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RESULTS OF THE EXPERT SURVEY ASSESSING THE EFFICIENCY LEVEL OF THE NATIONAL REGULATORY SYSTEM IN THE FIELD OF MEDICINES TURNOVER

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The aim. *The aim of the research is to analyze the efficiency level of the national regulatory system in the field of medicines circulation using self-diagnostic tools, which will allow identifying reserves for its optimization and further improvement.*

Materials and methods. *The research materials consisted of the results of a survey conducted among government officials of national regulatory authorities in the field of medicines circulation. The research utilized methods of sociological survey, descriptive statistics, graphical analysis, data grouping, and generalization techniques. The research includes the development of a questionnaire based on the World Health Organization's "Global Benchmarking Tool" methodology, adapted to the national healthcare system. The questionnaire consisted of 2 questions to determine respondent characteristics and 104 statements about the functioning of the national regulatory system in the field of drug circulation.*

Results*. According to 75 % of the surveyed officials in Ukraine, an effective regulatory system operates in the field of drug circulation. Based on the number of affirmative answers, all statements were divided into 4 groups: high, sufficient, moderate, and low. Thus, the quality management system of national regulatory authorities was evaluated at a high level, while the funding system of national regulatory authorities received the lowest ratings. The grouping allowed us to identify weaknesses in the activity of the national regulatory system in the field of drug circulation, such as the lack of funds in budgets for staff training and overall insufficient funding for national regulators, including insufficient funding from international donors, lack of clarity and comprehensiveness in the regulatory framework for the pharmaceutical sector, etc.*

Conclusions*. In accordance with the aim of the article, we conducted research on the efficiency level of the national regulatory system in the field of drug circulation, which revealed that the most mature and effective direction of its activity today is the development and implementation of quality systems in national regulatory authorities*

Keywords*: national regulatory systems, national regulatory authority, drug circulation, self-diagnosis*

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1. Introduction

One of the key elements of public and national security in the conditions of the European integration processes is the provision of high-quality and safe medicines, which is an important social function of the state and a prerequisite for preserving the health and quality of life of the population of Ukraine [1, 2]. To ensure such processes, the state must develop and implement an effective pharmaceutical regulatory policy that will comply with international recommendations, consider national aspects and, at the same time, be effective in practice [3].

International experience shows that countries in which the public administration works properly are successful because they have favourable conditions for business development, respectively, conditions for reducing the level of poverty, and for citizens to receive high-quality public services [4, 5]. In addition, in government decision-making processes, it is mandatory to consider public opinion, which lays the foundation for citizens' trust in the state and contributes to the construction of their partnership relations [6, 7]. Therefore, in view of the above, the processes of formation, functioning and development of the regulatory system in the field of drug circulation, are of great importance in modern conditions.

According to the guideline "Medicinal products. Proper regulatory practice" regulatory activity in the field of drug circulation – a direction of activity aimed at improving the legal regulation of economic relations, as well as administrative relations between the central executive authority in the field of health care or other authorized bodies, expert institutions and business entities (applicants, manufacturers, doctors, patients, consumers), preventing the adoption of economically impractical and ineffective regulatory acts, reducing the intervention of the Ministry of Health in the activities of economic entities and eliminating obstacles to the development of economic activity, which is carried out within the limits, in the order and in the manner established Constitution and laws of Ukraine [8, 9].

To understand the effectiveness of regulatory activity in the field of drug circulation, which has a significant impact on the quality of pharmaceutical provision of the population, it is necessary to carry out its assessment, which will allow to determine the reserves of its optimization and further improvement [10, 11].

To date, various theoretical and practical issues regarding the improvement of the state management system of the pharmaceutical sector of health care in Ukraine have been considered by various domestic scientists. In particular, the research of S. V. Knysh [12, 13] is devoted to state policy and legal relations in the field of health care, the general principles of state management of pharmacy were studied by O. S. Khovpun [2, 14]; public administration in the field of drug circulation is considered in the works of O. H. Strelchenko [15, 16]; the legal basis of the state management of the circulation of medicinal products, taking into account the European experience, are devoted to the works of O. G. Alekseev and V. M. Pashkov [17, 18], the issue of the management of the medical supply of the Armed Forces of Ukraine under martial law is covered in the research of D. V. Karamyshev, L. P. Gordienko [19, 20], certain aspects of the regulation of pharmaceutical supply were studied by A. A. Kotvitska [18, 21], A. S. Nemchenko [22–24] V. M. Khomenko [24, 25].

However, as the analysis shows, despite a sufficient number of publications devoted to the issues of improving the state management of the pharmaceutical industry of Ukraine, some problems of assessing the effectiveness of regulatory policy in the field of drug circulation still remain outside the attention of scientists, which determined the relevance of the research topic.

Conducting an analysis of the regulatory system in the field of drug circulation and identifying its status using the WHO methodology "Global comparison tool" will contribute to the identification of reserves and directions for its improvement, as well as the development of reasonable plans for its development. Under such conditions, the problem of selection and substantiation of key indicators that best reflect the national aspect and can provide an objective and comprehensive description of the state and features of the development of the national regulatory system (NRS) becomes urgent [26, 27].

