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New Approaches to the Assessment of Foreign Trade in High-Tech Pharmaceuticals

The pharmaceutical industry's R&D expenditure at the global level in 2007–2018 is analyzed. Two-thirds of the global pharmaceutical companies' spending on R&D are accounted for by 20 multinationals companies located mostly in the U.S. and EU.

With low level of R&D funding, Ukraine cannot produce cutting-edge pharmaceutical technologies. Imports of intermediate goods for pharmaceutical industry are the most widely used and most influential channel for attracting advanced technologies. The aggregation of high-tech goods by functional purpose (high-tech capital goods, high-tech intermediate and high-tech consumer goods) is analyzed. This aggregation is made by combining the Classification by Broad Economic Categories by SITC Rev. 4 (UN Statistics Division) and the High-Tech Aggregation SITC Rev. 4 (Eurostat). Based on this approach, the article identifies a range of high-tech pharmaceutical goods that are essential for pharmaceutical production, and introduces the concept of "high-tech pharmaceutical intermediate goods". The author compiled a nomenclature of high-tech pharmaceutical intermediate goods by SITC Rev.4 (17 nomenclature positions with 6 digits). For the first time, this statistical tool made it possible to estimate the scale of national economy spending on advanced foreign technology embodied in commodities that are inputs in the pharmaceutical industry.

New indicators are proposed: "ratio of import dependence of pharmaceutical production", "'purified' exports of pharmaceutical goods" and "coverage ratio of imports of high-tech intermediate pharmaceutical goods"; their algorithms are given and used in the author's calculations for Germany (strong innovator), Poland (moderate innovator), and Ukraine as a country with low level of technological innovation in the analyzed field. The author recommends using the proposed new indicators for statistical monitoring and analysis of the effectiveness of science & technology and innovation policy measures aimed at building competitive pharmaceutical industry in Ukraine, reducing its dependence on imports and enhancing its export potential.

Key words: *advanced technologies, high-tech goods, production, imports, exports, pharmaceuticals, intermediate goods, import dependence.*

Introduction. In 2007–2018, the global pharmaceutical industry invested more than 1.3 billion USD in research and development (R&D). According to the data of 2017, R&D expenditure reached 163 billion USD, which is 3.9% higher than in the previous year. It is expected that with the annual growth of 3.0%, R&D investment can reach 213 billion USD in 2024 (Figure 1, constructed by data from [1]).

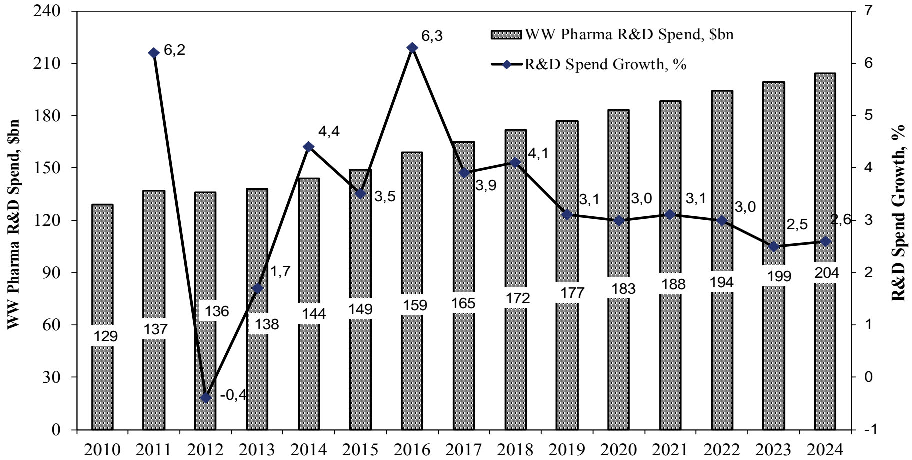

Figure 1. Global R&D expenditure of the pharmaceutical industry in 2010–2024

The results of this vast investment are illustrated by the stably increasing numbers of new approvals by the Food and Drug Administration (FDA): while in 2016 they were 27, in 2017 and 2018 their respective numbers grew up to 55 and 59. Industry experts estimate that the costs for the development and launch of a new medical drug make nearly 900 million USD (30 years ago they did not went higher than 300 million USD), with the average duration of the development varying from 10 to 15 years.

