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DETERMINATION OF RISKS FOR BUSINESS ENTITIES IN THE SPHERE OF MANUFACTURING MEDICINES IN MILITARY CONDITIONS IN UKRAINE

Victoriia Zhurenko, Lebedynets Viacheslav

The aim: determination of risks for business entities in the field of production of medicinal products under the conditions of martial law in Ukraine.

Materials and methods. The research materials are the results of a sociological survey in the form of a questionnaire among representatives of the senior management heads of structural units related to the environmental component of business entities' activities in the pharmaceutical production field. Method of sociological survey was used to collect primary information. A questionnaire was conducted, and respondent's answers were registered using google-forms. The method of comparative analysis and generalization of statistical data was used to process the results.

Results. The study identified, analyzed, and assessed risks for business entities in producing medicinal products under martial law in Ukraine.

Significant risks of the destruction of infrastructure and the occurrence of man-made disasters have been identified. Thus, 10 % of pharmaceutical enterprises received critical damage, which makes it impossible to operate the enterprise until the destructive consequences are eliminated; another 15 % received some damage, but the company's activities are carried out. More than 75 % of enterprises can fully comply with the current licensing conditions (LC) for producing and selling medicinal products under martial law.

How critical risks were assessed: supply of raw materials and materials (logistics problems) (60 %); decrease in demand for the company's products (45 %); termination of gas supply (45 %); power outage (40 %); inflation, rising prices of raw materials and energy resources (35 %); termination of communications (35 %); difficulties in purchasing equipment, consumables, devices (30 %); termination of water supply (30 %); lack of competent personnel (30 %).

In the zone of critical risk at this stage remains the ability and willingness of enterprises to work following the plans of the state environmental policy following the Association Agreement between the EU countries and Ukraine. Respondents admit that the company lacks resources to comply with all requirements (20 %), that environmental aspects of activity are currently irrelevant (25 %), and that there are not enough competent specialists to implement the environmental policy and support the relevant procedures (25 %); that there is not enough informational support from the State (30 %).

Conclusions. In fact, 30 % of pharmaceutical enterprises are located in regions that are currently included in the List of territories where hostilities are (were) being waged or temporarily occupied. In general, Ukrainian business entities in the field of pharmaceutical production remain in the zone of uncertainty and significant risk of man-made disasters, non-fulfilment of requirements regarding production conditions, technological processes and constant quality control of production, non-fulfilment of environmental safety of production due to the direct threat of destruction of infrastructure and supply chains, due to the threat of termination of reliable supply of electricity, gas, water, resources, as well as due to high migration of qualified personnel.

Considering the current state of the economy and the environmental consequences of the war, particularly man-made disasters, the implementation of plans to comply with the state environmental policy and the fulfilment of some requirements of the Association Agreement between the EU and Ukraine is at risk.

In the long term, careful scientifically based planning of the rehabilitation program of the pharmaceutical sector is needed, taking into account the risks of pharmaceutical pollution and the adverse impact of the pharmaceutical industry on the natural environment, in particular through the implementation of environmental management systems (EMS) as part of the overall management system of the enterprise to manage environmental aspects; fulfilment of mandatory legal requirements and voluntary obligations following the goals and environmental policy of the enterprise; and to address issues related to risks and opportunities, especially concerning emergency preparedness and emergency response

Keywords: risk assessment, pharmaceutical company, drug production, war martial law in Ukraine, environmental safety, environmental risk, environmental management system

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1. Introduction

Pharmaceutical enterprises under the conditions of martial law, which are business entities in the field of pro-

duction of basic pharmaceutical products and pharmaceutical preparations, face significant risks that complicate or make impossible the prompt and proper functioning of

production, and the integrity of business entities is at risk. Since the beginning of the full-scale invasion of the RF in Ukraine, domestic industrial potential has suffered significant losses, especially in the eastern and southern regions. Significant damage and losses occurred to industrial enterprises, agricultural lands, energy facilities, highways, railways, natural resource bases, water supply systems, and infrastructure of residential and non-residential buildings, including institutions of the medical system. According to estimates of the Kyiv School of Economics, as of the beginning of September 2022, 412 industrial enterprises were damaged and destroyed, taking into account large and medium-sized facilities in the eastern and southern regions of Ukraine, direct damage caused to infrastructure during the war in 2022 reached more than 105.5 billion US dollars [1].

Significant risks remain due to the consequences of damage to the energy infrastructure. A new PAX Environment and Conflict Alert (ECA) in Ukraine has documented how the ongoing bombing of critical infrastructure has damaged more than 213 power plants and more than 63 substations, resulting in health and environmental risks [2].

The threat of new destruction and migration of the labour force made the issue of the relocation of production facilities relevant. A state program for relocating enterprises was adopted [3], but relocation also has numerous risks, some of which are specific to pharmaceutical industries.

This work presents the results of a study that was conducted under martial law in Ukraine and aimed at the determination of risks for business entities in the field of drug production under martial law in Ukraine.

2. Planning (methodology) of research

To conduct the research, the following stages were performed:

I stage (preparatory):

- analysis of professional publications and other sources of information dedicated to the identification, analysis and assessment of risks, the implementation of which may lead to the termination of the functioning of pharmaceutical productions or significantly complicate the implementation of economic activities related to the industrial production of medicinal products (pharmaceuticals);

- analysis of statistical data regarding licensees in the field of economic activity and places of activity for the production of pharmaceuticals in Ukraine;

- analysis of scientific publications on pharmaceutical policy in the European Union and prospects for greening in Ukraine.

II stage (methodical):

- planning of sociological research by the questionnaire method;

- development of questionnaires with questions for interviewers, dedicated to the identification, analysis and assessment of risks inherent in business entities in the field of production of medicinal products in the conditions of martial law in Ukraine. Justification of the required number of respondents in the regions and the selection of respondents.

