

## ORIGINAL ARTICLE

# Characteristics of development and dissemination of environmental management systems in the area of production of medicines in Ukraine

## Charakteristika vývoje a uplatňování systémů environmentálního řízení v oblasti výroby léčivých přípravků na Ukrajině

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### Summary

The article presents the results of a study based on an expert survey of senior management and leading experts of enterprises for the production of medicines in Ukraine and typical problematic aspects of implementing environmental management systems (EMS). It was found that among the enterprises whose respondents took part in the survey, only 25% implemented EMS and passed the certification procedure following the requirements of ISO 14001. A significant problem identified is the lack of influential information tools and methodological developments for the implementation, operation, and benefits of EMS in pharmaceutical production, especially to ensure processes regarding the readiness of enterprises to respond to emergencies. Insufficient support was noted, particularly in regulatory and financial incentives, and no benefits could encourage more efficient greening of pharmaceutical production. The negative consequence is the lack of interest of small and medium enterprises in investing in new technologies and sustainable business practices to reduce environmental pressures. EMS should be implemented as a part of the overall management system of the enterprise to

manage environmental aspects, meet mandatory legal requirements and voluntary commitments in accordance with the objectives and environmental policy of the enterprise, as well as to address risks and opportunities. It is important to note the urgency of developing theoretical and methodological principles of design, implementation, and further development of EMS to increase the environmental efficiency of the enterprise, greening in medicines production, and achieving sustainable development goals.

**Key words:** environmental management system • EMS • EMAS • ISO 14001 • environmental aspects • pharmaceutical company • production of medicines

### Souhrn

Článek prezentuje výsledky studie založené na expertním průzkumu mezi vrcholovým managementem a vedoucími odborníky podniků na výrobu léčiv na Ukrajině a typické problematické aspekty zavádění systémů environmentálního řízení (EMS). Bylo zjištěno, že z podniků, jejichž respondenti se zúčastnili průzkumu, pouze 25 % zavedlo EMS a prošlo certifikačním řízením podle požadavků normy ISO 14001. Významným zjištěným problémem je nedostatek vlivných informačních nástrojů a metodického vývoje pro zavádění, provoz a přínosy EMS ve farmaceutické výrobě, zejména pro zajištění procesů týkajících se připravenosti podniků reagovat na mimořádné události. Nedostatečná podpora byla zaznamenána zejména v oblasti regulačních a finančních pobídek a chybí výhody, které by mohly podpořit efektivnější ekologizaci farmaceutické výroby. Negativním důsledkem je nezájem malých a středních podniků o investice do nových technologií a postupů udržitelného podnikání, které by snížily zátěž na životní prostředí. EMS by měl být zaveden jako součást celkového systému řízení podniku za účelem řízení environmentálních

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aspektů, plnění povinných právních požadavků a dobrovolných závazků v souladu s cíli a environmentální politikou podniku, jakož i řešení rizik a příležitostí.

Je důležité upozornit na naléhavost rozvoje teoretických a metodických zásad navrhování, zavádění a dalšího rozvoje EMS za účelem zvýšení environmentální účinnosti podniku, ekologizace při výrobě léčiv a dosažení cílů udržitelného rozvoje.

**Klíčová slova:** systém environmentálního řízení • EMS • EMAS • ISO 14001 • environmentální aspekty • farmaceutická společnost • výroba léčiv

## Introduction

Adverse events in Ukraine related to the Russian military aggression, in addition to the direct threat of death and destruction of critical infrastructure, have led to numerous man-made disasters, causing severe damage to the ecosystem, survival, and health in the long run. Catastrophic humanitarian consequences and threats to the environment are growing. It is getting impossible for Ukraine to fulfill its international environmental obligations. Currently, the Operational Headquarters of the State Ecological Inspectorate of Ukraine (<https://shtab.gov.ua/>) has been established to compile a list of all violations in the area of environmental protection during the military conflict.

According to the CEOBS (Conflict and Environment Observatory), registered with the Charity Commission of England and Wales and accredited by the UN Environment Assembly (UNEA) in 2009, the process of combining the principles of international humanitarian law with the principles of environmental law and human rights was initiated at the international level. Since 2013, the UN Commission on International Law has carried out this process. This expert body makes recommendations to the UN General Assembly on the progressive development and codification of international law. Protection of the environment in relation to armed conflicts (PERAC) has so far identified 28 draft principles and is due to be completed by autumn 2022<sup>1)</sup>.

Concerning the state environmental policy of Ukraine, its principles were aimed at introducing an ecosystem approach to all areas of socio-economic development, according to the Law of Ukraine «Basic principles (strategy) of state environmental policy of Ukraine until 2030» from 28.02.2019. № 2697-VIII, which entered into force on January 1, 2020<sup>2)</sup>. To ensure Ukraine's entry into international and European markets, compliance with international standards on environmental management and product labeling has been provided, as well as stimulating the implementation of environmental management systems (EMS) in enterprises while improving environmental performance, including through international certification systems and labelling.

Voluntary systems, such as environmental management, are global systems that support businesses in

minimizing environmental impact and implementing sustainable production practices<sup>3)</sup>. EMS is an integral part of the organization's overall management system. It is used to develop and implement environmental policies and objectives and monitor and manage environmental aspects to reduce negative environmental impacts, including implementing and supporting processes to prepare for potential emergencies<sup>4)</sup>. The latter becomes extremely relevant in the context of recent events in Ukraine.

Our study was accomplished in the period before the military invasion started (24.02.2022). The research focused on identifying the nature of the development and spread of EMS among businesses in the area of drug production in Ukraine. Particular attention was paid to EMS, which are certified in accordance with the international standard ISO 14001 and EMAS standard of the European Union. The above-mentioned ecological systems are two of the most common ones in Europe. They have the same goals for developing a sustainable economy and provide practical solutions for all types of organizations that are actively committed to sustainable management of their environmental responsibilities. In total, 348,473 companies (568,798 sites – permanent locations where the organization performs work or services) were certified according to the ISO 14001 standard in 2020, and among them were 1,418 pharmaceutical companies<sup>5)</sup>. Also, 3851 organizations (12,856 sites) available in the EU register (as of December 2021)<sup>6)</sup> received EMS certification according to the EMAS standard.

During the research we were guided by the following works which constitute the main theoretical and methodological basis of our study: standardization and application of voluntary environmental management standards (Testa, Heras-Saizarbitoria, Daddi, I I Boiral, 2016)<sup>7)</sup>; dissemination of standards for environmental management systems (EMS), especially the European Union's environmental management and audit systems (EMAS) and the International Standardization Organization (ISO) 14001 (Montobbio & Solito, 2018; Papagiannakis, Voudouris, Lioukas, & Kassinis, 2019)<sup>8, 9)</sup>; the use of EMS as a foundation in corporate sustainability management (Fanasch, 2019)<sup>10)</sup>; global governance in environmental management and the impact of voluntary standards (Marcus Wagner, 2019)<sup>11)</sup>; EMS certification and trust in the certification process (Nowicki, 2021)<sup>12)</sup>; application of an initiative approach in management (Epstein et al., 2017)<sup>13)</sup>; implementation of alternative environmental solutions (Herghiligi et al., 2019)<sup>14)</sup>; EMS analysis as a method that allows companies to internalize environmental issues, demonstrate an active approach to environmental issues (Testa et al., 2018)<sup>4)</sup>. It is widely recognized that EMS is an effective tool for developing active environmental strategies for the long term and can be implemented in various ways, such as a separate EMAS or ISO 14001 standard or as part of an integrated management system that may include other standards (ISO 9001, ISO 50001, GxP, etc.).

