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THEORETICAL AND PRACTICAL APPROACHES TO PHARMACEUTICAL SAFETY

Over the years the pharmaceutical system of the Republic of Moldova as a component of the health-care system has faced many problems, such as the reduction of both availability due to the disappearance of vital medicines from the pharmaceutical market, and affordability due to the imperfection of the drug pricing mechanism; the involvement of non-specialists in pharmaceutical activities, which leads to a drastic decrease in the quality of pharmaceutical services; monopolization of some processes and products in the chain of drug supply actions, etc. In recent years, various aspects that directly or indirectly related to pharmaceutical safety (PS) and related health risks have been increasingly discussed in the Republic of Moldova.

Aim. To substantiate theoretically and scientifically the concepts of PS using the principles of the systematic approach and assess the quality and degree of legislative support for pharmaceutical safety in the Republic of Moldova.

Materials and methods. The research was conducted according to the methodology based on the systemic approach, including analysis and synthesis; the study of factors and processes; decomposition and construction of systems; the analysis of legislation; the argumentation and preparation of draft legislative acts, norms, strategies, programs.

Results. The analysis conducted in the course of the study demonstrates that the concept of “pharmaceutical safety” in different countries by different authors covers several aspects – the quality, safety and effectiveness of medicines, their transportation and storage according to the requirements, availability and import independence, their ethical development and promotion, their rational use, etc. In the course of the study, the definition of factors affecting and characterizing the PS system was proposed – “*elements that determine the functionality and characterize the state of the pharmaceutical safety system in the country*”. Three groups of factors affecting and characterizing the PS system of the Republic of Moldova were argued. Based on the classification of the factors, the method of analysis using the quantitative and qualitative expertise was developed. The quality of the PS system in the Republic of Moldova was assessed taking into account the current state of the safety level. To assess the quality of this system, the 7-point scale was used, the relative quality coefficient was determined, which was – 1.03; experts rated the quality of the PS system as “*low*”. To determine the degree of legislative coverage of the PS system, the algorithm was developed; it was used as a methodological tool for determining the degree of legislative and regulatory coverage of the PS system. The results of the studies allowed the elaboration of legislative proposals, which were put forward and adopted.

Conclusions. The legislative framework of the PS system was created by the adoption of Law No. 312 of 30.11.2018, which amended the Law on pharmaceutical activities, the Law on medicines, the Law on health protection, the Law on state material reserves and mobilization. The advanced training program in the field of pharmaceutical management and legislation to train practicing pharmacists has been supplemented with the topic “Pharmaceutical safety”.

Key words: pharmaceutical safety; availability; pharmaceutical risk; pharmaceutical system.

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ТЕОРЕТИКО-ПРАКТИЧНІ ПІДХОДИ ДО ФАРМАЦЕВТИЧНОЇ БЕЗПЕКИ

Фармацевтична система Республіки Молдова як складова системи охорони здоров'я протягом багатьох років стикалася з безліччю проблем, таких, як: зниження як фізичної доступності через зникнення з фармацевтичного ринку життєво важливих препаратів, так і економічної доступності внаслідок недосконалості механізму ціноутворення на ліки; залучення нефахівців до провадження фармацевтичної діяльності, що призводить до різкого зниження якості фармацевтичних послуг; монополізація деяких процесів та виробів у ланцюжку дій з постачання ліків тощо. Останніми роками в Республіці Молдова все частіше обговорюють різні аспекти, прямо чи опосередковано пов'язані з фармацевтичною безпекою та відповідними ризиками для здоров'я населення.

Мета – теоретично та науково аргументувати поняття фармацевтичної безпеки із застосуванням принципів системного підходу та оцінити якість і ступінь законодавчого забезпечення фармацевтичної безпеки в Республіці Молдова.

Матеріали та методи. Дослідження виконували за методологією, заснованою на системному підході та його похідних, а саме: аналіз і синтез; вивчення факторів і процесів; декомпозиція та побудова систем; аналіз законодавства; аргументація та розробка проектів законодавчих актів, положень, стратегій, програм.