III stage (organizational):

- preparation of official letters to organizations whose employees are selected as respondents of sociological research;

- technical organization of questionnaires using Google Forms.

IV stage (analytical):

- collection and statistical processing of the survey results;

- critical evaluation of the received data, their statistical analysis, identification of common opinions and disagreements of respondents' judgments.

As a result, the design of the study includes four stages that reflect the peculiarities of conducting a sociological study in the format of a questionnaire survey of business entities in the field of the production of medicinal products in the conditions of martial law in Ukraine.

3. Materials and methods

The research is conducted following the scientific program of the National University of Pharmacy «Quality management in the field of creation, production and circulation of medicinal products» and within the framework of the dissertation research on the topic «Development of the methodology for the implementation of the environmental management system at domestic (at Ukrainian) pharmaceutical enterprises».

The main theoretical and methodological basis for conducting our research were the works of scientists studying the following topics:

- state regulation and implementation of environmental management systems [4];

- environmental management systems and environmental product innovation: the role of stakeholder engagement. Business strategy and the environment [5];

- the impact of eco-certification and reputation on firm performance. Business Strategy and the environment [6];

- global governance in new public environmental management: an international and intertemporal comparison of voluntary standards' impacts [7];

- sustainable environmental management system integration and business performance [8];

- credibility of certified environmental management systems, environmental impact assessment review [9].

In the conditions of limited information and instability of the operating environment of enterprises, it was possible to obtain adequate information about the level of competitiveness of the enterprise and its competitive advantages through the use of expert evaluation methods. A condition for obtaining a high-quality and realistic assessment of the company's competitiveness is the involvement of highly professional specialists with practical work experience in conducting examinations (or in the composition of a group of experts).

Considering the nature of the investigated issues and goals, the most appropriate strategy was sociological research using the questionnaire survey method among business entities in the field of medicinal product production.

It should be noted that our previous research was conducted in the period from July 2021 to January 2022 regarding the identification of the main opportunities and obstacles in the process of implementing environmental management systems (EMS) at pharmaceutical enterprises, as a standardized tool for environmental planning and control of environmental aspects, resource- and energy-efficient technologies and sustainable business methods. The experts were respondents from 24 pharmaceutical enterprises, whose positions are directly related to the management systems of enterprises and environmental management, and therefore meet the criteria for their competence (37 % – senior management: general directors, technical directors, deputy director for quality; 42 % heads of structural units related to the environmental component of the activities of business; 21 % – ecologists). Among the respondents were representatives of enterprises of various forms of ownership; the vast majority of about 70 % of respondents represented large enterprises with more than 250 employees [10].

Our new research, the results of which are presented in this publication, was conducted with the involvement of the same respondents – the senior management of pharmaceutical enterprises and heads of structural divisions that are related to the sphere of environmental activity of the pharmaceutical enterprise, but already under the conditions of martial law in Ukraine. The sociological survey was conducted in the period of April–May 2023. Regarding the sociological survey procedure, respondents were guaranteed anonymity. Questionnaires of 20 respondents containing answers to all questions were selected for the sample. The convergence of respondents' opinions (in particular, the concordance coefficient) was not calculated because each of the respondents provided risk assessments regarding their enterprise. A priori, the convergence of respondents' opinions in this case is not calculated.

The main substantive element of the study consisted of conducting a sociological survey in the form of a questionnaire survey of respondents at pharmaceutical enterprises of Ukraine, licensees of the State Service of Ukraine on Medicines and Drugs Control, who carry out economic activities in the production of medicinal products (21 code according to the classifier of types of economic activity, 2010/Code NACE, Rev.2).

Sociological research was conducted using a questionnaire. A Google Form was used to develop and administer the questionnaire.

The construction of questionnaires is typical and contains the following structural components:

- addressing the respondent, obtaining informed consent to participate in the research;
- main block with targeted questions.

The questionnaire was aimed at determination of risks for business entities in the field of the production of medicinal products under the conditions of martial law in Ukraine.

Research materials (objects) in the form of sociological survey results were studied using statistical, system-analytical methods and the generalization of statistical data (objects) of research. For the quantitative

assessment of immeasurable risk indicators, based on the respondents' assessments, the method of rank correlation with a system of ranks (by points) was applied.

4. Results

The results of the study are given according to the provided answers to the questions of the questionnaire.

A critical problem is the vulnerability of Ukraine's industry under martial law due to excessive regional and industry concentration. From February 24, 2022, active hostilities took place on the territory of 10 regions of Ukraine (Dnipropetrovsk, Donetsk, Kyiv, Mykolaiv, Sumy, Kharkiv, Kherson, Chernihiv, Zaporizhia, Luhansk) and the city of Kyiv.

According to the official data of the State Medical Service of Ukraine at the end of 2022, the number of licensees in the field of economic activity for the industrial production of medicinal products was 128 (230 places of activity) [11]. Currently, 41 economic entities in the field of production of basic pharmaceutical products and pharmaceutical preparations are registered in the regions included in the List of territories where hostilities are (were) being conducted or temporarily occupied by the RF [12]:

1. One of the defining questions of the questionnaire concerned finding out the location of the pharmaceutical enterprises where the respondents work. According to the results of the analysis of the answers of the respondents, it turned out that 30 % of pharmaceutical enterprises are located in the regions that are currently included in the List of territories where hostilities are (were) taking place or temporarily occupied. A third of pharmaceutical production enterprises have significant risks associated with military actions, which critically complicate or make impossible the prompt and proper functioning of production.

Today, the industry of Ukraine operates under conditions of unprecedented challenges associated with the limitation of production and export capacities as a result of the destruction of the relevant infrastructure.

2. To the question "Is there any damage caused to the infrastructure of your enterprise during the war?" respondents gave the following answers:

- 10 % – yes, there were critical damages that made it impossible to operate the enterprise until the destructive consequences were completely eliminated;
- 15 % – yes, there were some damages, but the company's activities are carried out;
- 75 % – no, the company's infrastructure was not damaged. Nothing prevents the company's activities.