2. Research planning (methodology)

To achieve the set goal, we have developed an algorithm for conducting research, which consists of 6 stages (Fig. 1).

At the first stage, we analyzed and systematized data on the state administration of the pharmaceutical sector of health care, which allowed us to choose the implementation methodology at the next stage. The use of self-assessment tools is one of the stages of the general assessment scheme of public authorities of the European Institute of Public Administration [28]. It should be noted that the proposed self-assessment method is appropriate for use by the countries themselves when conducting self-diagnosis and determining the degree of effectiveness and efficiency of the regulators' performance of their main functions, identifying the strengths and weaknesses of the regulatory system, diagnosing potential risks associated with its functioning and determining development prospects. The WHO methodology "Global comparison tool", which was used during the development of the questionnaire, is publicly available all over the world and used by 84 WHO member countries, 58 of which benchmarking was carried out independently (without the involvement of WHO experts) [11, 29].

The third stage of the study involved the development and preliminary approval of a questionnaire for self-diagnosis of the national regulatory system in the field of circulation of medicinal products by civil servants of the relevant bodies. During the development of the questionnaire, the WHO methodology "Global comparison tool" was used. The specified methodology includes more than 200 indicators (characteristics) that relate to various functions of the regulatory system: actual evaluation of the national regulatory authority, registration of pharmaceuticals, pharmacovigilance and quality control, licensing, organization of laboratory and clinical research, etc. To form the questionnaire, we used the statements included in Section 1 of the National regulatory systems of the WHO guidance on evaluation [26]. At the next stage, the actual survey was conducted.

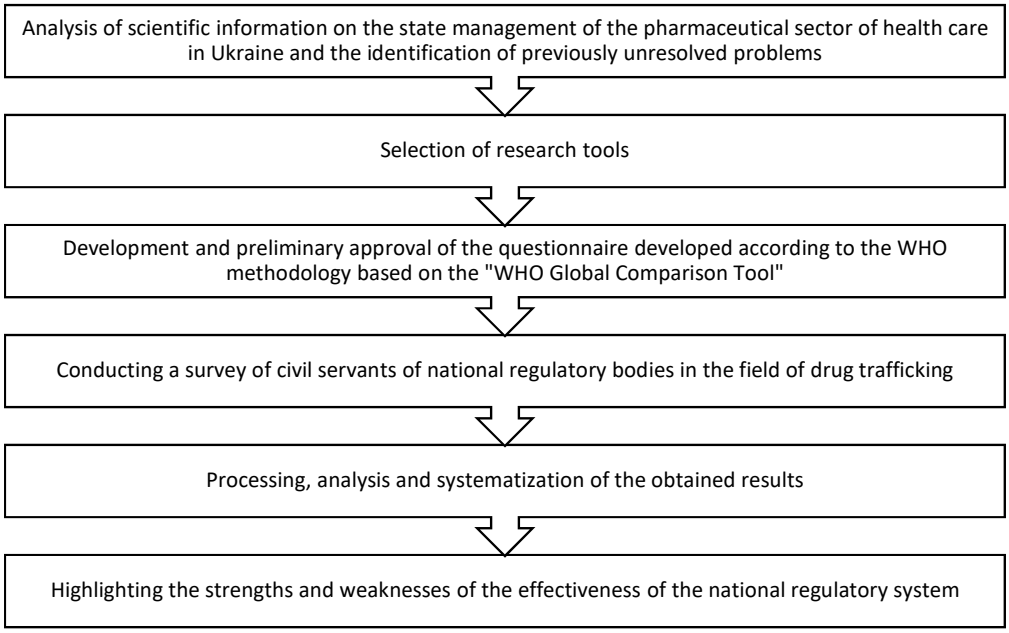

Fig. 1. Research algorithm

After processing the received data, we summarized the results, highlighted the strengths and weaknesses of the national regulatory system in the field of circulation of medicinal products, which made it possible to determine the strengths and weaknesses.

3. Research methodology

The questionnaire we developed included 106 statements: 2 questions – data on respondents, 104 statements – information on the functioning of the regulatory system in the field of drug circulation, which were divided into blocks, namely:

Block I – General information (15 statements);

Block II – Corporate management of the national regulatory authority (NRA) (6);

Block III – Institutional development of NRS (4);

Block IV – Organizational structure of NRS (4);

Block V – Quality management system in NRA (12);

Block VI – NRA financing (6);

Block VII – Human resources management (10);

Block VIII – Transparency and confidentiality of NRA activities (15);

Block IX – Independence and objectivity of NRA activity (4);

Block X – NRA Infrastructure (8);

Block XI – Communication activities of NRA (3);

Block XII – Monitoring and accountability of NRA (3);

Block XIII – Assessment of effectiveness and efficiency of regulatory activity in the field of drug circulation (6);

Block XIV – Risk management (8).