The R&D expenditure of 20 transnational companies (TNCs) accounts for nearly 60% of the total global R&D expenditure of the pharmaceutical industry; for ten and eight TNCs the mother company is located, respectively, in the U.S. and Europe (Table 1, constructed by the author using data from [1]). Their annual R&D investment ranges from 2 to 9 billion USD (from 12.5% to 55.8% of their income).

Table 1

R&D expenditure of key global transnational corporations

Rank	Company	R&D expenditure, billion USD		Share of R&D expenditure in sales, by recipe, %	
		2017	2024	2017	2024
1	Roche (Switzerland)	9.2	11.7	22.0	23.0
2	Johnson & Johnson (the U.S.)	8.4	10.0	24.3	21.0
3	Novartis (Switzerland)	7.8	9.0	18.7	16.9
4	Merck & Co (the U.S.)	7.6	8.3	21.4	21.8
5	Sanofi (France)	6.2	8.2	18.1	18.5
6	Pfizer (the U.S.)	7.6	8.0	16.8	15.7
7	GlaxoSmithKline (the U.K.)	5.0	6.2	17.4	16.2
8	AstraZeneca (the U.K.)	5.4	6.1	27.4	19.2
9	AbbVie (the U.S.)	4.8	5.9	17.4	15.9
10	Bristol-Myers Squibb (the U.S.)	4.8	5.7	25.0	19.9
11	Eli Lilly (the U.S.)	5.0	5.4	26.8	24.4
12	Celgene (the U.S.)	3.0	4.5	23.3	18.9
13	Amgen (the U.S.)	3.5	4.1	16.0	16.5
14	Boehringer Ingelheim (Germany)	3.1	4.1	21.5	22.3
15	Bayer (Germany)	3.3	4.0	18.4	20.0
16	Gilead Sciences (the U.S.)	3.5	3.5	13.7	18.3
17	Takeda (Japan)	2.9	3.3	21.6	19.5
18	Novo Nordisk (Denmark)	2.1	3.1	12.5	12.6
19	Regeneron Pharmaceuticals (the U.S.)	2.1	3.0	55.8	67.2
20	Astellas Pharma (Japan)	2.0	2.4	18.3	18.9
	Total Top-20	97.2	116.4	21.5	20.6
	Others	67.9	87.5	–	–
	Overall	165.1	203.9	20.9	16.9

For comparison: the total R&D appropriations in the public budget of Ukraine for 2020 amount to 10601.4 million UAH (0.235% of GDP) [4]. Given the official exchange rate it is nearly five times lower in absolute terms than the minimal R&D expenditure of Top-20 in the global pharmaceutics. It is obvious that in these perspectives Ukraine has nothing to do but develop the domestic pharmaceutical industry with the reliance on foreign technology transfer.

Today, just like nearly 30 year ago, it can be stated that: TNCs are at the core of the of advanced technology development at global scales [2]; the competencies are accumulated in the countries where mother companies of TNCs are located [3]; results of R&D invested by TNCs lay grounds for international technology transfer; for developing countries its offers an alternative to the endogenous growth in parallel with building domestic R&D and innovation capacities.

Materials and Methods. Models of economic growth based on technology adaptation imply that developing countries are able to catch up with developed economies by adapting advanced technologies imported from leading countries [5]. Such models have been widely used in practice, because introduction and absorption of foreign technologies is a less costly business than generation of new knowledge and products based on it. A. Gerschenkron was among the first ones who stressed the critical role of the advanced technology adaptation to ensure a rapid production growth in a recipient country, as he revealed that the capacity for a rapid growth had positive correlation with the gap between the average technology in a country and the best technology applied in advanced countries [6, p. 230].

In scientific literature it is suggested that foreign technologies can be adapted though formal (commodity imports, foreign direct investment, or purchase of licenses) and informal (imitation, movement of personnel, opening of patents etc.) market channels [7]. It was in 1990 that OECD experts formalized the channels of technology transfer [8], grouping them by the following types of carriers: capital embodied technologies; human-embodied technologies; written, audiovisual and other documentation, i. e. disembodied technology.

Researchers of technology dissemination mechanisms at global level emphasize that imports of goods offer developing countries the most appropriate and effective mechanism for acquisition of new knowledge [9]. A large part of works is focused on the analysis of foreign trade in capital goods as a dominating channel for transfer of embodied technologies [10]. However, some researchers also consider intermediate goods as technology carriers and emphasize that their use in manufacturing of finished products constitutes indirect introduction of technologies in embodied form and causes by-side effect, because the costs of acquired intermediate goods is less than the costs for performing R&D required to manufacture and market these products [11; 12].