The threat of new destruction and significant migration of the labour force brought the issue of relocation of production facilities. The state authorities adopted decisions aimed at guaranteeing the safe operation of the production sector, reducing destructive consequences, facilitating the conditions for conducting economic activities and stimulating European integration movements. A state program for the relocation of enterprises was adopted in Ukraine.

The purpose of the *enterprise relocation program* is to restore the state economy by relocating enterprises

from territories close to or located in the war zone to safe regions of Western Ukraine. (Resolution of the CMU dated March 17, 2022 No. 305 regulated the free transportation of property of domestic enterprises, institutions and organizations following the list formed by the Ministry of Economy and transferred to the Ministry of Infrastructure. Resolution of the CMU dated March 25, 2022 No. 246-r provides for a plan of emergency measures in case of the need to move the production facilities of economic entities from territories where hostilities are taking place and/or there is a threat of hostilities to a safe territory).

The state support package for relocated enterprises includes compensation for the cost of transporting assets, grant support through the «Diya Business» portal, assistance from local administrations to the effective functioning of enterprises in new locations, including connection to communications, simplification of procedures for providing or transferring land plots for use; soft credit program; organizational and methodological assistance in booking employees, etc. [3].

However, relocation also has numerous risks, some of which are specific to pharmaceutical industries: loss of part of the permanent team, lack of competent specialists at the new location, problems with the choice of premises for medium and large enterprises, high probability of damage or loss of property during dismantling, packing, transportation, re-installation and start-up of equipment, engineering systems, measuring equipment, etc.; the need for revalidation of clean rooms; negative changes in supply chains and others. A significant factor is that relocation requires registration at the place of the new location, as well as the reissuance of licenses. Although during the period of martial law, the CMU introduced the declarative principle of acquiring the right to conduct economic activity without the need to obtain documents of a permissive nature, licenses, etc., about 20 special licenses remained mandatory.

The results of our research on the relocation of pharmaceutical enterprises revealed that 15 % of respondents faced relocation issues, and another 5 % are planning such actions. The data are presented through the analysis of the following two questions.

3. To the question «Have the facilities of your enterprise been moved (relocated)?» respondents gave the following answers

– 65 % – no, our facilities did not move because they are located in an area where hostilities were not and are not being conducted;

– 20 % – no, our forces remained in the areas currently included in the List of territories where hostilities are (were) conducted or temporarily occupied by the RF. (Dnipropetrovsk, Donetsk, Mykolaiv, Sumy, Kharkiv, Kherson, Chernihiv, Zaporizhia, Luhansk);

– 10 % – no, our facilities did not move, but new sites were opened in other regions;

– 5 % – yes, the facilities were (fully or partially) relocated to other regions of Ukraine.

4. To the question «Is relocation of the facilities planned in the near future?» respondents gave the following answers:

– 80 % – no, there are currently no such plans;
– 15 % – the management has not yet decided on this issue;

– 5 % – yes, there are plans to relocate to other regions.

Despite the active state support for business after the start of a full-scale war, the introduction of relocation programs, and the provision of tax and customs benefits (in particular, for small businesses), the effectiveness of these measures for industry as a whole remains insufficient due to the constant increase in production costs of industrial enterprises.

According to the results of 2022, industrial production in Ukraine decreased by 36.9 %: more than a third of industrial enterprises stopped working. In the extractive industry, the drop in production was 30.1 %; in the processing industry – 41.2 %; in the supply of electricity, gas, steam and air conditioning – 30.7 %. Among the branches of the processing industry, the production of basic pharmaceutical products and pharmaceutical preparations experienced a significant decline of 29.9 % [13].

Our research also revealed the reduction of industrial capacities for the production of medical equipment due to physical destruction, the narrowing of sales markets due to the blocking or disruption of the logistics infrastructure, the migration of the population and the decrease in the purchasing power of the population. Thus, 60 % of respondents noted that their production volumes have decreased, and another 10 % noted that production is currently not carried out. A third of the enterprises have savings or even positive dynamics, which is tracked in the respondents' answers to the following questions of the questionnaire.

5. To the question «Are the pre-war (until 2022) production volumes preserved?» respondents gave the following answers

– 10 % – no, production is currently not carried out;

– 60 % – no, production volumes have decreased;

– 20 % – yes, production is carried out in the same volume as before the war;

– 10 % – production volumes increased.

The following questions of the questionnaire were aimed at determining risks (identifying and analyzing risks), which allows to assess the general picture of the vulnerability of the enterprise, that is, to identify all threats to the conduct of business activities.

Risk identification is the process of establishing a list of the main types of risks inherent in the activity of a specific organization, which can affect a specific area of work, a field of activity or the organization as a whole.

Risk identification makes it possible to assess the probability and consequences of the occurrence of adverse events. Make it possible to assess the probability and consequences of the occurrence of adverse events. Assessing the level of risk is one of the most important stages of risk management since, in order to manage this risk, it must first be analyzed and evaluated. There are many definitions of this concept in the scientific literature; in general, risk assessment is understood as a systematic process of

identifying risk factors and types and their quantitative assessment, i.e. risk analysis methodology combines complementary quantitative and qualitative approaches.

6. Analysis of the answers to the question «Provide an assessment of the risks, the implementation of which can significantly complicate or lead to the termination of the operation of production».

During the assessment of risks, the implementation of which can significantly complicate or lead to the cessation of the operation of production, a situation was revealed when there are neither statistics nor the possibility to build a mathematical model, there was a place for the study of objects with uncertain parameters. Therefore, a quantitative assessment of the risk was carried out based on processing the answers of the respondents.