It should be noted that according to our previous study on the implementation of EMS (Zhurenko, Leb-edinets, 2021)<sup>15)</sup>, involving 115 Ukrainian pharmaceu-tical manufacturers, only a third of licensees provide data on the implementation and certification of their management systems, 35% had experience in imple-menting quality management systems (ISO 9001); 12% – environmental management systems (ISO 14001, EMAS); less than 10% – food safety manage-ment systems (ISO 22000) and quality management systems in the production of medical devices (ISO 13485); isolated cases of implementation of safety and health management systems (ISO 45001), energy management (ISO 50001). It is worth noting that com-panies have several certificates of management sys-tems. Due to the fact that ISO standards are voluntary, apparently, there are organizations which for some reason did not certify their management systems or did not provide information about their certificates on official websites.

The aim is to provide an analysis of the state and typical problematic aspects of the implementation of environmental management systems (EMS) in enter-prises manufacturing medicines in Ukraine based on the results of our study of the expert survey of senior management and leading experts in the environmen-tal management of medicines in Ukraine.

## Experimental part

### *Planning (methodology) of research*

In accordance with the aim and the issues of the stu-dy, the following work strategies were identified as the most appropriate: a thematic study of the state of EMS implementation in drugs producing enterprises in Ukraine based on their official websites and by con-ducting surveys among senior management, top man-agers and leading specialists of these enterprises. The survey was conducted in two stages: at the first stage, preliminary interviews were conducted with experts to

## Attachment 1

### QUESTIONNAIRE

Review of the conditions for the implementation and development of environmental management systems (EMS) at pharmaceutical enterprises in Ukraine.

Company name

Your position

Question:

1. What is the number of employees of the enterprise?\*
2. Has an assessment of the environmental risk (negative impact) of your en-terprise on the environment been carried out?
3. Are you involved in the preparation of reports on the environmental aspects of your enterprise, or do you have the opportunity to familiarize yourself with the reports on these issues?
4. Does your business have the following permits?
  - There is a permit for emissions into the atmosphere
  - There is a permit for disposal of solid waste
  - There is a permit for the use of biological resources (resources of plant, animal origin)
  - There is a permit for wastewater discharge, special water use
  - Has a permit for the handling of hazardous substances
  - There is no permit, but we adhere to the general requirements for environmental protection
  - Environmental requirements are enshrined in the license to carry out the activities of the enterprise
  - The enterprise is not subject to environmental regulation
  - Other:
5. How is your company informed about environmental requirements?
6. Has an environmental management system (EMS) been implemented at your enterprise? If not, what reasons influence the decision not to implement environmental standards?
7. If you did not implement SEM, then what reasons influenced this?
8. If an EMS was introduced at your enterprise, what factors complicated the introduction of an EMS and its development?
9. If your enterprise has implemented an EMS, what additional processes have been identified as necessary for its functioning?
10. If an EMS has been implemented at your enterprise, what are the most common non-compliances during internal audits?
11. Are any management systems implemented at your enterprise before that meet the requirements of other international, European standards?
12. Does the enterprise have resource saving programs?
13. What reasons positively influence management's decision to implement an EMS?
14. What kind of external support does your enterprise receive regarding the functioning and development of the EMS?
15. What kind of support can help to implement EMS or specific environmen-tal technologies?
16. Has your enterprise participated in tenders, public procurements, where environmental requirements are put forward?

identify problematic issues related to the greening of pharmaceutical production and determine risks and prospects for implementation and certification of EMS following European and international standards. In the second stage, a questionnaire was developed using *Google form*, and a survey was conducted among senior management, top managers, and leading specialists in the area of the ecology of pharmaceutical companies in Ukraine. In the third stage, the comparative statistical analysis and generalization of statistical data of the study in the form of questionnaire results were carried out.

### Materials and methods

The main element of the study was to conduct a survey of respondents among senior management, top managers, and leading specialists of Ukrainian pharmaceutical companies, licensees of the State Medical Service engaged in economic activities for the production of medicines (21 – Code NACE – 2010/ Rev.2). In the course of the research, we developed a questionnaire, which was sent to 115 enterprises producing medicines in Ukraine. Questionnaires of 24 respondents with answers to all questions were regarded as relevant and selected for further analysis. The survey was conducted in the period from July 2021 to January 2022. Respondents were guaranteed anonymity regarding the survey procedure.

The questions (Attachment 1) were aimed at identifying the main opportunities and obstacles in the process of implementing EMS as a standardized tool for environmental planning and control of environmental aspects, resource- and energy-efficient technologies, and sustainable business methods.

The analysis included control variables, particularly the enterprise's size, the respondents' positions, the respondents' participation in preparing reports on environmental aspects of the enterprise, and the availability of management systems in accordance with various ISO standards.

The research materials in the form of sociological questions were studied through statistical, system-analytical methods and generalization of statistical data. The data were calculated with the help of electronic

spreadsheets, which allowed us to systematize them, group, reveal statistical regularities, and present them in diagrams. Diagrams were used as a means of scientific summarization of statistical information. Further analysis with the help of conjugation tables (factor tables) made it possible to reveal the frequency distribution of variables and the presence or absence of relationships between variables.

### Results and discussion

The study results are presented in accordance with the order of questions in the questionnaire.

In the process of sociological surveys, the determining factor is selecting experts and assessing their competence. Therefore, the control variable was the positions of respondents. In our study, the experts were respondents whose positions are directly related to enterprise management systems, particularly environmental management, and therefore meet the criteria for competence. The composition of the respondents was as follows: 37% – senior management (CEOs, directors, technical directors, deputy director for quality); 13% – heads of departments, heads of departments of labor protection and ecology, heads of validation departments; 21% – environmentalists; 21% – managers; 4% – technologists; 4% – scientists.

In addition, the control variable identifies respondents' participation in the preparation of reports on environmental aspects of the enterprise. Thus, 67% of respondents participate in preparing reports on environmental aspects of the enterprise or have the opportunity to read reports on these issues, which indicates sufficient competence of respondents and serves as evidence to consider their answers as an expert assessment. Further analysis found that among 33% of respondents, EMS was not implemented or was only planned, as they were unaware of the reports on the environmental aspects of the enterprise. There were also answers that EMS was implemented but not certified (Fig. 1).