Результати дослідження. Аналіз, проведений у процесі дослідження, демонструє, що поняття «фармацевтична безпека» в різних країнах, у різних авторів охоплює декілька аспектів – якість, безпеку, ефективність лікарських засобів, їх транспортування та зберігання відповідно до вимог, доступність та імпортну незалежність, їх етичний розвиток і просування, їх раціональне використання тощо. У процесі дослідження запропоновано визначення факторів, що впливають і характеризують систему фармацевтичної безпеки: *елементи, що зумовлюють функціональність та характеризують стан системи фармацевтичної безпеки в країні*. Аргументовано три групи факторів, що впливають і характеризують систему фармацевтичної безпеки Республіки Молдова. На основі класифікації факторів розроблено методику аналізу із застосуванням кількісно-якісної експертизи. Оцінено якість системи фармацевтичної безпеки в Республіці Молдова з урахуванням поточного стану рівня безпеки, для чого було застосовано 7-бальну шкалу, визначено відносний коефіцієнт якості, який становив – 1,03. Експерти оцінили якість системи фармацевтичної безпеки як *низьку*. Розроблено відповідний алгоритм, який використано як методичний інструмент для визначення ступеня законодавчо-нормативного охоплення системи фармацевтичної безпеки. Результати досліджень дозволили розробити законодавчі пропозиції, що їх було висунуто та прийнято.

Висновки. Створено законодавчу базу системи фармацевтичної безпеки ухваленням Закону № 312 від 30.11.2018, яким було змінено Закон про фармацевтичну діяльність, Закон про лікарські засоби, Закон про охорону здоров'я, Закон про державний матеріальний резерв та мобілізацію. Програму підвищення кваліфікації в галузі фармацевтичного менеджменту та законодавства для підготовки фармацевтів, що практикують, було доповнено темою «Фармацевтична безпека».

Ключові слова: фармацевтична безпека; доступність; фармацевтичний ризик; фармацевтична система.

Statement of the problem. Over the years the pharmaceutical system of the Republic of Moldova as a component of the healthcare system has faced many problems, such as:

- the reduction of both availability due to the disappearance of vital medicines from the pharmaceutical market, and affordability due to the imperfection of the drug pricing mechanism;
- ignoring and violation of demographic and geographical regulations on the location and expansion of community pharmacies (the lack of branch pharmacies in about 200 villages);
- the involvement of non-specialists in pharmaceutical activities, which leads to a drastic decrease in the quality of pharmaceutical services;
- the continued presence of the illegal pharmaceutical market as a result of an imperfect automated mechanism for recording the drug turnover, the emergence of clandestine electronic pharmacies, the illegal import of medicines to the pharmaceutical market, including counterfeit medicines and forgeries, etc.
- monopolization of some processes and products in the chain of drug supply actions [1].

Due to these and other problems, the need for scientific research and argumentation of the pharmaceutical safety (PS) system, as well as measures to identify and prevent potential

hazards that may affect PS have become logical and current.

Objective statement of the article. The general objectives of the research were:

- to substantiate theoretically and scientifically the concepts of pharmaceutical safety using the principles of the systematic approach;
- to highlight the features of PS at different levels – global, regional, and national;
- to develop the methodological arsenal for quantitative assessment of factors affecting / characterizing PS in the Republic of Moldova;
- to assess the quality and degree of legislative support for pharmaceutical safety.

Materials and methods. The research was conducted according to the methodology based on the systemic approach, including analysis and synthesis; the study of factors and processes; decomposition and construction of systems; the analysis of legislation; the argumentation and preparation of draft legislative acts, norms, strategies, programs.

Presentation of the main material of the research. *At the global level*, the main ways to ensure PS are aimed at preventing/combating counterfeit medicines, as well as their theft during transportation [2].