The questionnaire includes the indicators described in the WHO methodology "Global comparison tool" [26]. For the questionnaire, only those indicators that can be evaluated by NRA civil servants and can be evaluated in the self-diagnosis process are included. To formulate the statements of the questionnaire, we have previously studied the structure and powers of NRAs, their powers and the processes provided by NRAs. In the course of the study, respondents were asked to answer "yes" or "no" as to whether the proposed statements correspond to the current state of functioning of the regulatory system.

The survey was conducted anonymously in April 2023 using the Google Form tool. Random sampling, namely, the "snowball" method, was used for the purposeful selection of experts. This method is used to work with small general populations and involves searching for an expert based on defined criteria. Within the framework of our research, the following primary criteria were: work experience in the regulatory system in the field of drug circulation and a managerial position. Thus, the search for experts is aimed at recruiting on a peer-to-peer basis with statistical adjustments. Formed an initial group of experts who meet the defined criteria, it was possible to collect contacts of other people who have strong connections in these communities and meet the research criteria. This process forms the basis for expanding the sample size, which grows like a "snowball". The process of finding experts using the specified method continues until the received contacts begin to repeat. As a result, the number of the sample is 41 experts who agreed to participate in the survey.

Specialists of state regulatory bodies in the field of drug circulation were invited to participate in the study. The NRS self-assessment tools are included in the general evaluation scheme of the European Institute of Public Administration [28], provided by the WHO methodology "Global comparison tool" [11], because the respondents are part of the internal environment of the NRA and are best informed about the aspects studied.

To determine the level of competence of experts, an appropriate technique was developed [30]. The assessment of the expert's awareness of the problem under study was considered as the initial variable when building the model, which, according to the results of the survey, assumed two values: fully satisfied need for information (1) and partially satisfied need for information (0).

Quantitative parameters affecting the degree of awareness of experts on the investigated problem are determined by age, scientific qualification, total work experience, work experience in the regulatory system in the field of drug circulation, the position held and the ability to make management decisions, the number of subordinates. These parameters were ranked by the level of importance using the information criterion Chi-sgure (χ^2) (Table 1). The most informative indicators (the position held and the ability to make management decisions and work experience in the regulatory system in the field of drug circulation) were included in the model for assessing the level of experts' competence. It should be noted that the experts represented all structural subdivisions of the NRA and cover all processes of its functioning.

The construction of the model for assessing experts' competence indicators was carried out by the method of logistic regression, which allows obtaining estimates of binary feedback in the form of a continuous function with a value from the interval [0; 1], which are interpreted as the probability that the output variable will take the value 1 [30]. When building the model, various methods of estimating its parameters were tested [31], the most relevant indicators were obtained using the quasi-Newton method and the Hooke – Jeeves method. According to the obtained results, the level of experts' awareness of the investigated problem was characterized in accordance with the Harrington scale (Table 2) [30].

Table 1

The results of the evaluation of indicators of the level of competence of experts

Parameter	Value	
	λ^2	P-value
The position held and the possibility of making managerial decisions	39.125	0.00134
Work experience in the regulatory system in the field of circulation of drugs	29.763	0.00224
Total work experience	12.114	0.00021
Scientific qualification	11.765	0.00034
Age	9.434	0.00026

Table 2

Harrington verbal-numerical scale

Gradation	Numeric interval
Very low	0.00–0.20
Low	0.20–0.37
Medium	0.37–0.63
High	0.63–0.80
Very high	0.80–1.00

Based on the results of the assessment, it was established that only 35 employees have a level of competence in the range of 0.63 – 1, which corresponds to a high and very high level and, thus, can act as experts on the investigated problem.

The degree of agreement of experts' conclusions, which was measured using the concordance coefficient (W=0.854), can be recognized as high. The significance of the concordance coefficient was assessed by calculating the Pearson test (χ^2) and comparing it with the table value for degrees of freedom n–1. The calculated value of χ^2 significantly exceeds the tabular value, which confirms that the consistency of experts' conclusions is not accidental.

To generalize the results of the survey, we used the technique of statistical grouping by the number of affirmative answers [32]. We have proposed a division into 4 levels in accordance with the maturity levels of the WHO methodology [11].

Intervals were determined by calculating a range that considered the maximum and minimum value of affirmative responses and was 4. The class interval is established empirically and is usually equal for all classes [33]. Class intervals were calculated from the maximum value and are presented in Table 3.

Table 3

Distribution of the level of efficiency and maturity of the national regulatory system depending on the number of affirmative answers

Level		Number of positive answers	
		abs.	%
I	high	32–35	90–100
II	sufficient	28–31	80–90
III	medium	25–27	70–80
IV	low	less than 25	less than 70

Processing of survey results was carried out with the help of mathematical and static methods using Statistica 13.5 Tibco Software.

4. Research results

The results of self-diagnosis of NRS effectiveness in the field of drug circulation are presented in Tables 4–17.