The analysis of microlevel data in many countries allows researchers to conclude that liberalization of trade enhances productivity and pushes up economic growth due to the essentially increased productivity in the firms using imported intermediate goods [13; 14]. Some researchers suggest that the trade in intermediate goods embodying technologies constitutes an exogenous factor of economic growth in a host country [15; 16].

Results and Discussion. O. Salikhova combined the Classification by Broad Economic Categories and the Aggregation of products by SITC Rev.4, to distinguish the goods embodying high technologies from the total intermediate goods [17]. It allowed for aggregating high-tech goods by functional purpose (capital goods, intermediate goods, and consumer goods), to create a new statistical tool for more reliable assessment of international trade flows of embodied advanced technologies and their impact on the host country's economy. We deepened this tool with reliance on this approach [18], outlined the range of pharmaceutical high-tech goods that were inputs for manufacturing of finished medical drugs, and introduced the notion of "high-tech pharmaceutical intermediate good" (HT PIG) in the scientific parlance. A nomenclature of HT PIGs was created on the basis SITC Rev. 4 (17 nomenclature positions by 6 digits) and the Ukrainian Classification of Goods for Foreign Economic Activities (33 positions by 6 and 10 digits). This statistical tool was the first one enabling to assess the domestic economy's expenditure on advanced foreign technologies embodied in goods that are inputs in manufacturing of pharmaceutical products.

A significant contribution in creating theoretical, methodical and statistical tools for performance assessment of high-tech industries in the context of globalization was the work of O. Salikhova. She proposed new approaches to determining international comparative advantages, which was the first one to propose a weighted coefficient to be used in calculating the high-tech component in the country's exports of goods and to introduce new indicators of comparative advantages based on the specialization criterion. These indicators include: Revealed Specialization of Production (RSP); Comparative Advantage in Value Added Activity (CAVA); Revealed Effective Export (REX) [19, p. 441–444]. But the assessment of specifics of the domestic pharmaceutical industry considering its imported high-tech component was out of focus.

In addition to the above mentioned tools, we developed new indicators for the assessment of foreign trade in high-tech pharmaceutical goods.

To analyze the domestic manufacturing of pharmaceutical goods, we propose to include the contribution of imported components, HT PIGs in particular, and calculate the import dependence ratio of pharmaceutical production ID_{HTph}:

$$ID_{HTph} = \frac{I_{HTph\_in}}{P_{HTph}}, \qquad (1)$$

where I_{HTph_in} is the imports of intermediate HT PIGs; P_{HTph} is the cost of produced pharmaceutical goods.

To assess supplies of HT PIGs to external markets, we propose to calculate 'purified' exports by weighting it by ID_{HTph}:

$$X^{w}_{HTph} = X_{HTph} \cdot (1 - ID_{HTph}), \qquad (2)$$

where X^{w}_{HTph} is 'purified' exports of high-tech pharmaceutical goods; X_{HTph} is total exports of high-tech pharmaceutical goods.

To assess the benefits from the international trade in high-tech pharmaceutical goods, we proposed to calculate the coverage ratio of HT PIGs imports by "purified" exports of high-tech pharmaceutical goods COV_{HTph}:

$$COV_{HTph} = \frac{X^{w}_{HTph}}{I_{HTph\_in}}, \qquad (3)$$

COV_{HTph} will be higher than 1 when the country's exports of high-tech pharmaceutical goods are based on the domestic production with a high localization in the country and a low dependence on imports of intermediate goods. COV_{HTph} is lower than 1 when the country's exports of high-tech pharmaceutical goods are based on a low localization of the domestic production and a high dependence on imports of technologies embodied in intermediate goods.

Using the database of Eurostat, formulae (1–3) were applied for assessment of the following countries:

– Germany, a strong innovator in EU, which, according to the results of 2018, demonstrated one of the highest global figures of value added in the pharmaceutical industry, 38 billion USD [20];

– Poland, a moderate innovator, which increased the value added in the pharmaceutical industry by nearly thrice, to 1.6 billion USD, in 2002–2018 [20];

– Ukraine, where the value added of the pharmaceutics made only 863 million USD in 2018 [21].