At the regional level, in addition to global issues, measures are being taken to strengthen PS through serialization, search for alternatives to patenting innovative medicines, exclusion

of conflicts of interest in the processes of creating new medicines, public procurement, and their promotion to the market.

At the national level, measures to ensure PS are mainly aimed at obtaining benefits for drug consumers, providing import independence, as well as the physical availability of medicines and their affordability.

In recent years, the Republic of Moldova has been increasingly turning to various aspects directly or indirectly related to PS and related risks to public health. There is a slow activation of the state factor in issues that pose a risk to PS.

A characteristic feature of PS of the Republic of Moldova is the fact that the main risks come from the distribution system, both wholesale and retail, but also partially from the production of medicines.

The analysis conducted in the course of the study demonstrates that the concept of “pharmaceutical safety” in different countries by for different authors covers several aspects – the quality, safety and effectiveness of medicines, their transportation and storage according to the requirements, availability and import independence, their ethical development and promotion, their rational use, etc. [3, 4-7].

One of PS definitions often used in the pharmaceutical environment specifies – “*all measures aimed at detecting and preventing potential threats to the health of the population caused by the availability, inadequate quality, falsification of medicines, as well as their misuse and/or for fraudulent purposes*” [8].

Issues related to PS, both in terms of content and volume, as well as in terms of depth, have today reached a degree of acuity not only at the national level, but also globally. In most

cases, when considering PS issues, aspects related to falsification and counterfeiting of medicines, physical availability of essential medicines and their affordability, as well as compliance with ethical principles in the relationship between the pharmaceutical industry and healthcare entities, which ultimately provide benefits to public health, are often emphasized [9, 10].

The importance of state provision of PS for its citizens is undeniable. As PS is a multidimensional and complex concept, it contains a set of activities, processes, technologies, goals, information, entities – all this is interconnected from an inter-functional, inter-organizational and interpersonal point of view, etc. The analysis allowed us to conclude that the following goal is relevant for PS: the state provides reliable protection of the entire human community and every resident from any threat (danger) that could arise as a result of unsatisfactory/non-compliant, illegal activities of the pharmaceutical system or its components.

According to the general theory of systems any system is composed of “*inputs*”, “*content*”, “*outputs*” and “*feedback*”. The input data for the PS system, the system content and the output data are given in Table 1.

Analyzing the components and characteristics of the PS system, we demonstrate its importance as a subsystem of the healthcare, which is an integral part of a more highly organized *social system*.

Having the staff as a separate component, the PS system has the right and obligation to constantly improve its professional knowledge, an integral part of the *educational system*.

Taking into account that pharmaceutical companies carry out entrepreneurial, and economic

Table 1

FEATURES OF THE PHARMACEUTICAL SAFETY SYSTEM

Parts of the system	Description
Input	Norms, requirements, characteristics, etc., established in relation to products, activities, processes in the pharmaceutical system and other related systems
Content	<i>Medicines</i> : development, standardization, production, preparation, quality control, transportation, storage, distribution, promotion, pharmacovigilance; <i>enterprises</i> : laboratories, pharmaceutical factories, pharmaceutical warehouses, pharmacies, <i>state bodies</i> ; <i>staff</i> ; <i>information</i> ; <i>technologies</i> ; <i>processes</i> ; <i>activities</i> , etc.
Output	Safety of the whole society and of each person lies in the quality, efficiency and safety of products, activities and processes carried out in the pharmaceutical system

and financial activities, according to the legislation, they are economic agents, which makes it possible to classify the PS system as the *economic system*.

The PS system is a system, in which decisions, are made, mainly regulatory ones, are made. Thus, this system can also be *managerial*.

Having pharmaceutical organizations, enterprises, regulatory and control bodies, professional and public organizations, various regional structures as a component, the PS system can also be defined as an *organizational system*.

The quality of all components is one of the most important features. This allows the PS system to be evaluated as a system of absolute *quality*.

