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PHARMACEUTICAL SAFETY OF THE STATE: RESULTS OF EXPERT ASSESSMENT

State Nonprofit Company “Danylo Halytsky Lviv National Medical University”, Lviv, Ukraine

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Introduction. In the context of current threats posed by the full-scale Russian armed aggression, approaches to understanding the development of the state's pharmaceutical safety (PS) require more in-depth investigation.

The aim of the work. To investigate the state of PS in Ukraine based on the views of the expert community, identify its components by importance, and determine how PS integrates into the national security system and contributes to the achievement of the UN Sustainable Development Goals.

Materials and methods. Scientific, analytical, legislative, and regulatory sources on national security and PS in Ukraine were used, incorporating methods including observation, survey, mathematical statistics, comparison, and generalization.

Results. Based on an expert evaluation conducted with the participation of 166 specialists drawn from scientific research, education, and practical pharmacy, a ranking was established to determine the relative importance and priorities of PS components. Additionally, the study assessed the degree of interrelation and influence these components exert on national security in the context of PS. Furthermore, the significance of advancing PS in alignment with the United Nations Sustainable Development Goals was identified.

Conclusions. The state of PS in Ukraine has been assessed in terms of its multidimensional structure, the interconnectedness of its components, and their influence on national security. A close connection between PS and the UN Sustainable Development Goals has been established, underscoring the need for a systemic approach to its development.

Keywords: national security, its components and priorities, pharmaceutical safety, pharmaceutical sector of the healthcare system, sustainable development goals.

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СТАН ФАРМАЦЕВТИЧНОЇ БЕЗПЕКИ ДЕРЖАВИ: РЕЗУЛЬТАТИ ЕКСПЕРТНОГО ОЦІНЮВАННЯ

ДНТ «Львівський національний медичний університет імені Данила Галицького», Львів, Україна

У статті на підставі експертного оцінювання 166 фахівцями, задіяних у науково-освітній та практичній фармації, з'ясовано стан фармацевтичної безпеки України з погляду її структури, спорідненості та впливовості складників національної безпеки, Цілей сталого розвитку ООН.

Ключові слова: національна безпека та її складники, фармацевтична безпека, фармацевтичний сектор галузі охорони здоров'я, цілі сталого розвитку.

Introduction

Pharmaceutical safety (PS) is aimed at meeting the population's needs for equitable access to quality pharmaceutical care based on the principles of sustainable development of the pharmaceutical sector within the healthcare system. It is an integral component of the national security system. In this context, PS functions as an integral component of the national security system, combining both an independent dimension and multifaceted connections with other elements [1].

Modern challenges caused by the full-scale Russian armed aggression significantly transform the national security system of Ukraine and its components, highlighting the need to reconsider approaches to the development of PS.

Elbe S. introduced the term “pharmaceuticalization of security,” which defines medicines as instruments of social stability, thereby expanding the understanding of PS: from drug quality control to the management of societal risks [2]. Pharmacy is increasingly integrating its activities with global frameworks – the UN Sustainable Development Goals, the Joint External Evaluation tool, and the One Health approach, emphasizing its key role in strengthening the resilience of health systems and ensuring security in response to pandemics and other threats [3]. In the same vein, the European Commission proposed Regulation COM

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(2025) 102, which establishes a regulatory framework for risk monitoring and ensuring the security of supply of critically important medicines [4].

Research also shows that transparency and accountability in pharmaceutical systems are key mechanisms of PS, as they reduce corruption risks, guarantee the quality of medicines, and strengthen patient trust [5]. At the same time, the WHO in its 2025–2030 roadmap identified strategic directions for ensuring access to safe and high-quality medicines and medical technologies, enhancing the resilience of pharmaceutical systems, harmonizing regulatory standards, and developing local production, which should reduce the risks of shortages and healthcare inequalities [6].

