

ОРГАНІЗАЦІЯ ТА ЕКОНОМІКА ФАРМАЦІЇ

UDC 615.1:616:340.13

<https://doi.org/10.24959/nphj.22.75>

M. V. Podgaina, N. A. Sliptsova

National University of Pharmacy of the Ministry of Health of Ukraine

The analysis of the legislative framework regarding pharmaceutical provision of orphan patients in Ukraine

A rare (orphan) disease is a disease that threatens a person's life or chronically progresses; it leads to a reduction in life expectancy or disability, which prevalence among the population is not more than 1:2000 in Ukraine and not more than 1:5000-8000 in other countries.

Aim. To analyze the current legal framework on pharmaceutical provision of orphan patients in Ukraine.

Materials and methods. The current regulatory framework on pharmaceutical provision of orphan patients in Ukraine was analyzed by constructing and studying the hierarchy of legislative acts regulating the issues of management of orphan (rare) diseases in the world and in Ukraine.

Results and discussion. The article describes the main stages of the legislation formation, starting from the USA in 1983 to the EU and Ukraine in 2021. The practical value of the article consists in the current list of normative acts regulating the provision of patients with orphan diseases. The scientific significance is in the use of the results of previous studies of others domestic researchers (2016). The analysis of the legislation and the main issues of providing orphan patients allowed us to formulate the basic problems of the national healthcare system listed in the article.

Conclusions. The current state of the legal regulation of orphan patients in Ukraine has been studied. It has been found that the legislative regulation of the issue under study has been actively carried out over the past 7 years by implementing the adopted Law of Ukraine, resolutions of the Cabinet of Ministers and orders of the Ministry of Health. The results of the study of international experience in introducing the basic concepts of orphan diseases and orphan patients into the healthcare system in the United States (since 1983), EU countries (since 1999), Japan (since 1993), etc., have been summarized. It has been found that 275 nosologies of orphan diseases have been approved in Ukraine; they are grouped by 11 nosological categories, there are 104 nosologies (+40 %) more than in 2016. A positive trend towards intensification of the process of improving the provision of orphan patients in Ukraine has been revealed.

Key words: rare diseases; orphan diseases; legislation; pharmaceutical provision; Ministry of Health

M. V. Подгайна, Н. А. Сліпцова

Національний фармацевтичний університет Міністерства охорони здоров'я України

Аналіз законодавчої бази щодо фармацевтичного забезпечення орфанних пацієнтів в Україні

Рідкісне (орфанне) захворювання – хвороба, що загрожує життю людини або хронічно прогресує, призводить до скорочення тривалості життя чи інвалідності й поширеність якої серед населення становить не більше 1:2000 в Україні та не більше 1:5000-8000 в інших країнах.

Метою дослідження був аналіз чинної законодавчої бази з питань фармацевтичного забезпечення орфанних пацієнтів в Україні.

Матеріали та методи. Проаналізовано чинну нормативну базу щодо фармацевтичного забезпечення орфанних пацієнтів в Україні шляхом побудови та вивчення ієрархії законодавчих актів, що регулюють питання керування орфанними (рідкісними) захворюваннями у світі та в Україні.

Результати та їх обговорення. У статті описано основні етапи формування законодавства, починаючи від США в 1983 р. до ЄС та України в 2021 р. Практична цінність статті полягає в наведеному переліку чинних нормативних актів, що регулюють забезпечення хворих на орфанні захворювання. Проведений аналіз законодавства та основних питань забезпечення орфанних пацієнтів дозволив сформулювати головні проблеми вітчизняної системи охорони здоров'я.