Among the respondents were representatives of enterprises of various forms of ownership from 5 regions of Ukraine (Zhytomyr, Zaporizhia, Kyiv, Luhansk,

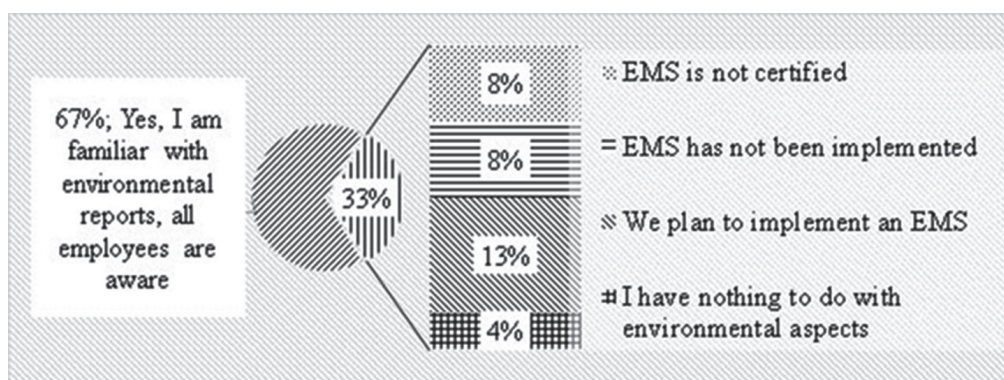


Fig. 1. Respondents' awareness about environmental reports in correlation with the implementation of EMS at the enterprise. Number of respondents,  $n = 24$

Kharkiv). The vast majority, 67% of respondents, were from large enterprises (more than 250 employees), 21% – from medium-sized enterprises (51–250 employees); 12% – from small businesses (number of employees 11–50) (Fig. 2). Representatives of micro-enterprises (number of employees 1–10) were not identified among the respondents who took part in the survey. It can be assumed that the survey questions are not relevant for micro-enterprises with low environmental risk.

It should be noted that in OECD member countries (Organization for Economic Cooperation and Development), environmental regulation is carried out not by the size of the enterprise, but by the principle of environmental risk<sup>16)</sup>. A similar principle has been introduced in Ukraine. The basis for the implementation of the European model of environmental assessment in Ukraine is the Law of Ukraine «On Environmental Impact Assessment» (from 23.05.17 № 2059-VIII)<sup>17)</sup>. The procedure for maintaining the Unified Register of Environmental Impact Assessment (EIA) is determined by the Resolution of the Government of Ukraine «On approval of the Procedure for submitting documentation for EIA opinion and financing of EIA» (from December 13, 2017. № 1026)<sup>18)</sup>. Criteria for the distribution of economic entities according to the degree of risk of their economic activities to the environment and the frequency of state supervision (control) are determined by the Resolution of the Government of Ukraine of 06-03-2019 № 182<sup>19)</sup>. Planned measures of state supervision (control) in the area of environmental protection, rational use, reproduction, and protection of natural resources for the activities of economic entities are carried out with the following frequency: with a high degree of risk – not more than once every two years; with a medium degree of risk – not

more than once every three years; with a low degree of risk – no more than once every five years.

In our study on the question «Has an environmental risk assessment been performed (of the company's impact on the environment)?» 79% of respondents answered positively (Fig. 3).

According to the Law of Ukraine «On Strategic Environmental Assessment», which entered into force on October 20, 2018, under № 2354-VIII to identify, describe and assess the impact on the environment and public health through the implementation of state planning documents provides for strategic environmental assessment (SEA). Within its competence, the customer monitors the consequences of implementing the state planning document for the environment, including for public health, once a year publishes its report on the strategic environmental assessment of adverse environmental impacts, including for public health, and uses measures to eliminate them.

The SEA procedure requires the customer to have specialized knowledge of sanitary and environmental legislation, methods of assessing environmental aspects, risks, and impacts, as well as to develop measures to prevent, reduce and mitigate possible adverse effects on the environment and public health. Usually, the implementation of this work is entrusted to an expert organization with a positive reputation and experience in performing the strategic environmental assessment. In this way, the company tries to reduce the likelihood of obtaining negative conclusions on the SEA while passing the procedure and obtaining permits.

Current legislation in Ukraine does not provide for the issuance of comprehensive permits covering all components of environmental impact. Separate emis-

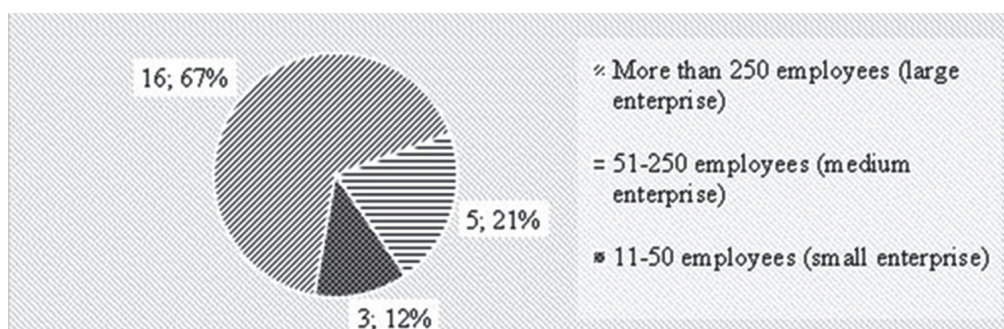


Fig. 2. Distribution of respondents by the size of enterprises. Number of respondents,  $n = 24$

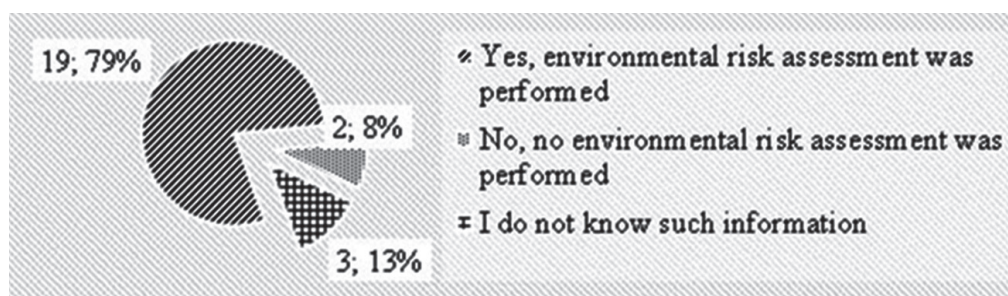


Fig. 3. Environmental risk assessment. Number of respondents,  $n = 24$

sion permits are issued to enterprises. Relevant separate registers of licensees, lists of enterprises and institutions, as well as information on revoked licenses and other news related to business licensing, are provided on the website of the Ministry of Environmental Protection and Natural Resources of Ukraine. But among the priorities of the Ministry's work is the introduction of an integrated permit for pollutants<sup>20</sup>.

According to the survey of our study, 13% of respondents indicated that their company is not subject to environmental regulation. The vast majority of enterprises face issues of environmental regulation in their economic activities: 75% of respondents have permits for air emissions; 46% – for solid waste disposal; 50% – for wastewater discharge; 38% – for the handling of hazardous substances; 4% – for the use of biological re-

sources (plant, animal origin); 17% of respondents indicated that the environmental requirements are set out in the license to operate the company (Fig. 4).

Permits obtained are legal requirements and can also be considered in the EMS as identified environmental aspects and related environmental impacts. The links between environmental aspects and environmental impacts are the links between causes and effects. Impacts can be local, regional, and global, as well as direct, indirect, or cumulative. Environmental aspects of the enterprise must control and determine which environmental aspects can be affected in different conditions: workers, deviations from the norm, non-working conditions, as well as reasonable forecasting of emergencies. Information on environmental aspects in the EMS is considered part of change management.