Table 4

Results of the self-diagnosis of the effectiveness of the national regulatory system in the field of circulation of medicinal products. Block *I.* General information

No.	Statement	Number of responses			
		yes		no	
		abs.	%	abs.	%
General information					
1	In Ukraine has been created an effective regulatory system in the field of drugs circulation	26	74.3	9	25.7
2	Responsibilities/functions/organizational structure of each of the authorized regulatory bodies are clearly defined	29	82.9	6	17.1
3	The activity of regulatory bodies in the sphere of regulation of drug circulation is effectively coordinated	26	74.3	9	25.7
4	In Ukraine, an appropriate mechanism has been built, aimed at coordinating the activities of regulatory bodies in the field of regulating the circulation of drugs	23	65.7	12	34.3
5	The legislative framework/regulations for the regulation of the pharmaceutical sector are clear and comprehensive and meet international requirements	21	60.0	14	40.0
6	The main stages (mechanisms) of law enforcement are clearly defined and effectively implemented	28	80.0	7	20.0
7	Legislatively defined relevant organizations/departments that develop regulations/resolutions/laws in the sphere of regulation of drug circulation	32	91.4	3	8.6
8	Regulatory bodies responsible for their implementation are involved in the development of resolutions/laws/regulations	28	80.0	7	20.0
9	Different sectors of public society are involved in the development of resolutions/laws/regulations in the field of regulation of drug circulation (patients, medical workers, drug manufacturers, etc.)	27	77.1	8	22.9
10	Relevant resolutions/laws are implemented and published in a timely manner	31	88.6	4	11.4
11	Statutory powers of the NRA, which gives them the right to appoint specialists/inspectors and give them appropriate powers to carry out inspections/inspections of pharmaceutical products	34	97.1	1	2.9
12	The right and authority of the NRA to issue and publish relevant guidelines or explanatory materials on the regulation of the circulation of drugs are legally defined	33	94.3	2	5.7
13	The legislation empowers the NRA to set up technical/scientific advisory committees for regulatory purposes	32	91.4	3	8.6
14	Legislation defines the limits of competence for each advisory committee and in particular their role in decision-making and the conditions/circumstances under which the recommendations of experts/advisory committees must be provided to the NRA	29	82.9	6	17.1
15	Legislation empowers NRAs to charge fees for providing regulatory services	21	60.0	14	40.0

The first block contained 15 general statements about the functioning of the NRA (Table 3). Thus, according to the results of the survey, it was established that according to 75 % (26 out of 35 respondents) of the interviewed officials, an effective regulatory system in the field of drug trafficking is functioning in Ukraine. The results of the survey demonstrate a high level of legal certainty of the authority of the NRA, which gives them the right to appoint experts and give them the appropriate authority to conduct inspections (34 affirmative answers), the rights and powers of the NRA to issue and publish relevant guidelines (33 affirmative answers), to authorize the NRA to create advisory committees for regulatory purposes (32 affirmative answers). At the same time, 14 experts (40 % of those interviewed) identified insufficient clarity and comprehensiveness of the legal framework regulating the pharmaceutical sphere.

The next block of statements evaluated NRA's corporate governance (Table 5). 4 out of 6 proposed statements were evaluated at a sufficient and high level. 12 experts did not mention the presence in the NRA structure of a department for providing advisory support on scientific issues and future development; 10 experts from the structural unit on strategic development.

Block III included 4 statements regarding the institutional development of the NRS (Table 6). At the average level, only the presence of a developed institutional development plan, which is implemented and regularly updated, was evaluated.

The organizational structure of the NRS was assessed at high (3 statements) and sufficient (1 statement) levels (Table 7). It should be noted that all experts confirmed the statement that the activity of regulatory bodies is regulated by standards, guidelines, and procedures.

In block V, the quality management system (QMS) at NRA was evaluated (Table 8). All 12 statements were rated at a high level.

At the next stage, NRA financing was assessed (Table 9). Of the 6 proposed statements, only 2 were evaluated at a sufficient level: the determination of the NRA's funding sources and the need for mandatory periodic publication of its budget data.

Table 5

Results of the self-diagnosis of the effectiveness of the national regulatory system in the field of circulation of medicinal products. Block II. Corporate management of NRA

No.	Statement	Number of responses			
	Corporate management of NRA				
16	The functions of the NRA divisions are defined, documented and effectively implemented, especially in relation to the strategy and development of the NRA	31	88.6	4	11.4
17	NRA has a structural unit/council for strategic development	25	71.4	10	28.6
18	In the structure of NRA, there are departments/bodies that perform routine (day-to-day) functions	31	88.6	4	11.4
19	The tasks and responsibilities of these departments/structural divisions are defined and documented	33	94.3	2	5.7
20	The order of interaction and coordination between NRA departments is defined and documented	32	91.4	3	8.6
21	The NRB has a department to provide advisory support on scientific issues and the future development of the NRS	23	65.7	12	34.3

Table 6

Results of the self-diagnosis of the effectiveness of the national regulatory system in the field of circulation of medicinal products. Block III. Institutional development of NRS

No.	Statement	Number of responses			
	Institutional development of NRS				
22	An NRS institutional development plan has been developed, which is being implemented and regularly reviewed/updated	27	77.1	8	22.9
23	The mission and long-term development goals of NRS are defined	31	88.6	4	11.4
24	The NRA has developed and is implementing a plan of measures to achieve the set goals for improving the regulation of drug circulation	33	94.3	2	5.7
25	Indicators have been developed for monitoring and evaluating the effectiveness of NRS activities in achieving the defined goals of the development of the national health care system	30	85.7	5	14.3