In the course of the study, the definition of factors that affect and characterize the PS system was proposed – “*elements that determine the functionality and characterize the state of the pharmaceutical safety system in the country*”.

The analysis and synthesis of the PS system components allowed highlighting the following three main directions that determined PS in the Republic of Moldova:

I. ensuring the efficacy, safety and good quality of medicines – 11 factors;

II. ensuring the physical availability of medicines and their affordability – 14 factors;

III. ensuring the good quality of all pharmaceutical services and a proper functioning of the pharmaceutical system – 18 factors.

Considering the three directions determining PS, three groups of factors affecting and characterizing the PS system of the Republic of Moldova were developed.

The results of the assessment of factors that affect /characterize the PS system of the Republic of Moldova was described in the PhD thesis in pharmacy “*Legislative and managerial landmarks of pharmaceutical safety*” (V. Buliga, Chisinau 2019) [11].

Based on the classification of the factors, the method of analysis using the quantitative and qualitative expertise was developed. The algorithm of this analysis included the preparation of the questionnaire, the selection of experts, actual questioning, the analysis of results, summaries and conclusions.

Questionnaire elaboration. The purpose of the expert questionnaire was to conduct a multidimensional assessment of the factors affecting / characterizing the PS system in the

Republic of Moldova: duration of impact of factors over time (short-term, medium-term, long-term and postponement); type of influence (positive, negative); influence dynamics (increasing, constant, decreasing); relative share of impact (very large, significant, moderate, weak, insignificant); probability of occurrence of a change in the effect of the factor (certainly will not change, may not change, 50 % x 50 %, may change, will definitely change); quality of the PS system, taking into account the current state (during questioning) of the degree of safety provided by the pharmaceutical system in the Republic of Moldova (unsatisfactory, very low, low, medium, good, very good and excellent).

Selection of experts. The main criterion for selecting experts was “*a broad professional vision*” on pharmaceutical safety issues. The criteria for selecting the experts were: the workplace (Parliament of the Republic of Moldova, Government of the Republic of Moldova, Ministry of Health, Labor and Social Protection, Medicines and Medical Devices Agency, Pharmacy Faculty Administration of *Nicolae Testemitanu* State University of Medicine and Pharmacy, Scientific Center of Medicine, Association of Pharmacists of Republic of Moldova, local drug producers, pharmaceutical warehouses, community and hospital pharmacies), work experience, educational background, scientific title, authorship of scientific articles in the field of pharmacy, position responsible for decision-making in the pharmaceutical coordination system or in government departments. The quantitative evaluation of the criteria allowed the pre-selected expert to accumulate a minimum of 4.5 and a maximum of 10 points. In order to ensure a high level of competence of the experts selected, the minimum score limit of 7.5 was set. During the selection process, 23 specialists were enrolled; among them 15 candidates passed the minimum score corresponding to all workplaces mentioned above.

The results of the assessment and quantification of factors affecting the PS system, the degree of impact of factors on the PS system (the analysis performed for three groups of factors and for each factor) allowed assessing the importance of three groups of factors and the order of priorities that must be taken into account in the process of formation and consolidation of the PS system.

Thus, the group of factors affecting the physical availability of medicines and their affordability took the first place with an average score of 65.57. The second place was taken by the group ensuring the efficacy, safety and good quality of medicines, with an average score of 59.09, and the third place was taken by the factors ensuring the good quality of all pharmaceutical services and a proper functioning of the pharmaceutical system with a 55.28 score.

During the research, the quality of the PS system was assessed taking into account the current state of safety provided by the pharmaceutical system of the Republic of Moldova. To assess the quality of this system, the 7-point scale was used, the relative quality coefficient was determined, which was - 1.03; experts rated the quality of the PS system as "low" (Table 2) [11].