Data sources used in calculations of formulae (1–3):

- for I_{HTph_in}: data of UN Comtrade for the author's Nomenclature of HT PIGs [21];
- for P_{HTph}: data of Eurostat for the indicator "Production value", section 21 "Output of main pharmaceutical products and pharmaceutical preparations" (in 2018 it made 51 797.6 million euro for Germany and 2938.1 million euro for Poland [22]), the official average exchange rate euro/USD in 2018 (1.18), [23]; for Ukraine: data of the State Statistics Service of Ukraine for the indicator "Sales of industrial products" section 21 (34633.2 million UAH in 2018) [25], the official average exchange rate UAH/USD in 2018 (2720.049 UAH for 100 USD) [24];
- for X_{HTph}: data of UN Comtrade for nomenclature categories "Pharmaceutics" of the aggregation of high-tech goods of Eurostat [21; 22].

The results of author's calculations are shown in Table 2.

Table 2

Indicators of foreign trade in high-tech pharmaceutical goods, 2018

Country	$I_{HTph\,in}$, million USD	P_{HTph}, million USD	ID_{HTph}	X_{HTph}, million USD	X^{w}_{HTph}, million USD	COV_{HTph}
Germany	3 948.24	61 121.17	0.06	31 622.00	29 579.32	7.49
Poland	1 196.25	3 466.96	0.35	1 121.68	734.65	0.61
Ukraine	400.05	1 273.05	0.31	60.93	41.78	0.10

The figures given in Table 2 show that COV_{HTph} is the highest in Germany, which demonstrates a high localization of the manufacturing in this country and its low dependence on imports of intermediate goods. The exports of high-tech pharmaceutical goods account for 52% of their domestic output, in which the share of imported HT PIGs makes only 6.5%. The pharmaceutical industry earns on external markets 7.5 times more than spends to purchase the imported components.

In Poland COV_{HTph} is 0.61. This country exports 32.4% of its pharmaceutical output, in which imported components make 34.5%. Only two thirds of the purchases of intermediate goods for the pharmaceutical industry are covered by the earnings from high-tech exports of the industry.

As regards Ukraine, COV_{HTph} makes 0.10. The pharmaceutical output is intended mostly for the domestic market. The exports of high-tech pharmaceutical goods make only 4.8% in the output, with the share of imported components exceeding 1/3. The exports cover only one tenth of the purchased imported components.

The computations show that Ukraine and Poland have similar shares of imported components in the output: 31.5% and 31.4% respectively. But their data on exports are strongly different: 32.4% against 4.8%. Being focused mostly on the domestic market, the Ukrainian pharmaceutics fails to earn currency to cover the costs for purchase of imported substances, whereas Poland exports a major part of its products to the EU market.

The Eurostat indicator "Apparent labor productivity", which is the ratio of value added to employment, is used to assess the production performance. We made its assessment for the countries under study (Table 3, data taken from [20; 25; 26]).

Table 3

Production performance in the pharmaceutical industry, 2018

Country	Employment, persons	Value added, thousand USD	Value added per employee, thousand USD
Germany	133 743	38 077 000	284.70
Poland	25 172	1 568 000	62.29
Ukraine	24 000	863 000	35.96

The employment in the pharmaceutical industry of Ukraine is close to the one in Poland, but the industry performance is 1.7 times lower: 35.96 thousand USD per employee against 62.29 thousand USD per employee. German expectedly demonstrates the highest figure among the countries under study: 284.70 thousand USD per employee.

As emphasized in [19], the value added in the manufacturing is an indicator of the innovation-driven modernization of the economy and a signal of the good performance of high-tech products manufacturers. It is one of the indicators used in the computation of Global Innovation Index (Bloomberg), in particular its component "manufacturing capability", derived as the ratio of value added to the population number.

Conclusions. Considering the low financing of R&D and innovation in the pharmaceutical industry of Ukraine and its heavy dependence on intermediate HT PIGs imports, it can be concluded that this industry in Ukraine has to rely in its development on TNC technologies, and the increasing demand on the domestic market does not result from the implementation of national science & technology and innovation priorities.

International experts predict that in the forthcoming years "countries with transitional economies will be the most rapidly increasing markets, with the annual average growth rate of 9.3%, and the highest growth is expected in Ukraine, in 15.2% CAGR in U.S. dollars" [27].

In 2019, the negative balance of trade in goods in Ukraine made 10.7 billion USD. In view of the demand projections, the continuing increase in the imports of high-tech pharmaceutical goods (both intermediate and finished) will worsen the trade balance, strengthen the risks of UAH devaluation, trigger negative effects in the industry, put under threat the national economy and security.