Висновки. Розглянуто сучасний стан правового регулювання орфанних пацієнтів в Україні. З'ясовано, що законодавче регулювання зазначеного питання активно здійснюється протягом останніх 7 років шляхом виконання затвердженого Закону України, постанов Кабінету Міністрів та наказів МОЗ. У статті узагальнено результати вивчення міжнародного досвіду щодо впровадження в систему охорони здоров'я основних понять, що стосуються орфанних захворювань і пацієнтів у США (з 1983 р.), країнах ЄС (з 1999 р.), Японії (з 1993 р.) та інших. З'ясовано, що в Україні визнано 275 нозологій орфанних захворювань і згруповано їх за 11 нозологічними категоріями. Це на 104 нозології (+40 %) більше, ніж у 2016 році. Виявлено позитивну тенденцію до активізації процесу покращення забезпечення орфанних хворих в Україні.

Ключові слова: рідкісні хвороби; орфанні хвороби; законодавство; фармацевтичне забезпечення; Міністерство охорони здоров'я

М. В. Подгайна, Н. А. Слепцова

Национальный фармацевтический университет Министерства здравоохранения Украины

Анализ законодательной базы относительно фармацевтического обеспечения орфанных пациентов в Украине

Редкое (орфанное) заболевание – болезнь, которая угрожает жизни человека или хронически прогрессирует, приводит к сокращению продолжительности жизни или инвалидности и распространенность которой среди населения составляет не более 1:2000 в Украине и не более 1:5000-8000 в других странах.

Целью исследования был анализ действующей законодательной базы по вопросам фармацевтического обеспечения орфанных пациентов в Украине.

Материалы и методы. Проанализирована действующая нормативная база относительно фармацевтического обеспечения орфанных пациентов в Украине путем построения и изучения иерархии законодательных актов, регулирующих вопросы руководства орфанными (редкими) заболеваниями в мире и в Украине.

Результаты и их обсуждение. В статье описаны основные этапы формирования законодательства, начиная от США в 1983 г. до ЕС и Украины в 2021 г. Практическая ценность статьи состоит в приведенном перечне действующих нормативных актов, регулирующих обеспечение пациентов с орфанными заболеваниями. Проведенный анализ законодательства и основных вопросов обеспечения орфанных пациентов позволил сформулировать основные проблемы отечественной системы здравоохранения.

Выводы. Исследовано современное состояние правового регулирования орфанных пациентов в Украине. Установлено, что законодательное регулирование исследуемого вопроса активно осуществляется в течение последних 7 лет путем выполнения принятого Закона Украины, постановлений Кабинета Министров и приказов МЗ. В статье обобщены результаты изучения международного опыта по внедрению в систему здравоохранения основных понятий по орфанным заболеваниям и пациентам в США (с 1983 г.), странах ЕС (с 1999 г.), Японии (с 1993 г.) и проч. Установлено, что в Украине утверждено 275 нозологий орфанных заболеваний, которые сгруппированы по 11 нозологическим категориям, что на 104 нозологии (+40 %) больше, чем было утверждено в 2016 году. Авторами указано на положительную тенденцию к активизации процесса улучшения обеспечения орфанных больных в Украине.

Ключевые слова: редкие болезни; орфанные болезни; законодательство; фармацевтическое обеспечение; Министерство здравоохранения

Introduction. A disease is considered to be rare when the number of people affected is less than 5 per 10 000. There are between 5 000 and 8 000 rare diseases, most of them with a genetic basis. A very rough estimate would be that 1 out of 15 persons worldwide could be affected by a rare (“orphan”) disease – 400 million people worldwide. Rare diseases are serious chronic diseases, and may be life-threatening [1-3].

In recent decades, considerable attention has been paid worldwide to efforts to stimulate the research, development and marketing of medicinal products for rare diseases, including the use of various regulatory incentives in the world [1, 2].

Rare diseases present fundamentally different challenges from those of more common diseases [4]. Basic problems include the small number of patients, the logistics involved in reaching widely dispersed patients, limited clinical expertise and expert centers [1, 3].

In Ukraine, a rare (orphan) disease is a disease that threatens a person’s life or chronically progresses; it leads to a reduction in life expectancy or disability, which prevalence among the population is not more than one case per 2,000 people (according to the EURO CERD European Committee of Experts), rare diseases are life-threatening or cause the development of a progressive disease [5-7].