Respondents identified the following as critical risks:

- supply of raw materials and materials, customs or logistics problems (60 % of respondents);
- decrease in demand for the company’s products (45 % of respondents);
- termination of gas supply (45 % of respondents);
- power outage (40 % of respondents);
- inflation, rising prices of raw materials and energy resources (35 % of respondents);
- termination of communication (Internet, mobile communication) (35 % of respondents);
- difficulties in purchasing equipment, consumables, devices (30 % of respondents);
- termination of water supply (30 % of respondents);
- lack of competent personnel (30 % of respondents).

Detailed information is presented in Fig. 1.

To quantify immeasurable risk indicators, based on respondents’ assessments ($n=20$), we applied the method of rank correlation with a system of ranks (by points), taking into account that critical risk – 3 points, medium risk – 2 points, insignificant risk – 1 point.

The determined sum of ranks for each risk factor made it possible to distribute risk factors according to their importance to de-

termine the risk rank. The average value of the ranks helps to determine the collective opinion about the significance of the risk factor. In this way, the rank of risks was determined, and the distribution was made from the most significant to the least significant risk factor and their average assessment (Table 1, Fig. 1).

According to the results of our study, the risk of disruption of the supply of raw materials and materials, customs, and logistics problems are recognized by the majority of respondents as critical. Based on the results of the applied rank correlation method, this factor was determined to be the first in the ranks of risks. The second in rank is the decrease in demand for the company’s products.

The data of the Institute of Economic Research and Political Consultations confirm this trend on a national scale. In particular, about the fact that a certain list of three main obstacles has been formed: in the first place – rising prices for raw materials and goods, in the second place – logistical problems, in the third place – a decrease in demand for products and services [14].

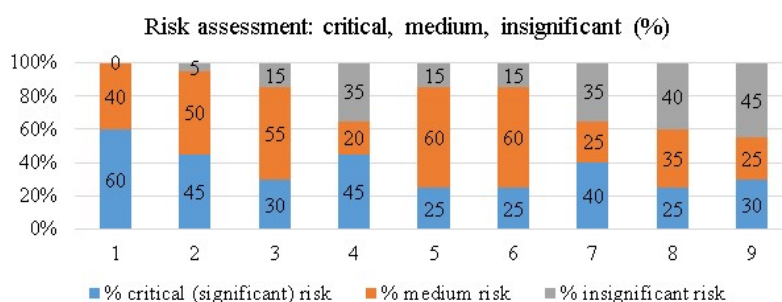


Fig. 1. Assessment of risks, the implementation of which can significantly complicate or lead to the cessation of production/distribution of risk factors by rank (significance), according to the sum of ranks. 1 – supply of raw materials and materials (customs, logistics problems); 2 – decrease in demand for the company’s products; 3 – inflation, rising prices of raw materials, energy resources; 4 – termination of gas supply; 5 – difficulties in purchasing equipment, consumables, devices; 6 – lack of competent personnel; 7 – power outage; 8 – termination of water supply; 9 – termination of communication (internet, mobile communication). Number of respondents, $n=20$

Table 1

Assessment of risks, the implementation of which can significantly complicate or lead to the cessation of production

Risks that can complicate/stop the operation of production	The number of respondents and their assessment of risks			The sum of ranks (points)	Average value of ranks (points)	Risk rating
	Critical risk (3 points)	Medium risk (2 points)	Insignificant risk (1 point)			
Supply of raw materials and materials: customs, logistics problems	12	8	–	52	2.6	1
Decrease in demand for the company’s products	9	10	1	48	2.4	2
Inflation, rising prices of raw materials and energy resources	6	11	3	43	2.15	3
Stoppage of gas supply	9	4	7	42	2.1	4
Difficulties in purchasing equipment, consumables, devices	5	12	3	42	2.1	5
Lack of competent personnel	5	12	3	42	2.1	6
Power outage	8	5	7	41	2.05	7
Stopping water supply	5	7	8	37	1.85	8
Termination of communication (Internet, mobile communication)	6	5	9	37	1.85	9

The problem lies in the changes and disruption of global supply chains, affecting food security, energy and other critical sectors, including for key pharmaceutical and pharmaceutical companies. The blockade of the ports led to the suspension of supplies to Ukraine of imported materials and raw materials (ampoules, infusions, etc.). The departure abroad of women, children and the elderly, who are the main consumers of medicines, caused a significant reduction in domestic demand. The shortage and significant increase in the price of imported medicines at the background of interruptions in supply and the devaluation of the hryvnia, as well as the purchase of medicines for the needs of the Armed Forces, stimulated the demand for more affordable and cheaper domestic products.

The share of imports in the domestic consumption of chemical and petrochemical products decreased, which is due, among other things, to the cessation of imports from the RF and Belarus, which were important suppliers to the Ukrainian market of chemical and petrochemical products for many years. Import dependence decreased from 89.9 % to 84.6 % for basic chemical products, for pharmaceutical products – from 71.8 % to 64.6 %, for petrochemical products – from 82.2 % to 71.8 % [13].

The state of the pharmaceutical market is an essential factor for the strategic planning of the activities of pharmaceutical production enterprises. In general, in 2022, the retail farm market showed a decrease in sales volumes in hryvnia terms by 7 % compared to 2021; in natural terms, pharmacy sales decreased by 29 %. Inflation on the farm market was 19 % in 2022 [15].

The narrowing of the domestic market occurred as a result of a decrease in the real income of the population, the outflow of significant masses of the population abroad, the reorientation of consumers to meet basic needs, and the curtailment of investment programs by most enterprises. These factors are determined in statistical analyses of the Ukrainian pharmaceutical market.

There are significant risks of business termination due to such factors as maintaining high world prices for gas, which is used as an energy carrier and raw material for production. A risk factor is excessive dependence on centralized sources of energy supply. After the start of the massive shelling of energy facilities, there have been regular power outages at enterprises of the industry belonging to critical infrastructure. In the conditions of war, the opportunities for industrial enterprises to diversify sources of energy supply are extremely limited, as they require significant investments.