ENSURING THE QUALITY of the PS system:

$$Kc_i = Ae \times Ce_i$$

$$\bar{Kc} = \sum_{i=1}^{i=N} \frac{Kc_i}{Ne}$$

In which:

Kc_i – is the relative quality factor;

Ne – is the number of expert-respondents;

Ae_i – is the assessment of the PS system quality given by the expert i ;

Ce_i – is the competence degree of the expert i .

Table 2

ASSESSMENT OF THE QUALITY OF PHARMACEUTICAL SAFETY SYSTEM

The final assessment of the PS system quality	The interval, in which the \bar{Kc} coefficient is entered
Excellent	$\geq + 2.5 \dots\dots\dots + 3.0$
Very good	$\geq + 1.5 \dots\dots\dots + 2.4$
Good	$\geq + 0.5 \dots\dots\dots + 1.4$
Satisfactory	$\pm 0.01 \dots\dots\dots \pm 0.09$
Low	$\leq - 1.0 \dots\dots\dots - 1.5$
Very low	$\leq - 1.6 \dots\dots\dots - 2.6$
Unsatisfactory	$\leq - 2.7 \dots\dots\dots - 3.0$

To determine the degree of legislative coverage of the PS system, the algorithm was developed; it was used as a methodological tool for determining the degree of legislative and regulatory coverage of the PS system.

Stage I. The *de facto* analysis of the pharmaceutical system background. All the conditions necessary to ensure pharmaceutical safety were marked with Cn . The number of necessary conditions can be determined as the total number of Cn conditions or a set of conditions for providing pharmaceutical safety:

- Ccm – conditions for ensuring the quality, efficacy and safety of medicines;
- Cam – conditions for ensuring the physical availability of medicines and their affordability;

Table 3

THE DEGREE OF THE PS LEGISLATIVE COVERAGE

Domain	Legislative coverage			Gained points	Coverage degree
	Existence of norms	Absence of norms	"non-compliance", "insufficiency"		
1. Ensuring the efficacy, safety and good quality of medicines	6	3	2	7	6.36 Moderate
2. Ensuring the physical availability of medicines and their affordability	-	7	7	3.5	2.50 Insufficient
3. Ensuring the good quality of pharmaceutical services and a proper functioning of the pharmaceutical system	1	10	6	4	2.22 Insufficient
The entire PS system	7	20	15	14.5	3.37 Insufficient

- *Cca* – conditions for ensuring quality of the pharmaceutical activities (pharmaceutical services and good functioning of the entire pharmaceutical system).

Stage II. The emphasis on the presence / absence of legal norms regulating the use of various ways, methods, processes, procedures, norms and other measures that could impose compliance with the necessary conditions for ensuring PS.

Stage III. Determination of the degree of legislative coverage of the requirements for ensuring PS.

Stage IV. Development of a scale for quantifying the degree of legislative coverage of PS.

The analysis showed that the legislative coverage of PS in the Republic of Moldova was insufficient (Table 3).

All areas require the revision and development of new legal norms, but the least regulated are the areas related to ensuring good quality of pharmaceutical services, the proper functioning of the pharmaceutical system and the availability of medicines. The results obtained highlighted the legislative gaps that affect PS and can serve as guidelines for the creation of legislation in the field of pharmacy.

Conclusions. The results of the studies have made it possible to develop the following legislative proposals promoted and adopted.

1. By Law No. 269 of 07.12.2017, the concept of pharmaceutical safety was introduced in the National Security Strategy of the Republic of Moldova. It says, "*Pharmaceutical safety will be achieved when the state ensures a reliable protection of the entire community and each resident from any threat/danger arising from as a result of unsatisfactory/non-compliant/illegal activity of the pharmaceutical system or its components. The central state authorities will develop and implement the strategy and strategic plan to strengthen pharmaceutical safety in the Republic of Moldova aimed at preventing the appearance of counterfeit and non-compliant medicines at the pharmaceutical market, ensuring the drug safety by intensifying clinical*

research and pharmacovigilance, ensuring the compliance of medicines at pharmaceutical enterprises, developing the national pharmaceutical industry, etc."