The importance of PS issues also attracts the attention of Ukrainian scholars. Since the mid-2010s, the theoretical foundations of PS have been actively developed in academic works [7–11]. However, the structure and hierarchy of PS components have not yet been systematically defined, its interrelation with other elements of national security has not been established, and alignment with the UN Sustainable Development Goals until 2030 has not been achieved. These gaps determine the relevance of the present study.

The aim of the work. To investigate the state of PS in Ukraine based on the views of the expert community, identify its components by importance, and determine how PS integrates into the national security system and contributes to the achievement of the UN Sustainable Development Goals.

Materials and Methods

The research materials included scientific, analytical, legislative, and regulatory sources related to national security and PS in Ukraine. The study employed a methodological approach to expert surveying on social security issues [12], as well as methods such as observation, survey combined with the expert evaluation, mathematical statistics, comparison, and generalization.

For the survey and a priori ranking, a questionnaire was developed including socio-demographic characteristics of the experts and seven groups of evaluation questions. For the characterization of the level of PS, a five-point Likert scale was used: 5 = particularly threatening; 4 = threatening; 3 = moderately threatening/moderately safe; 2 = safe; and 1 = completely safe.

Validation of the questionnaire, i.e., the extent to which the questionnaire items correspond to the research problem, was conducted in two stages:

based on the discussion of the questionnaire by means of brainstorming among the academic staff of the Department of Organization and Economics of Pharmacy at Danylo Halytsky Lviv National Medical University (LNMU);

approved by the Ethics Committee on Scientific Research, Experimental Development, and Scientific Work at LNMU (Protocol No. 9, dated October 22, 2024).

The survey was conducted using Google Forms between October 24, 2024, and January 24, 2025, on a voluntary and anonymous basis. The sample was formed according to the “snowball” principle (i.e., each participant recruited other participants to complete the questionnaire). All respondents

provided informed consent, and the completion time did not exceed 15 minutes.

The questionnaire was distributed among academic and teaching staff of higher pharmaceutical education institutions (LNMU, Zaporizhzhia State Medical and Pharmaceutical University, O.O. Bohomolets National Medical University, Lviv Polytechnic National University, Odessa National Medical University, and Lesya Ukrainka Volyn National University) as well as specialists from pharmacy chains (D.S., Apteka Puls, ANC, Podorozhnyk, Apteka Optovykh Ts.).

A total of 166 respondents participated in the survey. Given the unknown size of the general population, the sample volume was determined to be sufficient. According to Cochran’s formula, with a 95% confidence interval and maximum variation ($p = 0.5$), the margin of error for the sample is 7.6%. In line with modern methodological recommendations, a margin of error within 5–10% is considered scientifically acceptable for drawing strategic conclusions [13].

Research results and their discussion

As shown in Figure 1, more than nine out of ten respondents (95.2%) were female. Nearly four-fifths (79.5%) held a pharmacist’s educational qualification. More than one-fifth (22.3%) had an academic degree, and approximately three-quarters (72.3%) worked in practical pharmacy.

The survey participants represented various age groups and lengths of professional experience, both academic and practical. The largest group consisted of specialists with extensive professional experience (30.1%). They were followed by mid-career professionals (23.5%), early-career professionals (20.5%), and those with established careers (15.5%). A smaller proportion of respondents belonged to the group with long-term professional experience (11.4%).

Thus, the conducted survey enables the assessment of the studied PS issues, taking into account the opinions of a sufficiently representative expert community based on their socio-demographic profile.

According to the importance ranking, all 15 components of PS received high ratings ranging from 42.8% to 88.6% (Table 1). This evaluation interval can be conditionally divided into five groups.

Respondents assigned drug safety and patient safety to the first group (88.6% and 87.3%, respectively). The high significance of these components is explained by the fact that they directly determine human life and health and have critical consequences in case of violations. At the same time, they reflect both societal and professional consensus: patient safety is the core of pharmaceutical activity and a key benchmark for the development of the PS system.