In December 2022, the Cabinet of Ministers of Ukraine (CMU) identified priority groups for electricity supplies, which include critical infrastructure, water and heat supply facilities, and hospitals. Critical infrastructure facilities include, in particular, the production of the chemical, metallurgical, defence, space, aviation, shipbuilding, pharmaceutical industries, production and processing of agricultural and/or food products [16].

Measures are being taken to provide Ukraine with the electricity required for the functioning of industrial enterprises and household consumers in the conditions of

massive RF missile strikes on critical energy infrastructure facilities – import duty-free «Starlink» and other energy equipment has been introduced through the adoption of the relevant Laws of Ukraine.

It was possible to stabilize work in conditions of energy restrictions thanks to the installation of powerful generators capable of providing the enterprise with electricity for 3 days, the opening of new factories abroad («Pharmak»), the transfer of certain production processes to night shifts and weekends, the use of LED lighting («Darnytsia», «Borshchagivsky HFZ»), diversification of energy resources, lowering the temperature in production premises, increasing the speed of machines («Arterium») [17].

7. Analysis of the question «How do you assess the likelihood of the realization of threats that may affect the staffing of domestic pharmaceutical enterprises in the next 6–12 months? »

Staffing remains a risk for pharmaceutical industries. There are problems with the outflow of specialists from abroad. The loss of human potential in hostilities and the migration of millions of displaced persons in Ukraine and abroad led to a humanitarian crisis. Currently, the number of refugees from Ukraine registered for temporary protection or similar national protection schemes in Europe has reached 6.28 million people [18]. There are also problems with the reservation of specialists from conscription for military service, in connection with the ban on the reservation of conscripts who have military accounting specialities that are in short supply for the Armed Forces of Ukraine (letter of the Ministry of Defense dated 11.03.2022 No. 220/1469).

In our opinion, the issue of providing qualified personnel will only worsen because today, there is a sharp decrease in the influx of applicants to specialized institutions of higher education to receive pharmaceutical education. According to the Testing Center (Ministry of Education and Science of Ukraine), for several years in a row, there has been a tendency to decrease the number of people registered for external independent assessment in chemistry; for example, in 2017 – 24,811 people, in 2019 – 15,488 people, and in 2021 – 9 885 people [19]. This is the pre-war situation.

The results of our research regarding the question «How do you assess the probability of the realization of threats that may affect the staffing of domestic pharmaceutical enterprises in the next 6–12 months?» are given in Table 2 and Fig. 2.

Respondents identified the following as critical risks:

- decrease in the number of competent personnel due to departure abroad (40 % of respondents);
- reduction in the number of competent personnel due to the mobilization of men (40 % of respondents);
- increase in psychological problems due to the stressful state of the staff (30 % of respondents);
- decrease in the number of competent personnel due to their transfer to work in other industries (10 % of respondents);
- reduction in the number of competent personnel due to internal migration (5 % of respondents).

Table 2

Assessment of the likelihood of the realization of threats that may affect the staffing of domestic pharmaceutical enterprises in the next 6–12 months. Number of respondents, $n=20$

Threats (risks) that may affect the staffing of domestic pharmaceutical enterprises	The number of respondents and their assessment of risks			The sum of ranks (by points)	Average value of ranks (by points)	Risk rating
	High risk (3 points)	Medium risk (2 points)	Insignificant risk (1 point)			
Reduction in the number of competent personnel due to departure abroad	8	9	3	45	2.25	1
Reduction in the number of competent personnel due to the mobilization of men	8	7	5	43	2.15	2
Increase in psychological problems due to the stressful state of the staff	6	6	8	38	1.9	3
Reduction in the number of competent personnel due to their transfer to work in other industries	2	9	9	33	1.65	4
Reduction in the number of competent personnel due to internal migration	1	10	9	32	1.6	5

To quantitatively assess the likelihood of the realization of threats that may affect the staffing of domestic pharmaceutical enterprises in the next 6–12 months, based on the assessments of respondents ($n=20$), we applied the method of rank correlation with the rank system, taking into account that the high risk was estimated at 3 points, medium risk – 2 points, insignificant risk – 1 point.

The determined sum of ranks for each risk factor (threats) that may affect the staffing of domestic pharmaceutical enterprises made it possible to distribute the risk factors according to their importance to determine the risk rank. The average value of the ranks determines the collective opinion about the significance of the risk factor (Table 2, Fig. 2).

The distribution of risk factors by rank (significance) was determined according to the sum of the ranks:

- 1 – reduction of the number of competent personnel due to departure abroad;
- 2 – reduction in the number of competent personnel due to the mobilization of men;
- 3 – increase in psychological problems due to the stressful state of the staff;
- 4 – reduction of the number of competent personnel due to their transfer to work in other industries;
- 5 – reduction of the number of competent personnel due to internal migration.

8. To the question «How do you assess the ability of your enterprise to comply with the current Licensing Conditions (LC) for the production and sale of medicinal products during martial law?» respondents gave the following answers:

- 75 % – Nothing has changed in any way: we fulfil absolutely all LC requirements;
- 20 % – Due to lack of resources and other reasons, some non-critical provisions of the LC are not fully / not always fulfilled;
- 5 % – Other.

It should be noted that during the period of martial law, the CMU introduced the declarative principle of acquiring the right to conduct economic activity without the need to obtain documents of a permissive

nature, licenses, etc. However, about 20 special licenses remained mandatory. The term of validity of valid fixed-term licenses and documents of a permissive nature is automatically extended for the period of martial law. In addition, the government suspended the terms of issuing permits and licenses for the duration of martial law in Ukraine. Suspended terms are subject to renewal within 1 month after the termination or cancellation of martial law. Also, by Resolution No. 303 of the Cabinet of Ministers of Ukraine dated March 13, 2022, planned and unplanned measures of state supervision (control) and state market supervision have been suspended for the period of martial law.