The world statistics of orphan diseases show that 50 % of patients with rare diseases are children, 10 % of them live only up to five years, 12 % – up to fifteen years [2-3, 5, 6]. About 50 % of rare diseases lead to disability, every fifth patient suffers from pain, every third one can not lead an independent life [6-8]. It is a well-known fact that 80 % of orphan diseases are genetically determined,

last a lifetime and require constant treatment. All this defines orphan diseases as a significant economic and social problem in the world and in Ukraine in particular [8].

The problem of the quality treatment of orphan diseases is determined by the need for the centralized state control, which will provide an opportunity to improve the procedure of medical and pharmaceutical care of patients.

The **aim** of this study was to analyze the current legal framework on pharmaceutical provision of orphan patients in Ukraine.

Materials and methods. The current regulatory framework on pharmaceutical provision of orphan patients in Ukraine was analyzed by constructing and studying the hierarchy of legislative acts regulating the issues of management of orphan (rare) diseases in the world and in Ukraine.

Results and discussion. A rare (orphan) disease is a disease that threatens a person’s life or chronically progresses; it leads to a reduction in life expectancy or disability, which prevalence among the population is not more than 1:2000 [1-7]. Today, there are no general criteria for classifying a particular nosological unit as orphan, and therefore, there are own requirements for the inclusion of the disease in the list of rare diseases in different parts of the world.

The first legal document that defined the concept of an “orphan disease” was the “Orphan Drug Act” in the United States in 1983 (Table). In addition to the approved terms, the terms of the legislative defined grants and contracts with manufacturers of orphan drugs, the term of their patent protection and financial motivation for manufacturers [2-3]. As early as 2002, the United States

approved the Rare Diseases Acts, which planned to increase the financial capital to develop the production of orphan drugs. Following the adoption of the first Orphan Disease Regulation in the United States, it was joined by the Japan's Orphan Drug Regulation in 1993 and the Australia's Orphan Drug Policy in 1998. Both regulations were harmonized with the US program. The documents defined the concepts of "orphan disease" and "orphan drug", periods of the patent protection, preferential systems and simplified registration of orphan drugs [2, 5].

To take measures for regulating the provision of orphan patients in European countries, the EU Council Recommendation on Rare Diseases 2009/C 151/02 of 8 June 2009 was created. According to these Recommendations, rare diseases are a priority of the Seventh Framework Program of the Community for Research and Development as medical and diagnostic programs

for orphan disorders are developed. In order to conduct epidemiological studies of rare diseases, a nationwide approach is needed to increase the number of patients in each study. The concepts of "orphan drug" and "orphan disease", as well as the requirements for the status of an orphan drug, were defined in the Regulation of the European Parliament and the Council of the European Union 141/2000 of 16 December 1999 "On orphan drugs". According to this document, drugs are called "orphan" when certain diseases are so rare that the cost of development and marketing of drugs, diagnosis, prevention or treatment of the disease is not covered by the profit from the expected sales of the drug; when it is unprofitable for the pharmaceutical industry to develop a drug under normal market conditions. Summary data on the development of the concept of «orphan diseases» in some regions and countries of the world are given in Table.

Table

Regulatory documents of pharmaceutical provision of patients with orphan diseases in different regions