2. By Law No. 312 of 30.11.2018, the Law on Pharmaceutical Activity, the Law on Medicines, the Law on Healthcare, the State Material and Mobilization Reserves, have been supplemented [12-15].

3. Amendments and supplements to the Regulation on the activities of the Agency for Medicines and Medical Products concerning the PS system as a subsystem of the Pharmaceutical System and ensuring its functionality, the introduction of Good Pharmaceutical Practices (GPP) Rules in pharmacies, increasing the availability of medicines have been proposed.

4. The advanced training program in the field of pharmaceutical management and legislation to train practicing pharmacists has been supplemented with the topic "Pharmaceutical safety" (*Nicolae Testemitanu University, Vasile Procopisin Department of Social Pharmacy*).

5. After the research conducted, the following recommendations have been argued, submitted for implementation and partially implemented:

- to create the legislative basis for the PS system;
- to set up the PS system as a subsystem of the Pharmaceutical System;
- to create a permanent interdepartmental commission in the Government for ensuring and monitoring PS;
- to actively involve the Association of Pharmacists in ensuring the functionality of the Pharmaceutical System, including PS;
- to implement the GPP Rules in pharmacies;
- to improve the availability of medicines;
- to develop the Strategy for the development of the pharmaceutical system of the Republic of Moldova.

Conflict of interests: authors have no conflict of interests to declare.

References

1. Buliga V., Safta V., Aduji S., Luta A. Conceptual landmarks in pharmaceutical security. *Moldovan Journal of Health Sciences*. 2016. Vol. 7 (1). P. 78-87. URL: <https://core.ac.uk/download/pdf/335259412.pdf>.
2. Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011. URL: <https://eur-lex.europa.eu/eli/dir/2011/62/oj>.

3. Ekwall D., Bröls H., Wyer D. Theft of pharmaceuticals during transport in Europe. *Journal of Transportation Security*. 2016. Vol. 9 (1-2). P. 1-16. DOI: 10.1007/s12198-015-0162-x.
4. Maury Pasquier L. Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests? *Parliamentary Assembly*. 2015. URL: <https://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?fileid=22030&lang=en>.
5. Ten shocking revelations about the American pharmaceutical industry. *Black Jack/s blog*. 2012. URL: <https://2blackjack1.wordpress.com/teoria-conspiratiei/zece-dezvaluiri-socante-despre-industria-farmaceutica-americana/>.
6. Walter E., Dragosits A., Said M. Access to pharmaceutical products in six European countries - analysis of different pharmaceutical distribution systems. *Farmaeconomia. Health Economics And Therapeutic Pathways*. 2012. Vol. 1 (13). P. 33-41. DOI: <https://doi.org/10.7175/fe.v13i1.192>.
7. Безопасность пациентов. Украина перенимает опыт стран Европы. *Щотижневик «Аптека»*. 2011. № 47 (818). URL: <https://www.apteka.ua/article/110150>.
8. Горячев А. Б. Безопасность фармацевтических услуг. URL: https://studopedia.ru/3_72038_tema---bezopasnost-farmatsevticheskikh-uslug.html.
9. Bratucu G., Bratucu T. Qualitative methods used in market research. URL: <http://www.managementmarketing.ro/pdf/articole/4.pdf>.
10. Buliga V., Safta V. Accessibility of medicines-indicator of the level of pharmaceutical assistance. *INF Bulletin*. 2002. Vol. 12. P. 14-17.
11. Buliga V. G. Legislation and management references of pharmaceutical security. PhD thesis abstract. Chisinau, 2019. URL: http://www.cnaa.md/files/theses/2019/54652/valentina_buliga_abstract_en.pdf.
12. Law approving the Concept of national security of the Republic of Moldova No. 112-XVI of 22.05.2008. *The official monitor*. 03.06.2008. No. 97-98. Article 357. URL: https://www.legis.md/cautare/getResults?doc_id=24400&lang=ru.
13. Law on Medicines No. 1409-XIII of 17.12.1995. *The official monitor*. 11.06.1998. No. 52-53. Article 368. URL: https://www.legis.md/cautare/getResults?doc_id=135049&lang=ru.
14. Law on Healthcare No. 411-XIII of 28.03.1995. *The official monitor*. 22.06.1995. No. 34. Article 373. URL: https://www.legis.md/cautare/getResults?doc_id=135137&lang=ru#.
15. Law on Pharmaceutical Activity No. 1456-XII of 25.05.1993. *The official monitor*. 15.04.2005. No. 59-61. Article 200. URL: https://www.legis.md/cautare/getResults?doc_id=136240&lang=ru.