Table 7

Results of the self-diagnosis of the effectiveness of the national regulatory system in the field of circulation of medicinal products. Block IV. Organizational structure of NRS

No.	Statement	Number of responses			
	Organizational structure of NRS				
26	Regulatory activity in the field of drug circulation is organized and effectively performed at the national level	32	91.4	3	8.6
27	The activity of regulatory bodies is regulated by standards, guidelines and procedures	35	100	–	–
28	An established mechanism for information exchange between NRA and subordinate institutions	33	94.3	2	5.7
29	An established mechanism for sharing experience and harmonizing best regulatory practices in the field of drug circulation regulation, as well as effective cooperation and interaction between various regulatory bodies	29	82.9	6	17.1

Table 8

Results of the self-diagnosis of the effectiveness of the national regulatory system in the field of circulation of medicinal products. Block V. Quality management system at NRA

No.	Statement	Number of responses			
Quality management system at NRA					
30	NRA has built a quality management system (QMS)	34	97.1	1	2.9
31	NRA management supports the development and implementation of QMS	33	94.3	2	5.7
32	NRA's QMS is based on recognized standards (e.g. WHO, PCS, ISO)	34	97.1	1	2.9
33	The quality policy and corresponding goals in the field of organization of NRA activities are defined and documented	34	97.1	1	2.9
34	An authorized person has been appointed for the development and implementation of QMS in the activities of NRA	34	97.1	1	2.9
35	For each regulatory function of the NRA, a quality management procedure, process (service) quality control methods are defined	33	94.3	2	5.7
36	The documentation necessary for the creation, implementation and sustainable functioning of the QMS of the regulatory body is defined (methodical recommendations, SOPs, etc.)	33	94.3	2	5.7
37	The documentation required within the QMS of the regulatory body is effectively controlled according to a documented procedure	34	97.1	1	2.9
38	NRA has developed a mechanism for evaluating the effectiveness of QMS implementation and operation	34	97.1	1	2.9
39	The QMS audit is carried out at least once a year	32	91.4	3	8.6
40	Based on the results of the audit, measures are being developed to improve the QMS system	34	97.1	1	2.9
41	NRA management regularly reviews (improves) the QMS and the results are documented	34	97.1	1	2.9

Table 9

Results of the self-diagnosis of the effectiveness of the national regulatory system in the field of circulation of medicinal products. Block VI. NRA financing

No.	Statement	Number of responses			
NRA financing					
42	Identified sources of funding for the NRA to carry out its regulatory activities	31	88.6	4	11.4
43	The amounts of payment for the provision of NRA regulatory services are clearly defined and are public (presented on the official website)	24	68.6	11	31.4
44	Discounts on payment or exemption from payment for the provision of regulatory services are defined by an official resolution	20	57.1	15	42.9
45	NRA is partly financed by donors such as WHO and others	19	54.3	16	45.7
46	The national regulatory authority has the necessary powers and a defined mechanism for collecting fees for services and spending funds	25	71.4	10	28.6
47	NRA's duties include mandatory periodic publication of its budget data	28	80.0	7	20.0

Block VII provided for the assessment of human resources management (Table 10). Out of 10 proposed statements, 4 were rated at a high level, 5 – at a sufficient level. 18 experts (53 %) noted that the NRA budget does not include funds for staff training. Document confirmation of functional duties and responsibilities in job descriptions by all experts.

An important stage is the assessment of the transparency and confidentiality of the NRB's activities (Table 11). As can be seen from Table 11, at the medium and low levels, the involvement of external stakeholders in the development of NRB directives, participation as observers in meetings of NRB advisory units, holding meetings, etc. was assessed.

In the Table 12 there are the results of self-assessment regarding the independence and objectivity of NRB activity. 100 % of experts confirmed the existence of a documented code of conduct for NRB employees. At the same time, 8 experts noted the lack of NRB's policy to prevent the concentration of powers to register procurement contracts with the same body.

The results of the assessment by NRB infrastructure group are presented in Table 13. 5 of the 8 proposed statements are assessed at a sufficient level. At the average level, the presence of the necessary equipment and a common computer network for the implementation of regulatory functions was assessed.

At the next stage, the communication activity of NRB was analyzed (Table 14). Thus, 28 out of 35 experts confirmed the existence of a communication strategy, 27 – confirmed that it considers the interests of various stakeholders and evaluates the effectiveness of communication activities.

Monitoring and accountability of the NRB was analyzed at the next stage (Table 15), which was assessed at a high and sufficient level.

Subsequently, the system for evaluating the effectiveness and efficiency of regulatory activity in the field of drug circulation was analyzed (Table 16), which was also evaluated at the high (2 statements) and medium (4 statements) levels.

The last block of the questionnaire included questions about risk management (Table 17). Yes, none of the 8 statements was rated highly. 14 experts noted the lack of risk management specialists in the NRB staffing schedule.