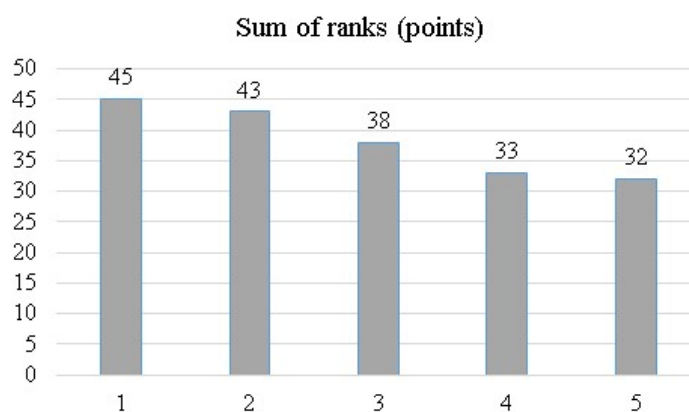


Fig. 2. Assessment of the likelihood of the realization of threats (risks) that may affect the staffing of domestic pharmaceutical enterprises in the next 6–12 months. Distribution of risk factors by rank, corresponding to the sum of ranks: 1 – reduction of the number of competent personnel due to departure abroad; 2 – reduction in the number of competent personnel due to the mobilization of men; 3 – increase in psychological problems due to the stressful state of the staff; 4 – reduction in the number of competent personnel due to their transfer to work in other industries; 5 – reduction in the number of competent personnel due to internal migration. Number of respondents, $n=20$

9. Analysis of the question «How do you assess the financial prospects (for the next 6–12 months) of your enterprise on the domestic pharmaceutical market? »

The biggest uncertainty is the question of the financial prospects of enterprises in the pharmaceutical market of Ukraine for the next 6–12 months. The respondents' answers are given in Table 3. and Fig. 3.

Only 15 % of respondents predict positive changes in the growth of asset values; increase in net profit – 20 % of respondents; growth of sales volumes in natural terms (number of packages) – 30 %; sales growth in hryvnias – 40 %.

Table 3
Assessment of financial prospects (for the next 6–12 months) of enterprises in the pharmaceutical market of Ukraine. Number of respondents, n=20

Financial opportunities in the future	“Will increase” the number of responses/%	“Will decrease” the number of responses/%	“It is difficult to predict” the number of responses/%
Sales volumes in hryvnias	8/40 %	4/20 %	8/40 %
Sales volumes in natural terms (number of packages)	6/30 %	8/40 %	6/30 %
Net profit	4/20 %	7/35 %	9/45 %
Asset value	3/15 %	4/20 %	13/65 %

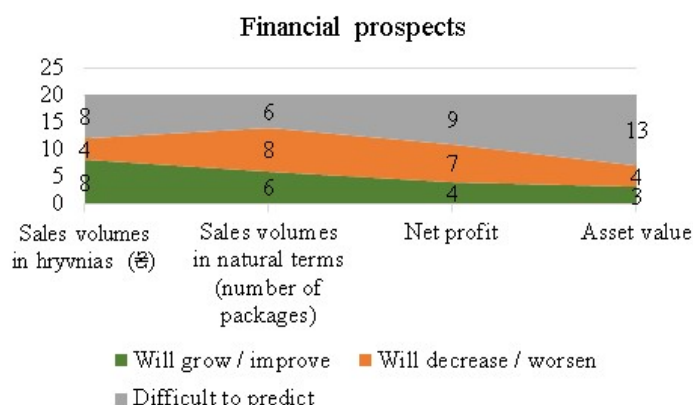


Fig. 3. Assessment of the financial prospects (for the next 6–12 months) of your enterprise on the domestic pharmaceutical market. Number of respondents, n=20

10. To the question, «How do you assess the ability and willingness of enterprises to work according to the principles of responsible business conduct and the implementation of plans for the implementation of state environmental policy in accordance with the Association Agreement between Ukraine and the EU at this stage?» respondents gave the following answers:

- 25 % – environmental aspects of activity are currently irrelevant;
- 20 % – insufficient resources to meet all requirements;
- 25 % – there are not enough competent specialists to implement the environmental policy and support the relevant procedures;
- 30 % – lack of informational support from the State.

In the future, taking into account the current state of the economy and the ecological consequences of the war, the plans for compliance with the state environmen-

tal policy and the implementation of the Association Agreement between Ukraine and the EU are under threat, in particular, the work of enterprises according to the principles of responsible business is significantly complicated or impossible (responsible business conduct, RBC).

During the period of martial law introduced by Decree 4 of the President of Ukraine dated 24.02.2022 No. 64 «On the introduction of martial law in Ukraine», changes were made to the legislation on environmental protection, in particular: obtaining some permit documents based on the submission of declarations with the need to carry out all procedures after the cancellation of martial law in accordance with the requirement of Resolution of the CMU No. 314 of March 18, 2022; termination of the provision of administrative services in the field of monitoring, reporting and verification of gas emissions, and therefore the lack of inspections and responsibility for untimely submission of such reports on this basis in accordance with the Resolution of the CMU of February 28, 2022 No. 165 and the Law of March 3, 2022 No. 2115; exemption from payment of environmental tax for 2022 of enterprises located in the territories of hostilities, in accordance with Law No. 2120.

5. Discussion

The pharmaceutical industry is a regulated field where quality standards must be strictly followed to ensure the safety and efficacy of medicines. It is important for pharmaceutical companies to be able to maintain a high level of organization and efficiency in their activities. More than 75 % of enterprises are able to fully comply with the current licensing conditions (LC) for the production and sale of medicinal products during martial law. In other cases, due to a lack of resources and other reasons, some non-critical provisions of the LC are not fully or not always implemented.

