Analysis of changes in the greening capacity of Ukrainian pharmaceutical enterprises before and after the introduction of martial law

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Abstract.
Since the European Union granted Ukraine the status of a candidate for EU membership, the self-screening of Ukrainian legislation and processes of harmonization with EU regulatory acts, in particular in the field of the production of medicinal products, have been ongoing. But in the conditions of military law and the continuation of hostilities in part of the territory of Ukraine, pharmaceutical enterprises remain in the zone of critical risk of infrastructure destruction, disruption of logistics, resource provision, etc. Therefore, there is a shift in priorities towards ensuring the basic conditions for ensuring the functioning of production. The lack of access to part of the territories, the destruction of infrastructure, the loss and migration of personnel, as well as the suspension of measures of state environmental control during the period of martial law negatively affected the possibility of full implementation of state management in the field of environmental protection. Environmental problems are accumulating, the risk of significantly lagging behind European countries in the field of "greening" of industry is increasing. All this significantly reduces Ukraine's ability to fulfill the conditions of EU membership on environmental and climate change issues. The aim of the study is to analyze and determine the capabilities of pharmaceutical enterprises for greening ("greening") in the pre-war and military-legal conditions of Ukraine on the basis of sociological research. Materials and methods. The materials of sociological research are the results of questionnaire surveys among representatives of the top management of pharmaceutical enterprises of Ukraine, which are business entities in the field of drug production. Respondents' answers were recorded using google-forms. Statistical methods were used to process the results. Results. The conducted analyze revealed a significant decrease in attention to environmental aspects, correspondingly, a decrease in the readiness and capacity for greening ("greening") of pharmaceutical enterprises due to the significant complication of production conditions and
the suspension of state environmental control measures for the period of martial law. In particular, 20% of respondents determined that the enterprise lacks resources to comply with environmental requirements; 25% of respondents noted that environmental aspects of activity are currently irrelevant; 25% of respondents noted that there is a lack of competent specialists to implement environmental policy and support relevant procedures; 30% of respondents noted that there is a lack of information awareness. However, 75% of pharmaceutical enterprises fully comply with the current license conditions for the production and sale of medicinal products, which also regulate environmental aspects, in particular industrial emissions. In other cases, due to lack of resources and other reasons, some non-critical provisions of the LU are partially fulfilled. Conclusions. Since 2022, Ukraine has been under martial law, and production, in particular, pharmaceutical enterprises are in a critical risk zone due to the direct threat of the destruction of infrastructure and the occurrence of man-made disasters. 30% of pharmaceutical enterprises remain in the territories where military operations were or are being conducted. These are force majeure factors that complicate or make production processes impossible, disrupt or complicate global supply chains, and are a threat to environmental security. The forced suspension of state environmental control measures for the period of martial law also has a negative impact on the possibility of fully implementing state management in the field of environmental protection in Ukraine. These factors significantly reduce the readiness and capacity of pharmaceutical enterprises for greening, accordingly, the ability of Ukraine to fulfill the conditions of membership in the EU on environmental issues and climate change at this stage is complicated.

**Keywords:**
- risk assessment
- pharmaceutical company
- martial law in Ukraine
- environmental risk
- environmental management system

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**Introduction.** Since the European Union granted Ukraine the status of a candidate for EU membership, the self-screening of Ukrainian legislation and processes of harmonization with EU regulatory acts have been ongoing. Part of the obligations under the Association Agreement between the EU countries and Ukraine, Article 292(4) [1] and the Treaty on the Functioning of the EU, Article 191(2) [2] is the implementation of the principles of the EU environmental policy: «Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay».

Precautionary principle; principle of prevention; the principle of correcting environmental damage at its source; the "polluter pays" principle was included in the Basic principles (strategy) of the state environmental policy of Ukraine for the period until 2030 [3].

As part of the implementation of the Association Agreement in Ukraine, certain issues from among the horizontal (end-to-end) instruments of EU environmental law have been settled. In particular, the issue of environmental impact assessment is regulated as a result of the implementation of directives 2011/92/EC, 2001/42/EC. Relevant laws on environmental impact assessment and strategic environmental assessment have been adopted and are in force [4, 5].

Environmental management is regulated by Regulation (EC) No. 1221/2009 of the European Parliament and the Council of November 25, 2009 on the voluntary participation of organizations in the eco-management and audit scheme (EMAS). The situation in Ukraine regarding the implementation of the EMAS Regulation requires administrative measures aimed at determining the authorized bodies, accreditation bodies, registration procedures of relevant subjects, etc.