The second group combined the safety of medical devices and other pharmacy assortment products, the safety of pharmaceutical professionals, and the safety of pharmaceutical services, with ratings of 74.7%, 74.1%, and 72.9%, respectively. Their ratings turned out to be somewhat lower, since their impact on the patient is indirect. At the same time, these components determine the overall level of PS: the safety of medical devices and other pharmacy assortment products minimizes

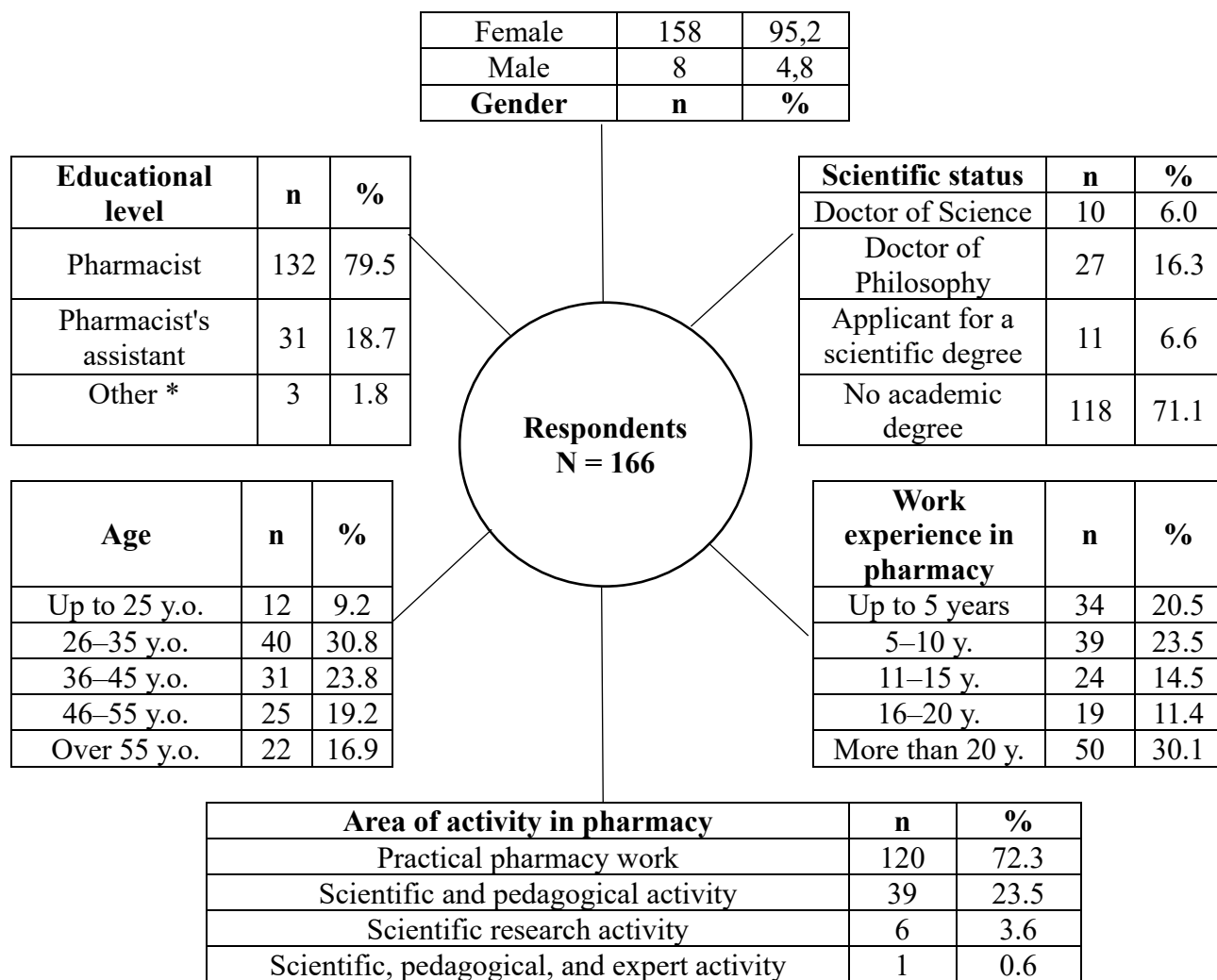


Fig. 1. Characteristics of the respondents' socio-demographic profile:

* – without pharmaceutical education

Table 1

Ranking of the importance of PS components in Ukraine

PS component name	Significance	
	n	share, %
1	2	3
The first group		
Drug safety	147	88.6
Patient safety	145	87.3
The second group		
Safety of medical devices and other pharmacy assortment products	124	74.7
Safety of pharmaceutical professionals	123	74.1
Safety of pharmaceutical services	121	72.9
The third group		
Implementation of state medical care guarantee programs regarding pharmaceutical provision	108	65.1
State regulation and self-regulation of the pharmaceutical sector of the healthcare industry and pharmaceutical activities	107	64.5
The fourth group		
Information and educational activities among the population on drug safety and pharmaceutical waste management	103	62.0
Logistics services – ensuring that patients receive the necessary medicines in the required dose, quality, cost, location, and time	98	59.0

1	2	3
Innovation in the development of the pharmaceutical sector of the healthcare industry	96	57.8
Stockpiling of medicines and medical devices for organizing pharmaceutical provision of the population and healthcare institutions during peacetime and wartime emergencies	93	56.0
Safety of pharmaceutical organizations	89	53.6
The fifth group		
Pharmageddon**	77	46.4
Import dependence, primarily concerning active pharmaceutical ingredients necessary for the production of essential medicines	74	44.6
Integration of concepts such as pharmaceutical care, good pharmaceutical practices, the “ten-star pharmacist,” social pharmacy, and social responsibility	71	42.8
*Risks arising from financial ties between pharmaceutical companies and physicians, regulatory authorities, professional organizations, patient groups, and medical journals, aimed at granting undue advantages and downplaying harm from specific medicines, as well as threats related to pharmaceutical biotechnology, drug falsification, and the disposal and neutralization of pharmaceutical waste.		

potential risks for patients; the safety of pharmaceutical professionals ensures professional competence and reduces the risk of errors; the safety of pharmaceutical services builds public trust.

The third group comprised the implementation of state medical care guarantee programs and the state regulation and self-regulation of the pharmaceutical sector of the healthcare system and pharmaceutical activities, rated at 65.1% and 64.5%, respectively. The significance of these components is lower, as they are perceived as institutional mechanisms that create conditions for PS but do not have a direct impact on the patient. At the same time, their importance is strategic – without effective regulation and state guarantees, it is impossible to ensure the systemic resilience of PS.

The fourth group consisted of information and educational activities among the population, logistics services, innovation in the development of the pharmaceutical sector, stockpiling of medicines and medical devices for emergency situations during peacetime and wartime, with corresponding ratings of 62.0%, 59.0%, 57.8%, 56.0%, and 53.6%, respectively. Their significance is lower because they are not always directly perceived by the patient. However, these components define the long-term systemic resilience of PS: the availability of medicines at the right time and place, the competitiveness of the pharmaceutical sector, preparedness for crisis situations, and the development of a culture of safe medicine use.

The fifth group included pharmageddon, import dependence, and the integration of diverse pharmaceutical management concepts (46.4%, 44.6% and 42.8%, respectively). The low scores can be explained by the fact that these components are perceived as distant or systemic risks, which are not always evident in pharmaceutical practice. At the same time, they are critically important for the systemic resilience of PS: “pharmageddon” concentrates risks of corruption, falsification, and the impact of pharmaceutical waste; import dependence makes the pharmaceutical sector vulnerable to global crises; the integration of managerial pharmaceutical concepts shapes a unified professional identity and standards. This group

outlines strategic risks and defines the long-term prospects for the development of PS.