The title of the regulation, country, year; Content, basis points
<i>Orphan Drug Act of 1983, USA</i>
Concepts of "orphan disease" and "orphan drug" were regulated. The conditions for granting the drug the "orphan" status and the conditions of its use were determined. It was proposed to amend federal laws in order to reduce the cost of drug production. The proposal for financial incentives for the production of orphan drugs was approved. The period of the patent protection of orphan drugs was agreed. The grants and terms of the manufacturer's contract with organizations for the development of orphan medicines were approved. The procedure for research of orphan medicines and the quality monitoring were developed
<i>Rare Diseases Act of 2002, USA</i>
To increase investment in the production of orphan drugs was proposed. The number of orphan drugs under development and production was increased. The criterion for classifying the disease as orphan was approved
<i>REGULATION (EC) No 141/2000 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 1999, EU countries</i>
The terms "orphan diseases" and "orphan drug" were approved. The procedure for granting the drug the "orphan" status, the term of the patent protection and benefits for production and promotion were approved
<i>COUNCIL RECOMMENDATION of 8 June 2009 on an action in the field of rare diseases (2009/C 151/02), EU countries</i>
The effectiveness of cooperation between different centers of expertise for the treatment of orphan conditions in Europe was determined. Strategy plans in the field of orphan diseases were substantiated
<i>Orphan Drug Regulation of 1993, Japan</i>
The concept of "orphan disease" was approved. The term of the patent protection for 10 years was approved. The regulated procedure for granting tax benefits for the production of orphan medicines
<i>Orphan Drug Policy of 1998, Australia</i>
The term "orphan disease" was approved. Conditions of the patent protection were determined. Harmonization of orphan diseases with the US legislation
<i>Order of the Minister of Health of the Republic of Kazakhstan dated May 11, 2011 No. 285 On the approval of the List of the orphan medical technologies intended for the treatment of rare diseases in the Republic of Kazakhstan (additions from 06/26/2014), Republic of Kazakhstan</i>
The List of orphan medical technologies intended for the treatment of orphan diseases was adopted. The use and purchase of orphan medicines, which did not pass the state registration procedure, but were included in the Order, were regulated; the controlling body for health issues was created
<i>Code of the Republic of Kazakhstan of September 18, 2009 No.193-IV "On the health of people and the healthcare system" (as amended and supplemented as of 04.07.2018), Republic of Kazakhstan</i>
The terms "orphan disease" and "orphan drug" were adopted

Currently, Ukraine is in the process of implementing the above principles and priorities, Ukraine has committed itself to providing orphan patients with orphan prevention measures, organizing the appropriate pharmaceutical care, permanent and free access to necessary medicines and related food products for special dietary consumption (hereinafter – special products of medical nutrition). On June, 8, 2009, the EU Council adopted the Recommendation on orphan diseases – the Action No. 2009/C 151/02, in which one of the tasks for EU Member States was to develop and implement a national program document with conceptual frameworks for orphan disease actions within the national health system by the end of 2013. Thus, implementing EU approaches the Ministry of Health of Ukraine has set the following tasks at the national level:

- to use definitions, codifications and classifications of orphan diseases;
- to organize the research work;
- to create reference centers and networks dealing with orphan diseases, develop the mechanism of examination for orphan diseases;
- to create and establish intersectoral cooperation of public authorities;
- to create public associations and communities, etc. [1, 9-10].

Ukraine has not yet adopted a comprehensive program as a document with conceptual principles for the provision of medical assistance to citizens suffering from orphan diseases. This situation does not allow our state to qualitatively, comprehensively and effectively implement state guarantees and policies in the field of providing medical services to citizens suffering from orphan diseases, as well as to solve urgent problems, such as prevention of new cases of orphan diseases among the population of Ukraine; improvement the quality of life of people suffering from orphan diseases; full integration of such persons into the society; ensuring the possibility of their active labor and other socially useful activities [11].

In fairness, it should be noted that the legislative regulation of the organization of medical and pharmaceutical care for patients with rare diseases in Ukraine has been carried out since 15.04.2014 by the Law of Ukraine “On Amendments to the Fundamentals of Legislation of Ukraine on Healthcare to Ensure Prevention and Treatment of Rare (Orphan) Diseases” No. 1213-VII (Law) [7, 10].