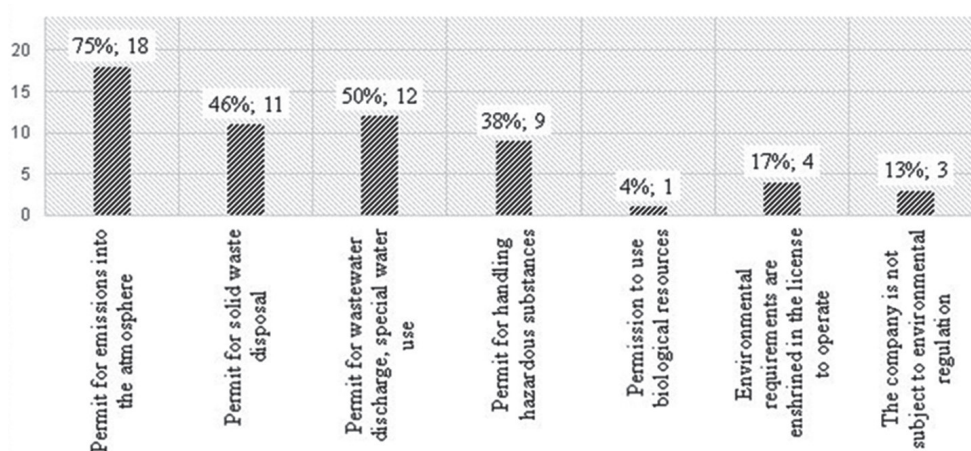


Fig. 4. Emission permits. Number of respondents,  $n = 24$

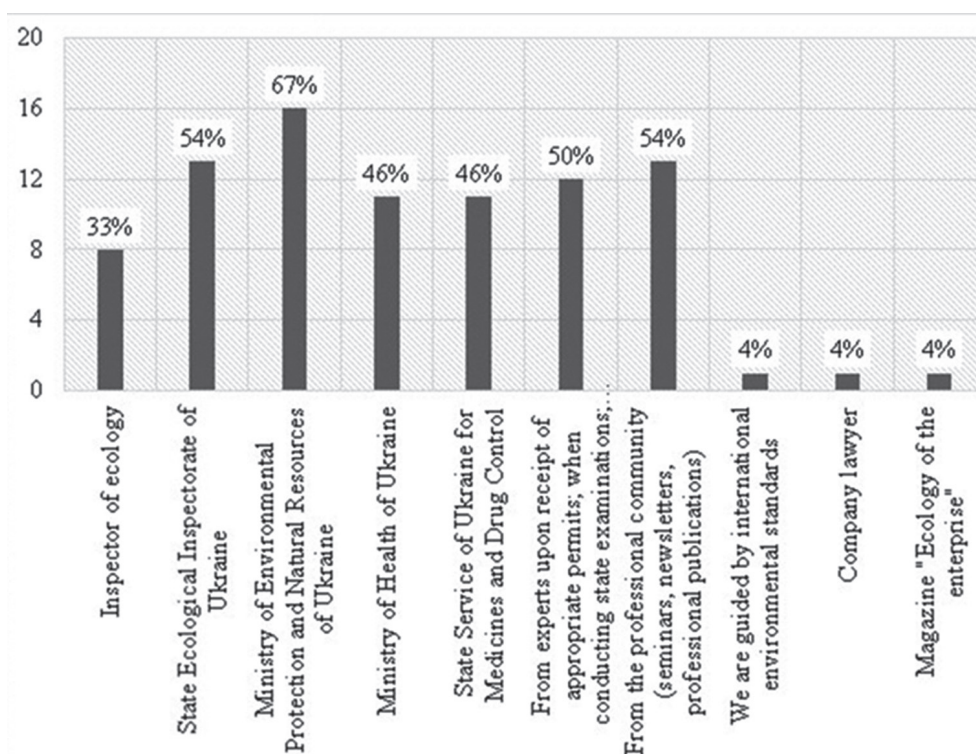


Fig. 5. Information on environmental requirements. Number of respondents,  $n = 24$

When asked how the company is informed about environmental requirements, 33% of respondents said that they learn about them from the environmental inspector during the inspection for compliance with environmental requirements; 50% of respondents receive information from experts when obtaining the appropriate permits during the state examination when assessing the impact on the environment. The main official source of information on environmental regulations is open resources on the Internet: 67% of respondents indicated the website of the Ministry of Environmental Protection and Natural Resources of Ukraine; 54% – the site of the State Ecological Inspectorate; 46% – the website of the Ministry of Health of Ukraine and the website of the State Service of Ukraine for Medicines and Drug Control; 54% – from the professional community (seminars, newsletters, professional publications); 4% – pointed to the journal «Enterprise Ecology»; 4% – are guided by international environmental standards; 4% – receive information from the company's lawyers. There is currently no single framework for environmental regulation, requirements, and best practices in

pharmaceutical production, so respondents point to several sources of information (Fig. 5).

The key issue was the status of EMS implementation and certification in accordance with the requirements of the ISO 14001 standard. After all, the most common practice is the development of EMS, which is based on the ISO 14001 standard<sup>21</sup>.

ISO standards are voluntary, but ISO 14001 has actually become a global meta-standard that ensures high overall diffusion and affects global supply chains and continues to become increasingly important for multinational corporations<sup>22</sup>.

According to the ISO survey for 2019–2020, the total number of valid ISO 14001 certificates reported by certification bodies has increased by 11%, and the number of sites where the organization performs work or services covered by valid certificates has increased by 17%<sup>5</sup>. However, in the pharmaceutical sector, there is a decrease in the number of certificates by 13%. In Ukraine, in general, there is an increase in the number of valid certificates by 36%, but in the pharmaceutical area, this standard is not common (Table 1).

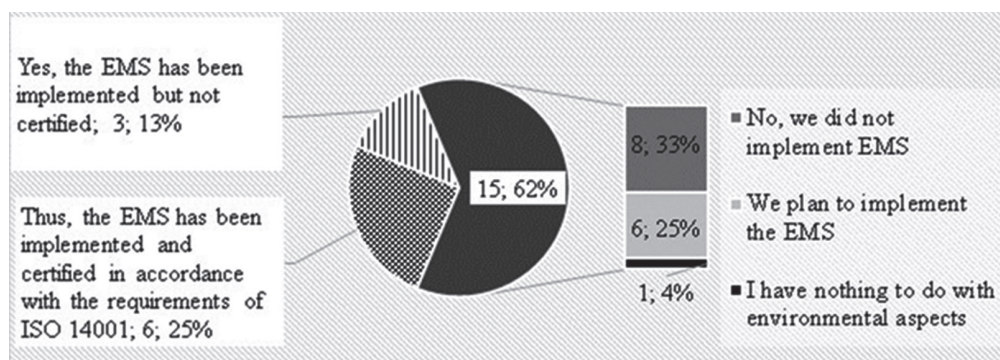


Fig. 6. The state of implementation of the EMS. Number of respondents,  $n = 24$

Table 1. The ISO Survey of Management System Standard Certifications 2019–2020 ISO 14001:2015 Environmental management systems – Requirements with guidance for use

| Year | Total valid certificates (Total number of sites) | Sector Pharmaceuticals | Total valid certificates (Total number of sites) Ukraine | Sector Pharmaceuticals Ukraine |
|------|--------------------------------------------------|------------------------|----------------------------------------------------------|--------------------------------|
| 2019 | 312,580 (487 950)                                | 1418                   | 251 (366)                                                | 4                              |
| 2020 | 348,473 (568 798)                                | 1239                   | 342 (447)                                                | 2                              |