According to the above and taking into account the fact that Ukraine has received the status of a candidate country for EU membership, the issues of not only the implementation of the Association Agreement, but also the implementation of
European approaches, standards and principles that will be implemented at the time of Ukraine's accession to the EU are relevant.

Therefore, the purpose of our work was to analyze and determine the readiness and capacity of pharmaceutical enterprises to green their production in pre-war and in military conditions in Ukraine on the basis of our sociological research.

**Materials and methods.** The research is conducted in accordance with 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 scientific works of scientists became the theoretical and methodological basis for conducting our research: Testa F. [6], Papagiannakis G., Voudouris I., Lioukas S., Kassinis G. [7], Fanasch P. [8], Wagner M. [9], Herghiligiu I.V., Robu I., Pislaru M. at all. [10], Nowicki P., Ćwiklicki M., Kafel P., Wojnarowska M. [11].

This work presents separate experimental data, which are the results of two stages of our sociological research:

**Stage 1** – identifying the main opportunities and obstacles in the process of implementing environmental management systems (EMS) at pharmaceutical enterprises of Ukraine (July 2021 – January 2022) [12].

**Stage 2** – identification, analysis, assessment of risks for pharmaceutical enterprises in military conditions in Ukraine (April–May 2023) [13].

(The research design scheme is presented in Fig. 1.)

Sociological research was conducted using the questionnaire method among the top management of pharmaceutical enterprises using Google forms. The construction of questionnaires is typical and contains the following structural components: addressing the respondent, obtaining informed consent to participate in the study; main block with target questions. Research materials (objects) – the results of the questionnaire were studied using
statistical methods.

Control questions → Selection of experts – respondents from top management or environmental management

→ Location and size of the enterprise

<table>
<thead>
<tr>
<th>Research</th>
<th>July 2021 – January 2022</th>
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<tr>
<td>The state of environmental regulation in Ukraine according to current legislation</td>
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<td>Integration of international management standards at pharmaceutical enterprises</td>
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<td>State of implementation of environmental management systems at pharmaceutical enterprises</td>
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<th>Research</th>
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<td>State of production of pharmaceutical enterprises, compliance with licensing conditions</td>
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<td>Assessment of risks that complicate / make impossible the functioning of pharmaceutical enterprises</td>
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<td>Assessment of the ability and readiness of pharmaceutical enterprises to implement environmental policy</td>
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**Results.** Analysis and comparison of the results of two stages of our sociological research on the state of environmentalization of pharmaceutical enterprises, which we conducted in pre-war times and under martial law in Ukraine,
The analysis of the results of the respondents' answers made it possible to identify the motives and obstacles for
the introduction of SEM at the pharmaceutical enterprises of Ukraine.

The first group of respondents, who had experience in the implementation of SEM, indicated the factors that positively influence the decision of the management of the enterprise regarding the implementation of SEM.

The second group of respondents, who were not involved in the implementation of SEM, indicated the factors that prevent the implementation of SEM (Tab.2).

Table 2

<table>
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<th>Groups</th>
<th>Factors that have a positive effect on the implementation of SEM</th>
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<td>The first group:</td>
<td>71% – savings of valuable resources</td>
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<td>63% – preservation of the natural environment</td>
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<td>54% – increasing the efficiency of the enterprise</td>
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<td>46% – awareness that legislative environmental requirements will continue to grow, desire to prevent legal risks</td>
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<td>33% – to create the image of an &quot;ecological&quot;, &quot;green&quot; enterprise; 13% – to keep up with competitors</td>
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<td>The second group:</td>
<td>62.5% – compliance with current environmental legislative requirements is sufficient;</td>
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<td>12.5% – the costs of implementing the CEM exceed the possible benefit;</td>
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<td>12.5% – SEM is not a priority of the enterprise;</td>
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<td>12.5% – the competence of the personnel is insufficient for the implementation of SEM</td>
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Thus, the I stage of our research made it possible to identify the state of spread of EMS among pharmaceutical enterprises, opportunities and obstacles in the process of implementing environmental management systems (EMS).

The II stage of our research made it possible to identify, analyze and assess risks for pharmaceutical enterprises, which are business entities in the field of drug production, in the conditions of martial law in Ukraine. A significant decrease in attention to the environmental component was also revealed due to the significant complication of production conditions and the suspension of state environmental control measures in military conditions in Ukraine (Fig. 2).

To the question "How do you assess the ability and readiness of enterprises to work in accordance with the state environmental policy plans in accordance with the Association Agreement between Ukraine and the EU at this stage?" almost all respondents gave negative answers: insufficient resources to meet all requirements (20%); environmental aspects of activity are currently irrelevant (25%); there are not enough competent specialists to implement environmental policy and support relevant procedures (25%); lack of informational support from the State (30%).