Improving the procedure of medical and pharmaceutical care for orphan patients is possible due to a clear understanding of an orphan disease definition. According to the Law of Ukraine “On Amendments to the Fundamentals of Legislation of Ukraine on Healthcare to Ensure Prevention and Treatment of Rare (Orphan) Diseases” the main points of orphan patients supply can be identified [5, 9]. An important aspect of the support of orphan patients is the provision of the necessary orphan drugs used in orphan diseases. To ensure the quality and safe therapy, the drugs must be approved for use in Ukraine. The registration procedure and permission to use orphan medicines is regulated by the Law of Ukraine “On Amend-

ments to the Law of Ukraine on Medicinal Products” to improve the procedure for providing the population with medicines intended for the treatment of socially dangerous and serious diseases.

The state regulation of orphan patients in Ukraine covers not only the legal framework for medicines, but also for the provision of dietary food. These needs are regulated in accordance with the Resolution of the Cabinet of Ministers of March 31, 2015, No. 160, Kyiv “On approval of the Procedure for providing drugs and related products for special dietary consumption to citizens suffering from rare (orphan) diseases” [5, 10].

To determine the need for prescribing, withdrawing, redistributing drugs and related food products for special dietary consumption, a commission was appointed, which activities were regulated by the Order of the Ministry of Health of Ukraine from 05.02.2015 No. 50 Kyiv “On approval of the Regulations, withdrawal, redistribution of medicines and related food products for special dietary consumption purchased at the expense of the state budget, as well as other sources not prohibited by the law, including humanitarian aid, to citizens suffering from rare (orphan) diseases” [9].

To understand the importance and danger of orphan diseases in the state, there must be a clear system of patient care. To do this, it is necessary to determine whether a certain disease belongs to the group of orphan diseases and whether it is included in the State list of rare diseases. Today, for the purpose of the state regulation, the current legal act on the list of rare (orphan) diseases is the Order of the Ministry of Health of Ukraine No. 731 from 29.06.2017 “On amendments to the List of rare (orphan) diseases that reduce the life expectancy of patients or their disability and for which there are recognized treatments” (Order of the Ministry of Health of Ukraine No. 778 of 27.10. 2014) [10]. The updated list of rare (orphan) diseases contains 275 items with the codes of the International Statistical Classification of Diseases and Related Health Problems – ICD-10 [10]. According to the Order, all orphan diseases are divided by nosologies (Fig.).

Over the past few years, there has been a significant improvement in providing patients with the necessary medicines at public expense. Drugs for orphan diseases are included in the Public Procurement of Medicines in accordance with the Law of Ukraine “On Amendments to Certain Laws of Ukraine on Ensuring Timely Access of Patients to Necessary Medicines and Medical Devices through Public Procurement with the Involvement of Specialized Procurement Organizations”. Ukraine has approved a List of medicines and medical devices that are purchased on the basis of procurement contracts with specialized organizations carrying out purchases in the areas of use of budget funds in 2019 within the framework of the program “Provision of medical measures of individual state programs and comprehensive measures of a program nature” (the CMU Resolution of March 13, 2019 No. 255, latest changes of the Resolution of the Cabinet of Ministers of Ukraine No. 984 of September 22, 2021) [9, 12].

I. Rare endocrine diseases, eating disorders and metabolic disorders
II. Rare diseases of blood and hematopoietic organs and some disorders involving the immune mechanism
III. Rare mental and behavioral disorders
IV. Rare diseases of the nervous system
V. Rare diseases of the circulatory system
VI. Rare diseases of the skin and subcutaneous tissue
VII. Rare congenital malformations, deformities and chromosomal abnormalities
VIII. Rare diseases of the musculoskeletal system and connective tissue
IX. Some rare infectious and parasitic diseases
X. Rare neoplasms
XI. Rare diseases of the sclera, cornea, iris and ciliary body

Fig. Nosological categories of orphan diseases

The latest improvement in the legislation concerning orphan patients was last year – the project of “The Concept of the development of a system of assistance to persons suffering from rare (orphan) diseases for 2020-2025” was presented. It was prepared in accordance with the goals of sustainable development for 2016-2030, in line with the objectives approved by the Summit Development Agenda UN, held in September 2015 as part of the 70th session of the General UN Assembly [11]. In fact, the Concept is a system of actions, measures, guarantees and priorities aimed at ensuring the rights of patients with rare (orphan) diseases in the field of healthcare, social protection, and education.