Table 10

Results of the self-diagnosis of the effectiveness of the national regulatory system in the field of circulation of medicinal products. Block VII. Human resources management

No.	Statement	Number of responses			
Human resources management					
48	The scheme of the organizational structure of the NRA (organizational chart) has been developed and is regularly updated	33	94.3	2	5.7
49	Differentiation in the level of payment of key NRA specialists is based on the level of their powers and responsibilities	28	80.0	7	20.0
50	Definition of functional duties and responsibilities of key employees are documented in the relevant job instructions	35	100	–	–
51	NRA has developed a list of necessary requirements for key employees (education, postgraduate training, skills, experience) who perform the relevant activities	32	91.4	3	8.6
52	NRA has the ability to select and hire employees in accordance with a documented procedure	29	82.9	6	17.1
53	NRA has established a system of primary periodic assessment (attestation) of personnel and determining the need for theoretical and practical training and setting personal goals	31	88.6	4	11.4
54	The familiarization procedure for newly hired employees has been defined	31	88.6	4	11.4
55	Developed training plan for all NRA employees in accordance with established needs. The implementation of the training plan is documented	31	88.6	4	11.4
56	Evaluation of the effectiveness of training results is carried out in accordance with the documented procedure (SOP)	34	97.1	1	2.9
57	The budget of the NRA includes funds for staff training	17	48.6	18	51.4

Table 11

Results of the self-diagnosis of the effectiveness of the national regulatory system in the field of circulation of medicinal products. Block VIII. Transparency and confidentiality of NRA activities

No.	Statement	Number of responses			
Transparency and confidentiality of NRA activities					
58	Current legislation stipulates the requirements for ensuring the confidentiality and transparency of the NRA's activities	34	97.1	1	2.9
59	NRA has a documented policy on public disclosure of necessary information	33	94.3	2	5.7
60	Information on the regulatory framework, directives, procedures and guidelines for the activities of the NRA is available to the community through posting on the official website or other appropriate mechanism that ensures wide access	35	100	–	–
61	NRA's annual report on allocation and use of budget funds is published and available to the community	29	82.9	6	17.1
62	The decision-making process at the NRA, as well as the criteria for their adoption, are transparent and public	29	82.9	6	17.1
63	Information on the results of NRA's regulatory activities is published and available to citizens	32	91.4	3	8.6
64	Information about NRA sanctions and revoked permits is transparent and available to citizens	32	91.4	3	8.6
65	Information on the rules for filing complaints and appeals regarding NRA regulatory decisions is available and transparent for citizens	31	88.6	4	11.4
66	A mechanism for appealing regulatory decisions of the NRA has been developed, worked out a nd made public	31	88.6	4	11.4
67	When developing directives, the NRA involves experts from among stakeholders	26	74.3	9	25.7
68	Proposals (observations) of internal and external experts regarding NRA activities are available to citizens	27	77.1	8	22.9
69	Stakeholder representatives participate as observers in the meetings of NRA advisory units	24	68.6	11	31.4
70	NRA has created a unit/identified contact person for communication with citizens	34	97.1	1	2.9
71	The national regulatory authority regularly organizes meetings with key stakeholders	25	71.4	10	28.6
72	NRA representatives participate in meetings organized by interested parties (associations of manufacturers, medical and pharmaceutical workers, pharmaceutical market subjects, patients)	31	88.6	4	11.4

Table 12

Results of the self-diagnosis of the effectiveness of the national regulatory system in the field of circulation of medicinal products. Block *IX. Independence and objectivity of NRA activities*

No.	Statement	Number of responses			
Independence and objectivity of NRA activities					
73	There is a documented code of conduct for NRA employees	35	100	–	–
74	NRA has developed an internal personnel policy regarding potential conflicts of interest	34	97.1	1	2.9
75	A standard model of a conflict-of-interest statement has been developed and made public	33	94.3	2	5.7
76	Developed and documented policy of NRA to prevent the concentration of powers to register procurement contracts in the same body (department, employee)	27	77.1	8	22.9

Table 13

Results of the self-diagnosis of the effectiveness of the national regulatory system in the field of circulation of medicinal products. Block X. NRA infrastructure

No.	Statement	Number of responses			
NRA infrastructure					
77	NRA has created the right conditions for work	28	80.0	7	20.0
78	The NRA has the necessary equipment to perform regulatory functions	26	74.3	9	25.7
79	Necessary services are available to ensure proper functioning of NRA	28	80.0	7	20.0
80	NRA has created and effectively uses a computerized system for processing and managing data and providing access to scientific information	29	82.9	6	17.1
81	All computers in NRA involved in regulatory activities are connected to a common computer network	27	77.1	8	22.9
82	NRA has its own website	34	97.1	1	2.9
83	NRA has IT specialists on staff	29	82.9	6	17.1
84	Data collection and use of applied computer programs at NRA are carried out in accordance with documented procedures	31	88.6	4	11.4

Table 14

Results of the self-diagnosis of the effectiveness of the national regulatory system in the field of circulation of medicinal products. Block XI. Communication activities of NRA