(The state of implementation of the EMS is presented in Fig. 3)

The decrease in the readiness and capacity of pharmaceutical enterprises for environmentalization ("greening") is caused by critical risks of functioning in the conditions of the continuation of martial law and hostilities on the territory of Ukraine. This causes limited production and export capacities as a result of destruction of the relevant infrastructure and disruption of global supply chain logistics. 30% of pharmaceutical enterprises are registered in regions that are currently included in the List of territories where hostilities are (were) being fought or temporarily occupied [14].

According to the results of our research, 10% of respondents noted that the enterprises received critical damage, which makes it impossible to operate the enterprise until the destructive consequences are completely eliminated; another 15% - there were certain damages, but the company's activities are carried out.
Assessment of the ability and readiness of pharmaceutical enterprises to work in accordance with the plans for the implementation of the state environmental policy in accordance with the Association Agreement between Ukraine and the EU at the stage in military conditions in Ukraine, $n = 20$

Some of the pharmaceutical enterprises relocated their production facilities: 5% of the respondents indicated that the enterprise was (fully or partially) relocated to other regions of Ukraine. 10% of respondents noted that their facilities were not moved, but new sites were opened in other regions.

The vast majority of pharmaceutical enterprises (75%) fully comply with the current licensing conditions for the production and sale of medicinal products. The license conditions also regulate environmental aspects, in particular industrial emissions. In other cases, due to lack of resources and other reasons, some non-critical provisions of the license conditions are partially fulfilled.

Our research also revealed the reduction of industrial capacities for the production of PPE 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 reduction of the
purchasing power of the population. Thus, 10% of respondents noted that production is currently not carried out; 60% of respondents noted that their production volumes have decreased. 30% of respondents answered about maintaining production volumes or even positive production dynamics.

Numerous critical risks in the activities of pharmaceutical enterprises under martial law were identified: supply of raw materials and 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, communications (35%); difficulties in purchasing equipment, consumables, devices (30%); termination of water supply (30%); lack of competent personnel (30%).

Thus, the significant complication of the operating conditions of pharmaceutical enterprises, the presence of a large number of critical risks causes a significant decrease in attention to the issues of environmentalization ("greening") of production in the conditions of martial law in Ukraine. Also, the suspension of state control measures for the period of martial law had a negative impact on the possibility of fully implementing state management in the field of environmental protection.

Conclusions. Today, Ukraine is in a state of war, so production is in a critical risk zone. Military actions are force majeure factors that complicate or make impossible production processes, disrupt or complicate global supply chains, and are a threat to the environmental safety of production.

The analysis of the results of the two stages of research revealed a significant increase in critical risks and a significant decrease in the readiness and capacity of pharmaceutical enterprises for environmentalization ("greening") of enterprises. In particular, according to the results of the research, 20% of respondents determined that the company lacks resources to comply with all requirements; 25% of respondents noted that environmental aspects of activity are currently irrelevant; 25% of respondents noted that there is a lack of competent specialists to implement
environmental policy and support relevant procedures; 30% of respondents noted that there is a lack of information awareness.

Taking into account the current state of the economy and the environmental consequences of the war, the plans for compliance with the state environmental policy and the implementation of the Association Agreement between Ukraine and the EU are under threat.

These factors significantly reduce the readiness and capacity of pharmaceutical enterprises for greening, accordingly, the ability of Ukraine to fulfill the conditions of membership in the EU on environmental issues and climate change at this stage is complicated.

Understanding the catastrophic consequences of such processes, the Government of Ukraine takes certain decisions to minimize the relevant risks. The National Council for the Recovery of Ukraine from the Consequences of the War developed a plan of measures for the post-war recovery and development of the country [15]. At the same time, it is worth stating: without a conscious and responsible attitude of each enterprise to the issues of preserving the natural environment, any initiatives of the Government will not be effective.

We consider the main directions for continuing our research to be scientifically based and planning programs for the recovery of the pharmaceutical sector, taking into account the risks of pharmaceutical pollution and the adverse impact of the pharmaceutical industry on the natural environment.

We consider it necessary to develop a methodology for the implementation of environmental management systems (EMS) as part of the overall enterprise management system for managing environmental aspects; fulfillment of mandatory legal requirements and voluntary obligations in accordance with the goals and environmental policy of the enterprise; and to address risks and opportunities related to emergency preparedness and emergency response.

References:
[1] Association Agreement between the European Union and the European Atomic Energy Community and their member states, of the one part,
MEDICINE AND PHARMACY


[14] Ministry of Reintegration. List of territories on which hostilities