The analysis of the legislation and the main issues of providing orphan patients allowed us to formulate the basic problems of the national healthcare system:

- the lack of a unique information space for exchanging information about patients with orphan diseases, in particular, systems of registration and accounting of patients with orphan diseases;
- difficulties in diagnosing rare diseases;
- the limited access of patients to the required medical care, including medicines, medical devices, special products of medical nutrition;
- the lack of information and psychological support for patients and their families;
- a high cost of the necessary medicines for the treatment of orphan diseases, medical devices and products of special medical nutrition.

The problems of medical care for orphan patients in Ukraine are aggravated by the annual budget deficit.

Conclusions and prospects of further research

1. The current state of the legal regulation of orphan patients in Ukraine has been studied. It has been found that the legislative regulation of the issue under study

has been actively carried out over the past 7 years by implementing the adopted Law of Ukraine, resolutions of the Cabinet of Ministers and orders of the Ministry of Health.

2. The results of the study of international experience in introducing the basic concepts of orphan diseases and orphan patients into the healthcare system in the United States (since 1983), EU countries (since 1999), Japan (since 1993), etc., have been summarized.
3. It has been found that 275 nosologies of orphan diseases have been approved in Ukraine; they are dispersed by 11 nosological categories, there are 104 nosologies (+ 40 %) more than in 2016. However, due to the lack of a register of orphan patients, the process of full provision of all citizens suffering from rare diseases is complicated.
4. A positive trend towards intensification of the process of improving the provision of orphan patients in Ukraine has been revealed. In particular, a concept for the development of the system of care for people suffering from rare (orphan) diseases for 2020-2025 has been created by the Ministry of Health (not approved yet). Since 2018, the public provision for the needs of orphan patients has been regulated; in particular, a list of drugs and medical devices for public procurements is formed.

This result has shown the need for future research in the issues of improving public procurement, scientific and practical substantiation of the formation of the Register of orphan patients, etc. Considering high social and economic influence of orphan diseases it is important to combine scientific and practical approaches in improving the quality of life for orphan patients.

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

REFERENCES

1. Priority diseases and reasons for inclusion. 6.19. Rare diseases : WHO's on-line report. *Priority Medicines for Europe and the World 2013 Update*. URL: https://www.who.int/medicines/areas/priority_medicines/Ch6_0Intro.pdf.
2. About rare disease : Orphanet website. 2020. URL: <https://www.orpha.net/consor/cgi-bin/index.php?lng=EN>.
3. What is a rare disease? *Eurordis. The Voice of Rare Disease Patients in Europe*. 2018. URL: <http://www.eurordis.org/about-rare-diseases>.
4. Eucerd. URL: http://www.rd-action.eu/eucerd/RDACTION_EUCERDARCHIVE.html.
5. Котвіцька А. А., Черкашина А. В. Дослідження сучасного стану державного регулювання медико-фармацевтичного забезпечення хворих на орфанні захворювання в Україні. *Соціальна фармація в охороні здоров'я*. 2016. Т. 2, № 1. С. 29–36. DOI: <https://doi.org/10.24959/sphhcj.16.25>.
6. Котвіцька, А. А., Черкашина А. В. Дослідження показників поширеності орфанних захворювань в Україні. *Соціальна фармація: стан, проблеми та перспективи* : матеріали наук. симпозіуму у рамках VIII Нац. з'їзду фармацевтів України, м. Харків, 15-16 верес. 2016 р. Харків, 2016. С. 29–35. URL: <http://dspace.nuph.edu.ua/handle/123456789/12673>.
7. On Amendments to the Fundamentals of Legislation of Ukraine on Health Care for the prevention and treatment of rare (orphan) diseases=Про внесення змін до Основ законодавства України про охорону здоров'я щодо забезпечення профілактики та лікування рідкісних (орфанних) захворювань : Закон України від 15 квіт. 2014 р. № 1213–VII. URL: <https://zakon.rada.gov.ua/laws/show/1213-18#Text>.
8. Орфанні захворювання в практиці дитячого інфекціоніста / С. О. Крамарьов та ін. *Дитячий лікар*. 2016. № 4 (49). С. 5–15.
9. Верховна Рада України : офіц. вебпортал. URL: <http://zakon4.rada.gov.ua/>.
10. Міністерство охорони здоров'я України : офіц. сайт. URL: <http://www.moz.gov.ua/>.
11. Концепція розвитку системи надання допомоги особам, що страждають на рідкісні (орфанні) захворювання на 2020-2025 роки / Міністерство охорони здоров'я України. URL: <https://bit.ly/3nxtbvZ>.
12. Про затвердження переліку лікарських засобів та медичних виробів, які закуповуються на підставі угод щодо закупівлі із спеціалізованими організаціями, які здійснюють закупівлі за напрямками використання бюджетних коштів у 2019 році за програмою “Забезпечення медичних заходів окремих державних програм та комплексних заходів програмного характеру” : Постанова Кабінету Міністрів України від 13 бер. 2019 р. № 255. URL: <https://zakon.rada.gov.ua/laws/show/255-2019-%D0%BF#Text>.

