manufacturing of new MDs and MPs and their components, in view of the new strategic documents approved by EU in response to the pandemic, namely “Pharmaceutical Strategy for Europe” and New Industrial Strategy for Europe”, revised in the context of COVID-19 pandemic, which contains guidelines on reshoring of pharmaceutical factories from Asia to Europe. The Comparative Advantage in Value Added Activity ( $CAVA_{ij}$ ) can be proposed as ones of the indicators [39]. In further studies this ratio should be adapted to the needs of identifying the advantages of EU countries’ specialization on MDs and MPs manufacturing.

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## **Фармацевтичне виробництво в країнах – нових членах ЄС: статистичний порівняльний аналіз із Німеччиною. Уроки для України**

Фармацевтичне виробництво – стратегічний сектор економіки Євросоюзу. Керівництво країн Центральної та Східної Європи (ЦСЄ), що у 2004 р. стали новими членами ЄС, розбудовують національні фармацевтичні індустрії, керуючись європейськими нормами та регламентами, з одного боку, щодо виробництва та реалізації лікарських засобів (ЛЗ) та медичних виробів (МВ), з іншого, – щодо державної допомоги суб'єктам господарювання та публічних закупівель. Метою статті є оцінка зміни після вступу до ЄС економічних результатів діяльності фармацевтики Польщі, Угорщини, Чехії та порівняльний статистичний аналіз із Німеччиною – лідера фармацевтичного виробництва ЄС; виявлення ключових проблем розвитку галузі у країнах ЦСЄ задля розробки рекомендацій щодо репродукції кращих практик та формулювання застережень для України.

Як засвідчили результати досліджень, виробники фармацевтичних товарів (ФТ) (гр.54 SITC Rev.4) країни ЦСЄ сьогодні орієнтуються переважно на ринок ЄС; їх головний партнер – Німеччина. Після вступу до ЄС товарообіг високотехнологічними фармацевтичними товарами (ВТФТ) в країнах ЦСЄ значно збільшився, водночас спостерігається суттєве зростання імпорту цих товарів і нарощування негативного сальдо. Встановлено, що на фармацевтичних підприємствах країн ЦСЄ значно зросла заробітна плата після вступу до ЄС, але вони дотепер мають дуже великий розрив в оплаті праці порівняно із Німеччиною. У виробників ЛЗ та МВ країн ЦСЄ збільшилась очевидна продуктивність праці (apparent labour productivity), але дотепер вони мають значний розрив з ефективності виробництва порівняно із Німеччиною. У досліджених країнах ЦСЄ значно зросли витрати фармацевтичних компаній на дослідження і розробки (Business enterprise expenditure on R&D), водночас розрахована частка витрат на дослідження і розробки фармацевтики в цих країнах залишається доволі низькою як порівняно із середнім значенням по ЄС (16,1%), так і по Німеччині (25,6%). Показано, що, зокрема у Польщі зі вступом до ЄС фармацевтика розвивалася повільнішими темпами, ніж інші галузі переробної промисловості, поступово втрачаючи свої позиції, а також збільшуючи імпортозалежність виробництва ЛЗ та МВ. Обґрунтовано, що розширення на фармацевтичну галузь дії майбутньої Угоди про оцінку відповідності та прийнятності промислової продукції (Угода АСАА, або “Промисловий безвіз”) з Євросоюзом, за якою нині ведуться переговори, матимуть зиск для української фармацевтики лише за певних умов: з одного боку – посилення ендogenous потенціалу розвитку галузі, з іншого – зміцнення переваг локалізації для заохочення європейських компанії створювати на території України центри досліджень і розробок та виробничі майданчики (у т. ч. для контрактних досліджень та виробництва). Обґрунтовано, що залучення інвестицій та технологічних ресурсів європейських фармацевтичних компаній, здатне прискорити

запуск виробництва та експорт ЛЗ та МВ продуктів (без втрат часу на послідовний розвиток), доповнюючи активи українських виробників (через передачу знань та навичок), але вони не замінять внутрішні зусилля з формування матеріальних і нематеріальних активів галузі. Україні в умовах євроінтеграції необхідно реалізовувати політику нарощування ендogenous потенціалу розвитку галузі, спиратися на комплексний підхід (не фокусуючись лише на ЛЗ та МВ), що охоплюватиме такі ключові напрями: біологічні та хімічні інгредієнти, медичне обладнання, фармацевтичні наповнювачі та упаковка, обладнання та апаратура фармацевтичного виробництва. Це зменшить залежність фармацевтики від імпорту та попередить проблему “усіченої індустріалізації”, котра може спричинити структурні проблеми, погіршить платіжний баланс та ослабить національну валюту.

**Ключові слова:** державна політика, євроінтеграція, фармацевтика, інновації, технологічний розвиток.

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