Table 2. Frequency distribution of variables: 1. Size of the enterprise (number of employees), 2. Implementation of EMS at the enterprise

| Variable 1                                                                                                       | Variable 2          |        |       |
|------------------------------------------------------------------------------------------------------------------|---------------------|--------|-------|
| Is the company implemented an environmental management system (EMS)?<br>Is EMS certified according to ISO 14001? | Number of employees |        |       |
|                                                                                                                  | More than 250       | 51–250 | 11–50 |
| Yes, we have implemented and certified EMS according to the ISO 14001 standard.                                  | 25%                 |        |       |
| Yes, we have implemented but not certified EMS.                                                                  | 13%                 |        |       |
| No, we did not implement EMS.                                                                                    | 13%                 | 12%    | 8%    |
| We plan to implement EMS.                                                                                        | 13%                 | 8%     | 4%    |
| I have nothing to do with environmental aspects.                                                                 | 4%                  |        |       |

According to the results of our survey in the area of medicines production, only 25% of respondents answered that they have implemented and certified EMS following the requirements of the ISO 14001 standard; the other 13% – implemented but did not certify EMS; 33% – were not involved in the implementation of such a system; 25% – have not implemented, but plan to implement EMS (Fig. 6).

Further analysis of conjugation tables (factor tables) reveals the frequency distribution of variables together with a significant relationship between two variables: the size of the enterprise and the implementation of EMS (Table 2). Pearson's correlation was 0.353, i.e., it is significant (one-sided, the correlation is significant at 0.05). EMS was implemented in 37.5% of large enterprises (with more than 250 employees). EMS has not been implemented in medium and small enterprises. This confirms the crucial role in the implementation and certification of EMS indicators, such as the size of the enterprise and its human resources.

To the question «What prevents the implementation of EMS?» respondents who did not implement EMS ( $n = 8$ ) cite various factors and barriers, in particular: 62.5% – determined that compliance with current environmental legislation is sufficient; 12.5% – indicated that the costs of implementing EMS outweigh the possible benefits; 12.5% – stated that EMS is not a priority of their company; 12.5% – admitted that the competence of staff is insufficient for the implementation of EMS (Fig. 7).

Among the main factors complicating the implementation of EMS or its development, respondents identified the following: 47% – lack of advisory, methodological, and informational support from the state; 27% – lack of knowledge and skills of staff regarding the environmental aspects of the enterprise; 27% – lack of motivating incentives and supervision by the state; 20% – excessive costs for actions and procedures provided by standard 14001, as well as for certification, supervision and current support of EMS; 15% – annual audit; 7% – lack of clear and comprehensive informa-

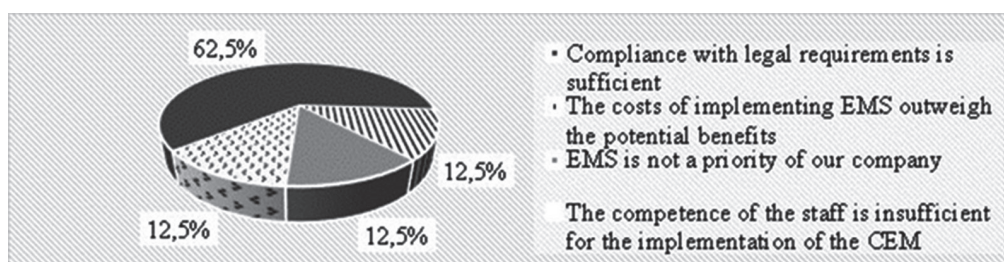


Fig. 7. What prevents the implementation of EMS? Number of respondents,  $n = 8$

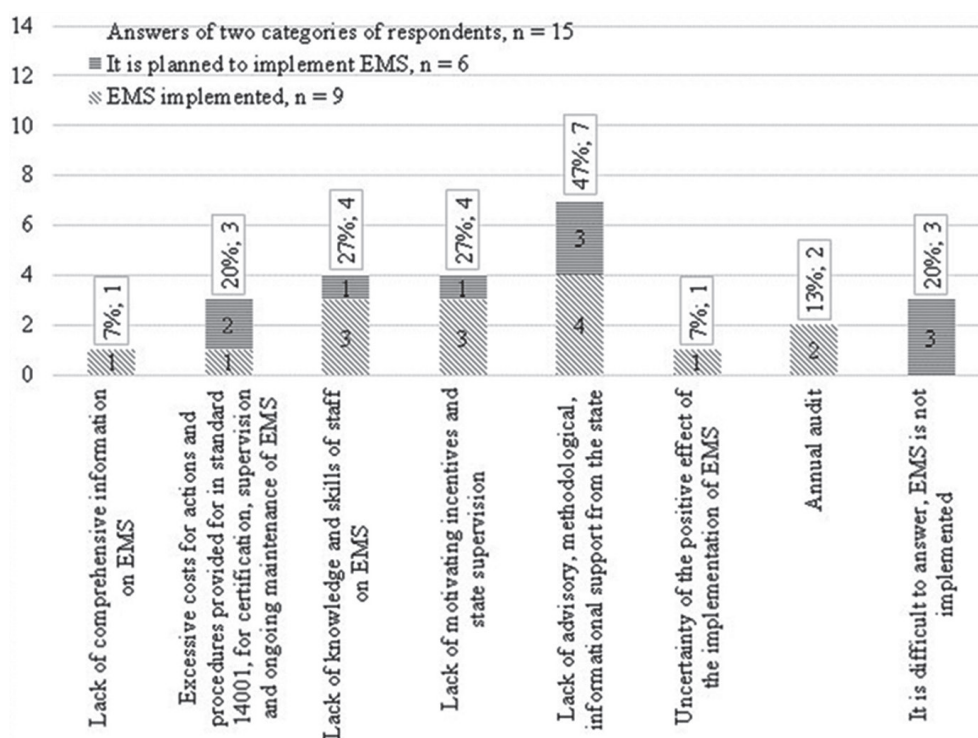


Fig. 8. Factors complicating the implementation of the EMS. Total number of respondents,  $n = 15$  (of which: number of respondents where EMS is implemented,  $n = 9$ ; the number of respondents where EMS is not implemented but planned,  $n = 6$ )

tion on the specifics of EMS implementation; 7% – the lack of evidence of a positive effect from the implementation of EMS (Fig. 8).

It should be noted that the international standard ISO 14001 and the European Union EMAS contain requirements that must be met before the certification procedure, but the methods for meeting these requirements are not defined. The criteria are specified, but not the ways to meet them. It is difficult for organizations to meet these requirements reliably. There is a need to create methodological developments to implement EMS in enterprises producing medicines.