No.	Statement	Number of responses			
Communication activities of NRA					
85	The NRA has developed a communication strategy for building trust in regulatory activities and providing timely and necessary information	28	80.0	7	20.0
86	NRA's communication strategy considers the interests of various stakeholders and the availability of available communication tools	27	77.1	8	22.9
87	Monitoring and evaluation of the effectiveness of NRA's communication activities are carried out	27	77.1	8	22.9

Table 15

Results of the self-diagnosis of the effectiveness of the national regulatory system in the field of circulation of medicinal products. Block XII. NRA monitoring and accountability

No.	Statement	Number of responses			
NRB monitoring and accountability					
88	Requirements for monitoring and accountability of the NRA's activities to interested parties are stipulated by law	29	82.9	6	17.1
89	Regulatory activities are regularly and systematically reviewed to identify problems, deficiencies, and inconsistencies within regulatory powers	30	85.7	5	14.3
90	Reports on the regulatory activities of the NRA are periodically submitted to the authorized institutions that exercise control over its activities	32	91.4	3	8.6

Table 16

Results of the self-diagnosis of the effectiveness of the national regulatory system in the field of circulation of medicinal products. Block XIII. Evaluation of the effectiveness and efficiency of regulatory activity in the field of drug circulation

No.	Statement	Number of responses			
Evaluation of the effectiveness and efficiency of regulatory activity in the field of drug circulation					
91	A system of indicators (indicators) has been developed to assess the effectiveness and efficiency of the NRA's regulatory activities in the field of drug circulation	32	91.4	3	8.6
92	The SOP was developed regarding the evaluation of the effectiveness and efficiency of the NRA's regulatory activities in the field of drug circulation	32	91.4	3	8.6
93	Appropriate methodological support has been prepared for conducting the procedure for assessing the effectiveness and efficiency of the NRA's regulatory activity	30	85.7	5	14.3
94	Identified personnel whose duties include evaluating the effectiveness and efficiency of NRA's regulatory activities	31	88.6	4	11.4
95	The results of the assessment are published on the NRA website and are transparent to all stakeholders	29	82.9	6	17.1
96	Based on the results of the assessment, a plan of measures aimed at increasing the effectiveness and efficiency of the regulatory activity of the NRA is being developed	31	88.6	4	11.4

At the next stage of the research, we summarized the results of the conducted survey by the presented blocks (Table 18).

As can be seen from the data in Table 18, 70 % of the statements were rated at a high and sufficient level (37.5 % and 37.5 %, respectively). The results of the evaluation by experts demonstrated a high level of effectiveness of the NRA quality management system (100 % of statements were evaluated at a high level). Also, the organizational structure of the NRS and the independence and objectivity of its activities were assessed by experts at a sufficiently high level (75 % of statements were assessed at a high level). At the same time, none of the statements in the risk management and financing blocks of NRA are rated highly. It should also be noted that the NRA financing system was determined by experts to be the least effective during self-diagnosis (50 % of statements were rated at a low level). According to experts, the NRA infrastructure, risk management system, monitoring and accountability, assessment of effectiveness and efficiency of activities in the field of drug trafficking are functioning at a sufficient level. The communication activity of NRA received an average rating. According to the blocks, there are statements that are evaluated by experts at both high and sufficient, medium, and low levels.

The grouping of statements by levels according to the number of affirmative answers became the basis for determining strengths (confirmed by more than 32 experts) and weaknesses (confirmed by less than 25 experts).

Table 17

Results of the self-diagnosis of the effectiveness of the national regulatory system in the field of circulation of medicinal products. Block XIV. Risk management

No.	Statement	Number of responses			
Risk management					
97	NRA has risk management specialists on its staff	21	60.0	14	40.0
98	In the structure of the NRA, a department (sector) whose responsibilities include the implementation of the procedure for identification, assessment and management of risks of regulatory activity	26	74.3	9	25.7
99	A classifier of risks inherent in the regulatory activity of the NRA in the field of drug circulation has been developed	30	85.7	5	14.3
100	Developed SOP on identification and assessment of risks inherent in regulatory activity in the field of drug circulation	31	88.6	4	11.4
101	Appropriate methodological support for identification, assessment, and risk management of regulatory activities in the field of drug circulation has been developed	28	80.0	7	20.0
102	Risks inherent in regulatory activity in the field of drug circulation are regularly monitored, critical points (zones)/processes are determined	27	77.1	8	22.9
103	The results of regulatory risk assessment are documented accordingly	29	82.9	6	17.1
104	Based on the results of the monitoring, a plan of measures aimed at minimizing (preventing) regulatory risks in the activities of the NRA will be developed	30	85.7	5	14.3

Table 18

The results of summarizing the answers regarding the self-diagnosis of the effectiveness of the national regulatory system in the field of drug circulation by blocks of the questionnaire