References

1. Buliga, V., Safta, V., Adauji, S., Luta, A. (2016). Conceptual landmarks in pharmaceutical security. *Moldovan Journal of Health Sciences*, 7 (1), 78-87. Available at: <https://core.ac.uk/download/pdf/335259412.pdf>.
2. Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011. Available at: <https://eur-lex.europa.eu/eli/dir/2011/62/oj>.
3. Ekwall, D., Bröls, H., Wyer, D. (2016). Theft of pharmaceuticals during transport in Europe. *Journal of Transportation Security*, 9 (1-2), 1-16. doi: 10.1007/s12198-015-0162-x.
4. Maury Pasquier, L. (2015). Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests? *Parliamentary Assembly*. Available at: <https://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?fileid=22030&lang=en>.
5. Ten shocking revelations about the American pharmaceutical industry. (2012). *Black Jack/s blog*. Available at: <https://2blackjack1.wordpress.com/teoria-conspiratiei/zece-dezvaluiri-socante-despre-industria-farmaceutica-americana/>.
6. Walter, E., Dragosits, A., Said, M. (2012). Access to pharmaceutical products in six European countries-analysis of different pharmaceutical distribution systems. *Farmaeconomia. Health Economics And Therapeutic Pathways*, 1 (13), 33-41. doi: <https://doi.org/10.7175/fe.v13i1.192>.
7. Bezopasnost pacientov. Ukraina perenimaet opyt stran Evropy. (2011). *Shchotyzhnevyyk "Apteka"*, 47 (818). Available at: <https://www.apteka.ua/article/110150>.
8. Goriachev, A. B. (2014). Bezopasnost farmatsevticheskikh uslug. Available at: https://studopedia.ru/3_72038_tema---bezopasnost-farmatsevticheskikh-uslug.html.
9. Bratucu, G., Bratucu, T. (n.d.). Qualitative methods used in market research. Available at: <http://www.managementmarketing.ro/pdf/articole/4.pdf>.
10. Buliga, V., Safta, V. (2002). Accessibility of medicines-indicator of the level of pharmaceutical assistance. *INF Bulletin*, 12, 14-17.
11. Buliga, V. G. (2019). Legislation and management references of pharmaceutical security. *PhD thesis abstract*. Chisinau. Available at: http://www.cnaa.md/files/theses/2019/54652/valentina_buliga_abstract_en.pdf.

12. Law approving the Concept of national security of the Republic of Moldova №. 112-XVI of 22.05.2008. (2008). *The official monitor*, 97-98, 357. Available at: https://www.legis.md/cautare/getResults?doc_id=24400&lang=ru.
13. Law on Medicines No.1409-XIII of 17.12.1995. (1998). *The official monitor*, 52-53, 368. Available at: https://www.legis.md/cautare/getResults?doc_id=135049&lang=ru.
14. Law on Healthcare No. 411-XIII of 28.03.1995. (1995). *The official monitor*, 34, 373. Available at: https://www.legis.md/cautare/getResults?doc_id=135137&lang=ru#.
15. Law on Pharmaceutical Activity No. 1456-XII of 25.05.1993. (2005). *The official monitor*, 59-61, 200. Available at: https://www.legis.md/cautare/getResults?doc_id=136240&lang=ru.

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