To the open-ended question of the questionnaire: «If EMS has been implemented at the enterprise, what additional processes had been identified as necessary for its operation?» respondents identified the following additional necessary processes:

1. development of relevant documentation and training of staff on compliance with the requirements of the standard;
2. processes according to the requirements of the ISO standard (DSTU) 14001;
3. activities of the environmental department.

To the question «What inconsistencies are most common on internal audits?» 13% of respondents said that no discrepancies were recorded; 20% of respondents answered that EMS had not been implemented; other 67% of respondents noted the follow-

ing discrepancies: 27% – documented information; 20% – emission control procedures; 7% – waste management; 13% – technical aspects of the production processes functioning (Fig. 9).

One of the questions aimed to identify other management systems verified in accordance with international standards applied at enterprises. In particular, the availability of a quality management system in accordance with the international standard ISO 9001 has been included as a control variable, as this standard is the most common and often implemented first and is compatible for integration with other ISO standards, which have an identical high-level structure (High-Level Structure, HLS), and apply the process approach and the principle of PDCA<sup>21</sup>). The results of our study revealed that the following management systems had been implemented at enterprises: 63% – ISO 9001; 54% – GMP; 42% – ISO 22000; 13% – ISO 13485; 4% – GVP; 4% – ISO 50001; 4% – SA 8000, OHSAS; 4% – Technical conditions (TU); 4% – in the development of ISO 9001 and ISO 13485; 8% – no ISO system.

Further analysis using conjugacy tables (factor tables) revealed a significant relationship between two variables: the size of the enterprise (number of employees) and the introduction of various certified management systems. The vast majority, 87% of standard certificates for various management systems, are implemented at large enterprises (Fig. 10).

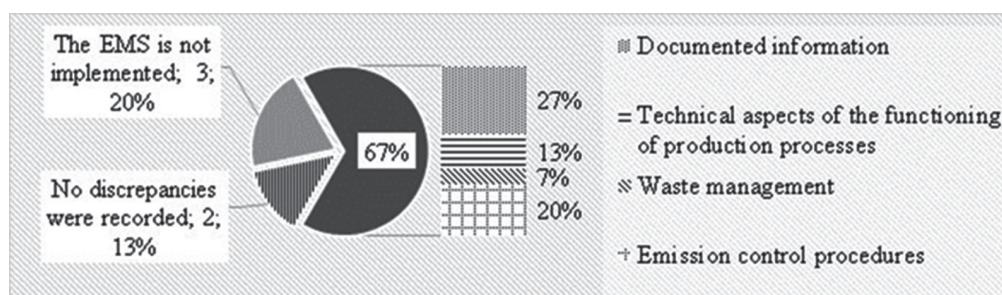


Fig. 9. Identified inconsistencies in the audit of the EMS. Number of respondents,  $n = 15$

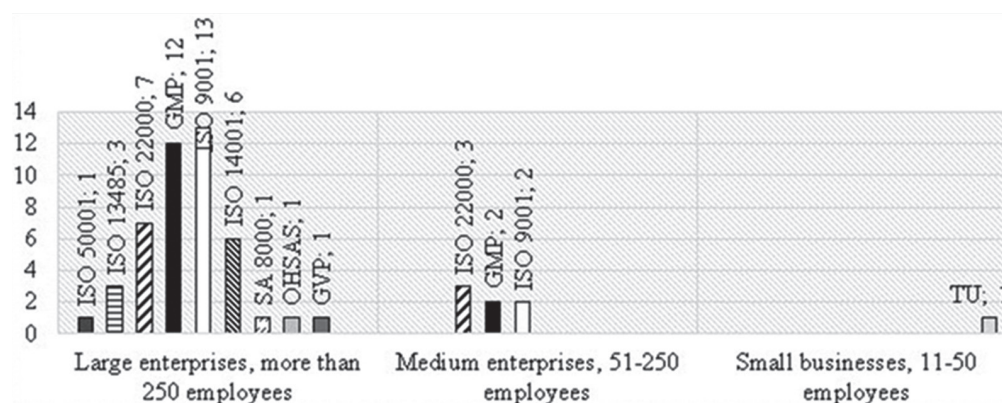


Fig. 10. Availability of other management systems that meet the requirements of international standards. Frequency of implemented management systems in accordance with the size of the enterprise. Number of respondents,  $n = 24$

The availability of multiple management systems is a hallmark of large enterprises that have available resources and the ability to share fixed costs, such as the operation of EMS<sup>11)</sup>. Further analysis revealed that in all enterprises where EMS was implemented in accordance with ISO 14001, quality management systems in accordance with ISO 9001 were also implemented. In some of the enterprises, other management systems were implemented following standards of ISO 22000, ISO 13485, SA 8000, OHSAS.

It should be emphasized that the enterprises are actively implementing measures to improve resource efficiency; in particular: 67% of respondents said that their companies have intentionally designed programs and certain measures are taken to save energy; 58% – are saving water resources; 42% – are saving and minimizing waste; 17% – plan and develop such measures; 8% – do not have specially designed resource-saving programs. Unfortunately, none of the respondents provided information on the use of renewable energy (Fig. 11).

Examples of doing business in the world show that the threats posed by global environmental problems force companies to take a proactive approach to management<sup>13)</sup>, which is why companies are increasingly implementing alternative solutions, especially environmental<sup>14)</sup>, and use EMS as a method, which allows companies to demonstrate an active approach to solving environmental problems<sup>4)</sup>.

According to the results of our study, among the reasons that positively influence the decision of the company's management to implement EMS, the main one for 71% of respondents from all categories (large, medium, and small) is the desire to save valuable resources (electricity, water, etc.). It is most likely that the main factor for saving resources is purely economic because companies must solve the problem of rising resource prices and expect further growth. 63% of respondents specified their intention to contribute to the preservation of the natural environment; 54% of respondents emphasized the understanding of the benefits of management systems (in particular, EMS) as a useful tool to improve the efficiency of the enterprise; 46% are aware that legal, environmental requirements will continue to grow, so legal risks should be avoided; 33% intend to create the image of 'ecological', 'green' enterprise; 13% expressed a desire to keep up with competitors (Fig. 12).