The aftermath of the war in Ukraine has jeopardized the recovery of the global economy after the COVID-19 pandemic. It is changing and disrupting global supply chains, affecting food security, energy, and other critical sectors such as pharmaceuticals and healthcare.

A critical problem is the vulnerability of Ukraine's industry due to excessive regional and sectoral concentration, it turned out that 30 % of pharmaceutical enterprises are located in regions that are currently included in the List of territories where hostilities are (were) being waged or temporarily occupied. Significant risks of infrastructure destruction and, as a result, significant risks of man-made disasters have been identified. According to our study, 10 % of pharmaceutical enterprises received critical damage, which makes it impossible to operate the enterprise until the destructive consequences are completely eliminated; another 15 % received some damage, but the company's activities are carried out.

To date, the industry of Ukraine operates under conditions of unprecedented challenges associated with the limitation of production and export capacities as a result of the destruction of the relevant infrastructure.

The following critical risks were assessed:

- supply of materials (customs or logistics problems) (60 %);
- decrease in demand for the company's products (45 %);
- termination of gas supply (45 %);
- power outage (40 %);
- inflation, rising prices of raw materials and energy resources (35 %);
- termination of communication (35 %);
- difficulties in purchasing equipment, consumables, devices (30 %);
- termination of water supply (30 %);
- lack of competent personnel (30 %).

In the zone of critical risk at this stage is the ability and willingness of enterprises to work according to the principles of responsible business conduct and in accordance with the plans for the implementation of the state environmental policy following the Association Agreement between the EU countries and Ukraine. In particular, 20 % of respondents determine that the company does not have enough resources to comply with all requirements; more than 25 % of respondents note that environmental aspects of activity are currently irrelevant; 25 % of respondents note that there is a lack of competent specialists to implement environmental policy and support relevant procedures; 30 % of respondents note that there is a lack of informational support from the State.

Enterprises, economic entities in the field of production of basic pharmaceutical products in Ukraine are faced with increased problems of supporting businesses in high-risk conditions (destructive effects of production, occurrence of man-made disasters, lack of reliable supply of electricity, resources, water, lack of safe the work of the production sector and the uncertain conditions of economic activity, problems with staffing).

Today, it is a fact that the pharmaceutical industry lags behind European countries in the field of «greening», which, in the long run, will inhibit the involvement of Ukrainian manufacturers in European value-added chains and reduce their competitiveness, making it difficult for Ukrainian exports to the EU.

The need to obtain a license for the sale of medicinal products for humans may become an obstacle to the entry of Ukrainian pharmaceutical companies into the markets of the European Union, which should be accompanied by “an indication of any potential risks that the medicinal product poses to the environment. a European Medicines Agency (EMA) guidance document, now called Environmental Risk Assessment (ERA), is available for this task [20].

As incentives for life-enhancing and life-prolonging innovation, the possibility of requiring pharmaceutical companies to conduct environmental impact assessments alongside clinical trials is being considered [21].

The movement towards a more environmentally sustainable pharmaceutical industry and plans to achieve zero carbon emissions in its activities are increasingly being considered [22, 23]

Under the realities of war, meeting the goals of the «green» transition seems impossible for Ukraine due to a

lack of resources and a shift in priorities towards ensuring the basic conditions for the survival of industrial production.

The restoration of the industrial infrastructure destroyed during the hostilities and the implementation of structural modernization will require a sharp increase in investment volumes. However, in the conditions of hostilities and the high risk of man-made disasters, Ukrainian industry is unattractive to private investors. If high-security risks persist in the medium term, the investment crisis may become protracted.

The main problem is the impossibility of long-term planning of activities due to possible hostilities.

Instead, the EU countries, despite making certain adjustments and softening the policy of the «green» course, will not abandon its implementation.

The need to include direct environmental requirements in EU pharmaceutical legislation instead of cross-referencing other EU environmental legislation is actively discussed, as well as recommendations to integrate environmental aspects and relevant verification mechanisms into GMP to ensure a minimum level of sustainable manufacturing practices [24].

There is a wide discussion among scientists about the actions of the pharmaceutical industry to sustainably reduce the negative impact of drugs on the environment [25, 26].

Production in Ukraine must comply with the European industrial policy, the agenda of which includes such competitiveness factors as automation of processes, energy efficiency, implementation of the principles of sustainable development, circular economy approaches, resource-efficient and clean production, etc. This will enable them to produce products certified according to European standards, to be included in global chains of added value creation, and to establish cooperation with European partners, in particular regarding the exchange of knowledge, and experience in the creation of modern technological and knowledge-intensive industries.

Granting Ukraine the status of a candidate for EU membership by the European Council on June 24, 2022 prompted the acceleration of European integration reforms in all spheres, including industry. The analysis of the implementation of the Association Agreement between Ukraine, on the one hand, and the European Union, the European Atomic Energy Community and their member states, on the other hand, for 2014–2022, shows progress in this area [27].

The implementation of European integration reforms will contribute to ensuring the stability of the industry in way of creating conditions for its integration into the European economy and the post-war recovery of Ukraine according to European norms and standards, which will make it possible to effectively resist the threats, challenges and risks of war, to adapt to changes in military circumstances without significant loss of functionality of industrial facilities, as well as lay a solid foundation for recovery and growth in the future. The activation of European integration movements opens up such prospects for Ukrainian industry as access to EU financial instruments.

It is worth noting that Ukraine can count on large-scale investments only after the end of hostilities. Accu-

mulating funds for the recovery of Ukraine through a special Solidarity Trust Fund, the EU will treat such investments as contributions to the financing of a potential future EU member. At the same time, the development of industry should take place taking into account the principles of the «green economy», which involves the restoration of destroyed enterprises with a higher level of labour productivity, energy efficiency, climate neutrality, and a larger volume of manufactured products.

In the long term, enterprises should take into account the risks associated with the adverse impact on people, the planet and society as a result of their activities or business relations and adhere to the principles of environmentally friendly, «green» reconstruction for the future development of Ukraine.