On its part, PS, as a component of national security, is influenced by all its other elements. As shown in Table 2, experts, having evaluated all elements of national security, recognized the closest affinity of PS with human security and vital (medical) security. This view is shared by 71.1% and 62.7% of experts, respectively. This is consistent, given that PS is intrinsically linked to human life and health.

At least half of the respondents acknowledged the interconnection of PS with information security (58.4%), social security (57.8%), biological and environmental safety (both 50.6%), and economic security (49.4%). While these indicators lack the immediate impact of human and medical security, they establish the institutional, social, environmental, and economic framework within which PS can evolve in a systemic manner.

About two quarters of experts also noted public safety and order, as well as state security (42.2% and 39.2%, respectively), which reflects the recognition of the role of these components of national security in strengthening the resilience of PS.

The weight of the affinity with the PS of other components of national security ranges from 18.7% to 36.1% and indicates that some experts understand national security as a complex system of interconnectedness of its elements. Such a distribution demonstrates that experts recognize PS as part of a complex system of interconnections among elements of national security, where even less obvious components matter in the long-term perspective.

To confirm the reliability of the results at this stage of the survey, respondents were asked to assess the above-mentioned components of national security in terms of their complete lack of influence on the state of PS. As shown in Table 2, according to the experts, the set of other components does not affect the state of PS at a level exceeding two quarters, specifically ranging from 8.4% (economic security) to 40.4% (security against terrorism). A correlation analysis between the ranks of national security components in terms of affinity with PS and non-

Table 2

Degree of affinity and influence of national security components in relation to PS

Components of national security	Affinity with PS			Do not affect the state of PS		
	n	share, %	rank	n	share, %	rank
Human security	118	71.1	1	17	10.2	16
Vital (medical) safety	104	62.7	2	14	8.4	18.5
Information security	97	58.4	3	19	11.4	14
Social security	96	57.8	4	19	11.4	14
Biological safety	84	50.6	5	21	12.7	12
Environmental safety	84	50.6	6	29	17.5	11
Economic security	82	49.4	7	14	8.4	18.5
Public safety and order	70	42.2	8	36	21.7	8
State security	65	39.2	9	16	9.6	17
Military security	60	36.1	10	19	11.4	14
Transport security	53	31.9	11	42	25.3	7
Energy security	44	26.5	12	35	21.1	9.5
Cybersecurity	43	25.9	13	49	29.5	3
International security	39	23.5	14	46	27.7	4.5
Technological security	36	21.7	15	43	25.9	6
Food security	35	21.1	16	46	27.7	4.5
Customs security	34	20.5	17	35	21.1	9.5
Security against terrorism	31	18.7	18.5	67	40.4	1
Political security	31	18.7	18.5	55	33.1	2
The correlation coefficient $r = -0.82$						

influence on the state of PS yielded a Pearson correlation coefficient [14] of $r = -0.82$. The high absolute value of the coefficient indicates a strong relationship between the responses to the two questions, i.e., a high consistency of respondents' opinions.

As for the level of PS, according to the five-point Likert scale only 7.2% of experts considered it particularly threatening, while at least one-fifth (21.7%) regarded it as threatening. More than half (53%) assessed the situation as moderately threatening/moderately safe. Those who considered the level of PS safe and completely safe accounted for 14.5% and 3.6% of experts, respectively. Based on the weighted arithmetic average, the overall level of PS was assessed at 3.1 points. Thus, based on the normative evaluation scale, which distinguishes between positive, negative, and mixed assessments [15], the level of PS in Ukraine is characterized by a mixed evaluation and reflects an intermediate stage between a threatening and a safe level.

By a decree of the President of Ukraine, with the aim of ensuring the national interests of Ukraine in the context of sustainable development of the economy, civil society, and the state, 17 UN Sustainable Development Goals (SDGs) to be achieved by 2030 were adopted for implementation [16, 17]. Therefore, the expert survey included an assessment of the significance of sustainable development processes in promoting the development of PS in Ukraine.