It is important to emphasize that among the reasons that positively influence the decision of the company's management to implement EMS, there are no concerns about planning their preparedness for emergencies and response processes. It can be assumed that the operational planning and control of current activities took place in peacetime, and the risks of hostilities were assessed as insignificant. However, the realities of today's Ukraine indicate that the very planning of

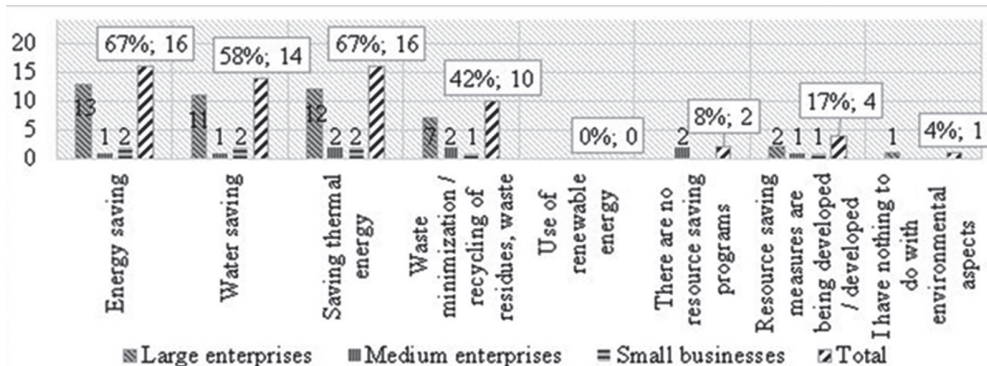


Fig. 11. Resource-saving programs that operate in enterprises. Number of respondents, n = 24

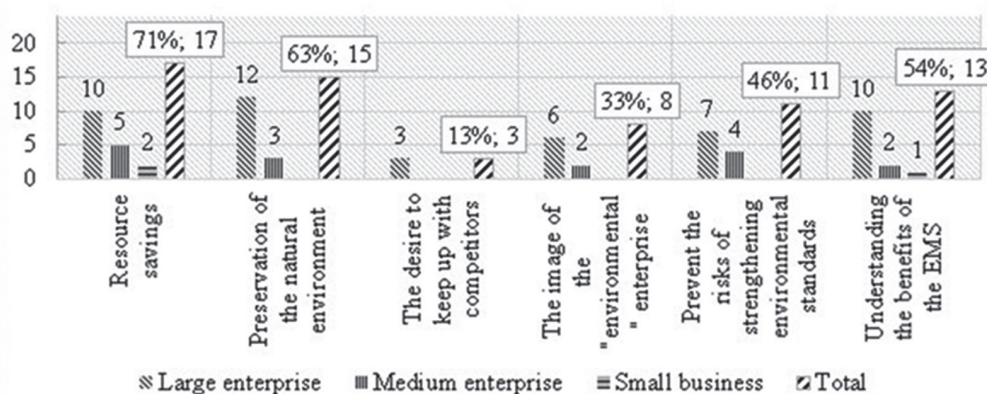


Fig. 12. Reasons that positively influence management's decision to implement the EMS. Number of respondents, n = 24

the company's readiness for emergencies is extremely important. The standard ISO 14001 «Environmental Management System. Requirements and guidelines»<sup>21)</sup> provides tools for the planning and implementation of production to ensure the readiness of the enterprise for emergencies, in particular, to determine:

- a) the most appropriate method(s) for responding to an emergency situation;
- b) internal and external communication process(es);
- c) the action(s) required to prevent or mitigate environmental impacts;
- d) mitigation and response action(s) to be taken for different types of emergency situations;
- e) the need for post-emergency evaluation to determine and implement corrective actions;
- f) periodic testing of planned emergency response actions;
- g) training of emergency response personnel;
- h) a list of key personnel and aid agencies, including contact details (e.g., fire department, spillage clean-up services);
- i) evacuation routes and assembly points;
- j) the possibility of mutual assistance from neighbouring organizations.

The consequences of the Russian military invasion of Ukraine are a clear example of the catastrophic negative impact on the environment, including the threat

of man-made accidents. It is the responsibility of every organization to be prepared for and respond to emergencies, which requires radical changes in the overall and environmental management of the enterprise.

It should be recognized that the constraining factors for the development of EMS are the lack of publications on indirect preferences and benefits of the application of voluntary standards ISO 14001 or side effects of EMS<sup>22)</sup>. Expectations of immediate environmental results can also be detrimental. As emphasized in the study by Nowicki, Paweł et al. (2021), from a management point of view, it is important to focus on the long term and encourage managers to strengthen the training of environmental management<sup>12)</sup>.

Regarding the main obstacles to the implementation of EMS, respondents point to the lack of external support from public funding and private funding from banks, investment companies, or funding from private enterprises and individuals. 67% of respondents indicate no support. Consultations, technical and methodological assistance are considered as external support: 17% – from private companies and professional organizations; 13% – from government agencies; 13% – from business partners; 4% – from educational institutions; 4% – through periodicals (Fig. 13).

Respondents indicated that the support that businesses really need and that can help to implement EMS, or certain environmental technologies is as fol-

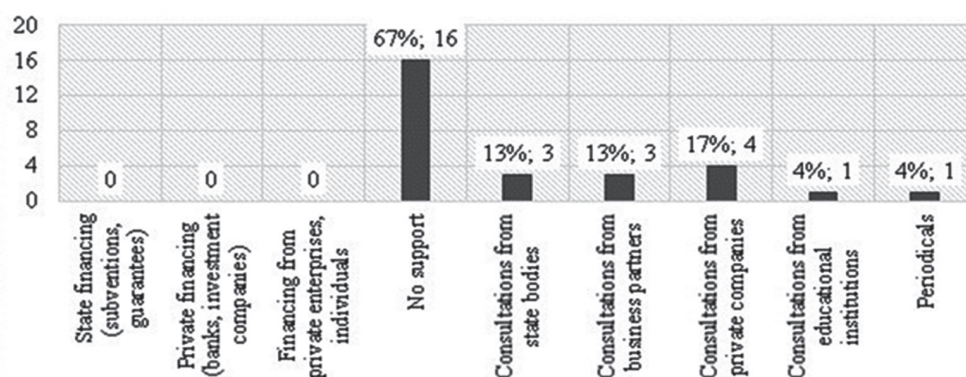


Fig. 13. External support received by the company in relation to the operation / development of EMS. Number of respondents,  $n = 24$

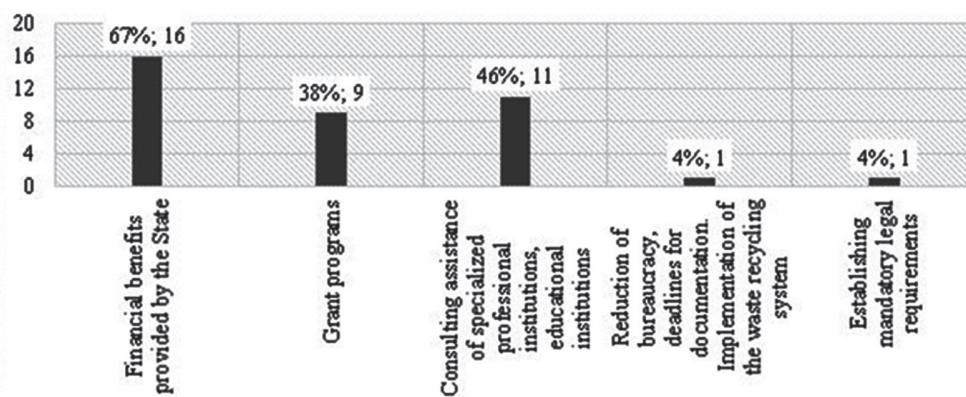


Fig. 14. Support that is needed and can help implement EMS or individual environmental technologies. Number of respondents,  $n = 24$

lows: 67% – financial benefits provided by the State; 37,5% – grant programs; 46% – consulting assistance of specialized professional institutions, organizations, educational institutions; 4% – reduction of bureaucracy and deadlines for documentation, as well as the implementation of the waste management system; 4% – mandatory legal requirements (Fig. 14).