Considering the problems occurring worldwide due to the pandemic COVID-19, the manufacturing of components for the pharmaceutics becomes a strategic sector. According to a report from Reuters, Europe is affected by the shortage of medical drugs from India [28]. The principal reason for this situation is that the latter are manufactured using the components originating from China that is a maker of active pharmaceutical ingredients for companies across the world. The outbreak of virus stopped this production and disrupted the stability of supplies. The study shows that in view of high dependence of the Ukrainian pharmaceutics on imported intermediate goods, domestic producers are also exposed to this negative influence. And bearing in mind that their main market is the Ukrainian one, consumers will not have access to home-made medical drugs with affordable prices, and the budget will receive less taxes and duties. It follows that to reduce the dependence of the Ukrainian pharmaceutics on foreign ingredients means to decrease the threats facing the economy and the national security.

This can be prevented by adopting mechanisms stimulating the innovation-driven development of the national pharmaceutical industry. One of these mechanisms for providing government assistance for research and innovation projects in the business sector is given in [29]. In project selection, the focus needs to be made on the projects on the development and mass-scale production of ingredients for the pharmaceutics. The production of these innovative goods will allow Ukraine not only to meet the domestic market demand, but to become a credible supplier to external markets, EU in particular.

The proposed indicators – the import dependence ratio of production, 'purified' exports of pharmaceutical goods and the coverage ratio of HT PIGs imports – and their algorithms can be used as criteria in selecting innovation projects, which can be eligible for government support.

The author's approach to the assessment of the external trade in high-tech pharmaceutical goods is worth to be applied across the pharmaceutical sector. Further research should be devoted to the assessment of the actual dependence of Ukrainian producers on imported components and the economic performance of countries supplying them, and to the elaboration of scientifically justified decisions to stimulate building up the facilities in Ukraine for the production of components for the pharmaceutics.

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Нові підходи до оцінювання зовнішньої торгівлі високотехнологічними фармацевтичними товарами

Проаналізовано витрати на дослідження і розробки у фармацевтичній галузі на глобальному рівні за період 2010–2017 рр. Дві третини загальносвітових видатків галузі на ДіР припадає на 20 багатонаціональних компаній, більшість із яких розташовані у США та ЄС. Україна має низький рівень фінансування науки, тому не може виробляти новітні фармацевтичні технології. Імпорт проміжних товарів для фармацевтичної промисловості є найбільш широко використовуваним та найвпливовішим каналом залучення передових технологій. Проаналізовано агрегацію високотехнологічних товарів за функціональним призначенням: високотехнологічні капітальні товари, високотехнологічні проміжні та високотехнологічні споживчі товари. Це агрегування здійснено шляхом поєднання Класифікації за широкими економічними категоріями за SITC Rev. 4 (Відділу статистики ООН) та Агрегації високотехнологічних товарів за SITC Rev. 4 (Євростат). Базуючись на цьому підході, у статті визначено вихідні товари для високотехнологічного фармацевтичного виробництва та введено у науковий обіг поняття “високотехнологічні проміжні фармацевтичні товари”. Сформовано Перелік високотехнологічних фармацевтичних проміжних товарів за SITC Rev. 4 (17 позицій номенклатури з шістьма кодами). Цей статистичний інструментарій вперше дозволив оцінити масштаби витрат національної економіки на передові зарубіжні технології, втілені в товарах, вихідних для фармацевтичної індустрії. У статті запропоновано нові показники: “коефіцієнт імпортозалежності фармацевтичного виробництва”, “очищений” експорт фармацевтичних товарів” та “коефіцієнт покриття імпорту проміжних високотехнологічних фармацевтичних товарів”, а також подано формули їх обчислення і проведено розрахунки за ними для Німеччини (сильного інноватора), Польщі (помірного інноватора) й України як країни з низьким рівнем технологічних інновацій у досліджуваній сфері. Авторка рекомендує використовувати запропоновані нові показники для статистичного моніторингу й аналізу ефективності заходів науково-технічної та інноваційної політики, спрямованих на створення конкурентоспроможного фармацевтичного виробництва на національному рівні, зменшення залежності від імпорту та підвищення експортного потенціалу.

Ключові слова: *передові технології, високотехнологічні товари, виробництво, імпорт, експорт, фармацевтичні товари, проміжні товари, імпортозалежність.*

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