No.	Questionnaire block	Total number of questions	Number of positive answers							
			High (32–35)		sufficient (28–31)		medium (25–27)		low (<25)	
			abs.	%	abs.	%	abs.	%	abs.	%
I	General information	15	4	27	5	33	3	20	3	20
II	Corporate management of NRA	6	2	33	2	33	1	17	1	17
III	Institutional development of NRS	4	1	25	2	50	1	25	–	–
IV	Organizational structure of NRS	4	3	75	1	25	–	–	–	–
V	Quality management system at NRA	12	**12**	**100**	–	–	–	–	–	–
VI	NRA financing	6	–	–	2	33	1	17	**3**	**50**
VII	Human resources management	10	4	40	5	50	–	–	1	10
VIII	Transparency and confidentiality of NRA activities	15	6	40	5	33	3	20	1	7
IX	Independence and objectivity of NRA activities	4	3	75	–	–	1	25	–	–
X	NRA infrastructure	8	1	12	5	63	2	25	–	–
XI	Communication activities of NRA	3			1	33	2	67	–	–
XII	NRA monitoring and accountability	3	1	33	2	67	–	–	–	–
XIII	Evaluation of the effectiveness and efficiency of regulatory activity in the field of drug circulation	6	2	33	4	67	–	–	–	–
XVI	Risk management	8	–	–	5	63	2	25	1	12
Total		104	39	37.5	39	37.5	16	15	10	10

5. Discussion of research results

Effective regulatory systems are an important component of health systems and contribute significantly to overall health coverage. The methodology of the WHO "Global Comparison Tool" is publicly available all over the world. To date, 84 WHO member countries have conducted diagnostics of national regulatory systems in the field of circulation of medicinal products. It is interesting that the WHO databases contain data on the results of formal or independent diagnostics of regulatory systems in the field of circulation of medicinal products. Most of the countries participating in the study represented the Asian or African continents [34, 35]. In Ukraine, a similar study using the WHO methodology "Global Comparison Tool" is being conducted for the first time.

According to the results of the self-diagnosis, which was based on the questionnaire developed by us, it was established that in Ukraine, according to experts, an effective regulatory system in the field of drug circulation is functioning (75 % of the interviewed officials answered in the affirmative). According to experts, the effectiveness of the regulatory system is confirmed thanks to the presence and functioning at a high level of the following provisions:

– a highly effective quality management system was built in NRA and its activities were ensured;

– regulation of the activities of regulatory bodies with standards, guidelines and procedures;

– availability of job instructions with documented functional duties and responsibilities of key employees;

– wide access to information on the regulatory framework, directives, procedures and instructions on NRA activities, through its own website;

– existence of a documented code of conduct for NRA employees, internal personnel policy regarding potential conflicts of interest;

– presence of a unit or contact person for community relations;

– transparency and regulation at the legislative level of the requirements to ensure the confidentiality and transparency of the NRA's activities, the NRA's powers, which gives them the right to appoint specialists/inspectors and grant them the appropriate powers to conduct inspections/inspections of pharmaceutical products.

However, in our opinion, the most important practically significant aspect of the conducted research is the identification of the weaknesses of the NRS. So, based on the results of the self-diagnosis, it can be attributed to weaknesses:

– lack of funds in NRA budgets for personnel training and, in general, insufficient funding of national regulators;

– lack or insufficient financing of NRA by international donors;

– insufficiency of the officially defined preferential provision of regulatory services for a limited list of vital drugs;

– the legal framework for regulating the pharmaceutical sector is insufficiently clear and comprehensive;

– lack of risk management specialists in NRA staff schedules;

– lack of a department in some NRAs to provide advisory support on scientific issues and future development of NRS;

– insufficient level of the mechanism aimed at coordinating the activities of regulatory bodies in the sphere of regulating the circulation of drugs;

– insufficient level of certainty and publication of payment amounts for the provision of NRA regulatory services;

– insufficient involvement of stakeholder representatives as observers in meetings of NRA advisory units.

Study limitations. A certain limitation in conducting this research, on the one hand, was the insignificant actual number of personnel of regulatory bodies in the field of drug circulation, who have a sufficient level of competence, which would allow us to involve them as experts on the outlined topics in our research. On the investigated problem, who would dare to use them as experts. In addition, conducting a self-assessment is part of a comprehensive study, which at this stage does not allow for the formation of appropriate recommendations.

Prospects for further research are related to the evaluation of the effectiveness of the national regulatory system in the field of drug trafficking by representatives of external stakeholders, a comparative analysis of the results obtained with the results of self-diagnosis, the identification of strengths and weaknesses, and the formation of recommendations for improving the effectiveness of NRS activities in the field of drug trafficking.

6. Conclusions

A study of the level of effectiveness of the national regulatory system in the field of drug trafficking was carried out by interviewing civil servants of the relevant national regulatory bodies.

The functioning of the regulatory system in the field of drug circulation in Ukraine is generally assessed by experts at a high and sufficient level, but the experts identified the problem of insufficient clarity of the legal framework in the field of drug circulation.

In general, the quality management system and corporate governance proved to be strong points, but financing, risk management and communication activities require improvement measures.

Based on the conducted analysis, the strengths, and weaknesses of the functioning of the NRS were determined. The weaknesses of the NRS include, in particular, the lack of sufficient funding, the insufficiency of mechanisms for coordinating the activities of regulatory bodies, as well as the insufficient involvement of stakeholders in regulatory processes.

Conflict of interests

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

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Data availability
Data will be provided upon reasonable request.

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