It should be noted that IMF estimates that global economic growth will slow from 5.5% in 2021 to 4.4% in 2022 and to 3.8% in 2023. The current difficult geopolitical situation, the consequences of pandemic constraints and the risk of new COVID-19 variants, significant increases in energy prices and disruptions in supply chains, local wage problems, all these factors mean high uncertainty about inflation and policies. In market economies and developing countries, with the exception of China, in the period 2020-2022, total per capita income is 22% lower than if there had been no COVID-19 pandemic<sup>23)</sup>.

Catastrophic consequences of the Russian military invasion of Ukraine significantly worsen the economic performance of economic entities in Ukraine. However, planning for economic recovery must also take into account environmental factors and emergency measures. While large enterprises have more opportunities, medium and small enterprises do not find a financial reserve for reorganization, training of employees, remuneration of consultants and certification of management systems, and subsequent supervisory audits<sup>24)</sup>.

When asked about the company's participation in tenders, and public procurement, where environmen-

tal requirements are set (for example, green public procurement), the vast majority, 68% of respondents, answered that they have never participated in such events; 25% – successfully participated in such events. Further analysis using factor tables revealed that these are large enterprises. But the state of implementation of EMS in enterprises is different: five out of six enterprises have implemented or plan to apply environmental management (Fig. 15).

Green public procurement projects have been operating in Ukraine since 2015. The new version of the Law of Ukraine «On Public Procurement» September 19, 2020 № 114-IX (as amended) established a clear legal basis for contracting authorities to use public procurement to achieve strategic environmental and social goals set by public policy. According to the law, the customer can announce a purchase, where in addition to the price factor, there will be other factors – non-price evaluation criteria. Non-price criteria are an additional benefit that is not a key parameter but may affect the choice of the winner.

More than 75 countries, including almost all EU and OECD countries, have adopted green public procurement systems.

Ukraine can already stimulate business to produce more environmentally friendly with the help of the green public procurement tool. Non-tariff barriers to trade with the EU are environmental (or climate) in nature, and investment is increasingly tied to the principles of compliance with EU climate goals and environmental sustainability<sup>25)</sup>.

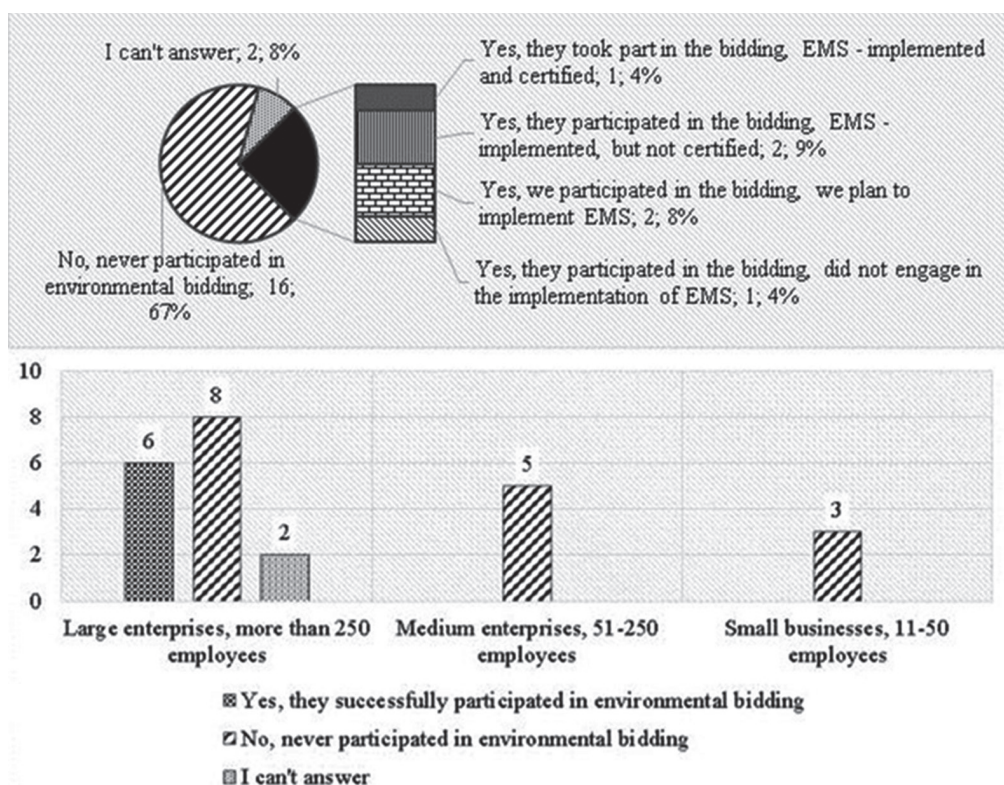


Fig. 15. Participation of the enterprise in tenders, public procurements where ecological requirements are put forward (green public procurement),  $n = 24$

## Conclusions

Analysis of the research results allowed to determine the nature of the development and spread of EMS in the area of drug production. It was found that among the respondents who took part in the survey, only 25% of companies have implemented EMS and passed the certification procedure in accordance with the requirements of the ISO 14001 standard. These enterprises belong to the category of large ones, with more than 250 employees. At all enterprises where EMS was implemented in accordance with ISO 14001, a quality management system in accordance with ISO 9001 was also implemented; at some enterprises, other management systems were implemented in accordance with ISO 22000, ISO 13485, SA 8000, OHSAS. The analysis provided evidence that the existence of several management systems is a characteristic feature of large enterprises that seek to implement their own management systems and allocate appropriate resources. Such large enterprises take part in the bidding, public procurement, where environmental requirements are set (green public procurement). However, small businesses cannot afford to invest in the implementation and maintenance of certified EMS and believe that such costs outweigh the potential benefits.

The main internal factors that directly impact the effective functioning of EMS are resources (enterprise size, financial capabilities), leadership, the competence of environmental staff, awareness and involvement of management and staff, and the desire to strengthen the company's brand. Senior management's lack of interest, lack of environmental knowledge in senior and middle management, lack of information of all staff, and lack of environmental policy and goals are significant obstacles to greening pharmaceutical production, achieving sustainability, and business responsibility.

External factors influencing the implementation of certified EMS are: general global trends in greening policy, fashion for certification, pressure from business partners, control and financial support from government agencies, and information support to other organizations. Determinants for business are state legal requirements for environmental protection and measures in case of emergencies.

A significant identified problem is the lack of influential information tools, methodological developments for the implementation, operation, and benefits of EMS, and environmental standards in pharmaceutical production, especially in emergencies (from forced shutdown to man-made disasters). Unfortunately, respondents did not consider EMS and the ISO 14001 standard as tools that are recognized globally as the best available technologies and management methods to anticipate ensuring the processes of preparedness of organizations for emergencies. And this is critical because drug production companies are potentially dangerous pollutants in the environment in emergencies.

The main contribution of this study is the analysis of the nature of development and dissemination of EMS in drug production enterprises in Ukraine, identifying the main factors influencing the functioning and development of EMS, and identifying common problems and risks in managing environmental aspects of pharmaceutical companies.

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