Research limitations. In connection with the state of war and the conduct of hostilities in part of the territory of Ukraine, under the conditions of the constant threat of the destruction of infrastructure and the cessation of the activities of pharmaceutical enterprises, the number of respondents who took part in the questionnaire became less than planned. About 30 % of letters with an invitation to participate in the survey remained unanswered. This percentage roughly correlates with the number of pharmaceutical enterprises located in regions with the status of territories where hostilities are (were) being waged or temporarily occupied.

Prospects for further research. An important condition for determining the real prospects for the greening of pharmaceutical production in Ukraine is an unbiased and reliable assessment of currently existing problems, as well as the identification, analysis and assessment of risks inherent in business entities in the field of pharmaceutical production in Ukraine in general and in the conditions of martial law in particular.

Among the priority tasks regarding the further development of the pharmaceutical industry is ensuring its functioning following the principles of the state environmental policy formulated following the Association Agreement between the EU and Ukraine. It is necessary to take into account the consequences of the implementation of the environmental requirements of the EU pharmaceutical legislation, as well as the integration of environmental aspects into the guidelines on the proper practices of medicinal products adopted in Ukraine through the harmonization of the relevant European directives.

Accordingly, in the future, we consider it necessary to continue conducting sociological research in order to determine the trends and dynamics of changes in the development priorities of domestic pharmaceutical enterprises, simultaneously expanding the scope of coverage of professional respondents.

Accordingly, we consider it necessary to update the research on issues of regulatory and legal regulation of the activities of pharmaceutical enterprises in relation to the management of environmental aspects, in particular – regarding responsibility for compliance with mandatory legal requirements and voluntary obligations regarding environmental goals and policies.

6. Conclusions

The main achievement of the conducted research is the determination of risk, in particular – environmental, of business entities in the field of the production of medicinal products under the conditions of martial law in Ukraine, which is a necessary condition and starting point for further measures to minimize the consequences of relevant problems in the future.

According to the results of a sociological study conducted in the form of a questionnaire survey of respondents in the period from April to May 2023 of pharmaceutical enterprises of Ukraine (licensees engaged in economic activity in the production of medicinal products), the main existing problems, threats and risks were determined that affect or may affect the activities of these enterprises.

Thus, the defining problem is the continuation of military operations on the territory of Ukraine and, as a result, the direct threat of destruction or damage to infrastructure, the occurrence of man-made disasters, the disruption of supply chains, the cessation of activities due to the unreliable supply of electricity, gas, water and other energy resources, as well as due to significant migration qualified personnel. In addition, some pharmaceutical companies were forced to change the location of production facilities, which in some cases is connected with the impossibility of full and permanent compliance with regulatory and legislative requirements, including requirements for environmental safety of production.

30 % of pharmaceutical enterprises are located in regions that are currently included in the List of territories where hostilities are (were) being waged or temporarily occupied.

The results of our research on the relocation of pharmaceutical enterprises revealed that 15 % of respondents faced relocation issues, and another 5 % are planning such actions.

Significant risks of the destruction of infrastructure and the occurrence of man-made disasters have been identified. Thus, 10 % of pharmaceutical enterprises received critical damage, which makes it impossible to operate the enterprise until the destructive consequences are eliminated; another 15 % received some damage, but the company's activities are carried out. More than 75 % of enterprises are able to fully comply with the current licensing conditions (LC) for the production and sale of medicinal products under martial law.

How critical risks were assessed: supply of raw materials and materials (logistics problems) (60 %); decrease in demand for the company's products (45 %); termination of gas supply (45 %); power outage (40 %); inflation, rising prices of raw materials and energy resources (35 %); termination of communications (35 %); difficulties in purchasing equipment, consumables, devices (30 %); termination of water supply (30 %); lack of competent personnel (30 %).

The biggest uncertainty is the question of the financial prospects of enterprises in the pharmaceutical market of Ukraine. Only 15 % of respondents predict positive changes in the growth of asset values; increase

in net profit – 20 %; growth of sales volumes in natural terms (number of packages) – 30 %; sales growth in hryvnias – 40 %.

Considering the current state of the economy and the environmental consequences of the war, we see the threat of non-fulfilment of the principles of Ukraine's state environmental policy and some requirements of the Association Agreement between the EU and Ukraine as quite serious.

Respondents admit that the company lacks resources to comply with all requirements (20 %); that environmental aspects of activity are currently irrelevant (25 %); that there are not enough competent specialists to implement the environmental policy and support the relevant procedures (25 %); that there is not enough informational support from the State (30 %).

Taking into account the serious risks of pollution of the natural environment and other negative consequences of the influence of the pharmaceutical industry on the ecosphere, which only intensified during military operations, in the long term, the need to develop a scien-

tifically based program of ecologically oriented restoration and development of the pharmaceutical sphere of the national health care industry is already obvious.

The practical significance of this work lies in the actualization of issues related to the greening of pharmaceutical enterprises based on the experimental data of the conducted research.

Conflict of interest

The authors declare that they have no conflict of interest in relation to this research, whether financial, personal, authorship or otherwise, that could affect the research and its results presented in this article.

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Data availability

The manuscript has no associated data.

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Victoriia Zhurenko*, Postgraduate Student, Department of Pharmacy Management and Economics, Institute of Advanced Training of Pharmacy Specialists, National University of Pharmacy, Pushkinska str., 53, Kharkiv, Ukraine, 61002

Lebedynets Viacheslav, Doctor of Pharmaceutical Sciences, Professor, Department of Pharmacy Management and Economics, Institute of Advanced Training of Pharmacy Specialists, National University of Pharmacy, Pushkinska str., 53, Kharkiv, Ukraine, 61002

**Corresponding author: Victoriia Zhurenko, e-mail: zhur@nuph.edu.ua*