As shown in Table 3, only 7 respondents, or 4.2%, did not express a clear opinion on this issue.

However, at least four-fifths of experts (82.5%) identified Goal 3 – Ensure healthy lives and promote well-being for all at all ages – as the most significant in terms of contributing to the development of PS in Ukraine. This is explained by its intrinsic alignment with the essence of PS.

More than two-thirds of respondents (68.1%) highlighted Goal 4 – Quality education, i.e., ensuring inclusive and equitable quality education, including pharmaceutical education, and promoting lifelong learning opportunities. Half of the experts (54.2%) gave preference to Goal 8 – Promote sustained economic growth, full and productive employment, and decent work, while nearly half (48.8%) identified Goal 1 – End poverty – as significant. This alignment is consistent, since quality education, sustainable economic growth, and poverty alleviation establish the fundamental basis on which the resilience of PS relies.

More than two-fifths of respondents recognized the significance of the following three goals for the development of PS: Goal 16 – Peace, justice and strong institutions, which refers to building peaceful and inclusive societies, ensuring access to justice for all, and creating effective, accountable and inclusive institutions at all levels (44%); Goal 12 – Responsible consumption and production (42.8%); and Goal 17 – Partnerships for the goals, i.e., strengthening global partnerships to support the achievement of the Sustainable Development Goals (40.4%). Collectively, these goals establish the framework for the systemic advancement of PS, reflecting experts' recognition of the significance of institutional trust, international collaboration, and responsible resource utilization.

The significance of the interconnection with Sustainable Development Goals 2, 5–7, 9–11, 13–15 ranges from 13.3% to 31.3%, confirming that a considerable proportion of experts understand the strengthening of PS through the achievement of the Sustainable Development Goals. The lower scores for goals related to climate, energy, infrastructure, and gender equality can be explained by their indirect impact on PS. At the same time, experts

Table 3

Ranking of the UN Sustainable Development Goals by their significance in promoting the development of PS in Ukraine

Goal number	Goal title	Significance	
		n	share, %
Goal 3	Ensure healthy lives and promote well-being for all at all ages	137	82.5
Goal 4	Ensure inclusive and equitable quality education and promote lifelong learning opportunities	113	68.1
Goal 8	Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all	90	54.2
Goal 1	End poverty in all its forms everywhere	81	48.8
Goal 16	Promote peaceful and inclusive societies for sustainable development, provide access to justice for all	73	44.0
Goal 12	Ensure sustainable consumption and production patterns	71	42.8
Goal 17	Strengthen the means of implementation and revitalize the global partnership for sustainable development	67	40.4
Goal 9	Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation	52	31.3
Goal 2	End hunger, achieve food security and improved nutrition, and promote sustainable agriculture	51	30.7
Goal 11	Make cities and human settlements inclusive, safe, resilient and sustainable	47	28.3
Goal 15	Protect, restore and promote sustainable use of terrestrial ecosystems	46	27.7
Goal 13	Take urgent action to combat climate change and its impacts	40	24.1
Goal 6	Ensure availability and sustainable management of water and sanitation for all	36	21.7
Goal 7	Ensure access to affordable, reliable, sustainable and modern energy for all	35	21.1
Goal 14	Conserve and sustainably use the oceans, seas and marine resources for sustainable development	34	20.5
Goal 10	Reduce inequality within and among countries	27	16.3
Goal 5	Achieve gender equality and empower all women and girls	22	13.3
No response		7	4.2

acknowledge that even these goals are components of a broader system that shapes PS. Their influence is less evident in the short term; however, they determine the long-term resilience and strategic orientation of PS.

Conclusions

The state of PS in Ukraine has been assessed in terms of its multidimensional structure, the interconnected-

ness of its components, and their influence on national security. A close connection between PS and the UN Sustainable Development Goals has been established, underscoring the need for a systemic approach to its development.

Conflicts of interest. The authors declare no conflict of interest.

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