REFERENCES

1. Priority diseases and reasons for inclusion. 6.19. Rare diseases : WHO's on-line report. *Priority Medicines for Europe and the World 2013 Update*. Available at: https://www.who.int/medicines/areas/priority_medicines/Ch6_0Intro.pdf.
2. About rare disease : Orphanet website. 2020. Available at: <https://www.orpha.net/consor/cgi-bin/index.php?lng=EN>.
3. What is a rare disease? *Eurordis. The Voice of Rare Disease Patients in Europe*. (2018). Available at: <http://www.eurordis.org/about-rare-diseases>.
4. Eucerd. Available at: http://www.rd-action.eu/eucerd/RDACTION_EUCERDARCHIVE.html.
5. Kotvitska, A. A., Cherkashyna, A. V. (2016). *Sotsialna farmatsiia v okhoroni zdorovia, 2 (1)*, 29–36. doi: <https://doi.org/10.24959/sphhcj.16.25>.
6. Kotvitska, A. A., Cherkashyna, A. V. (2016). Proceeding from *Sotsialna farmatsiia: stan, problemy ta perspektyvy: materialy nauk. sympoziumu u ramkakh VIII Nats. z'їzdu farmatsevtiv Ukrainy (15-16 veres. 2016 r.)*. (pp. 29-35). Kharkiv.
7. Law of Ukraine of 15.04.2014 № 1213-VII «On Amendments to the Fundamentals of Legislation of Ukraine on Health Care for the prevention and treatment of rare (orphan) diseases». *zakon.rada.gov.ua*. Available at: <https://zakon.rada.gov.ua/laws/show/1213-18#Text>.
8. Kramarov, S. O., Palatna, L. O., Vyhovska O. V., Buialo, V. K., Holovach, O. V., Zarudnia O. F. et al. (2016). *Aktual'ni pytannia dytichoi gastroenterologii, 4*, 5–15.
9. Verkhovna Rada Ukrainy: ofits. vebportal. *zakon4.rada.gov.ua*. Available at: <http://zakon4.rada.gov.ua>.
10. Ministerstvo okhorony zdorov'ia Ukrainy: ofits. sait. *moz.gov.ua*. Available at: <http://www.moz.gov.ua/>.
11. Ministerstvo okhorony zdorov'ia Ukrainy. (2020). *Kontseptsiia rozvytku systemy nadannia dopomohy osobam, shcho strazhdaiut na ridkisni (orfanni) zakhvoriuvannia na 2020-2025 roky*. Available at: <https://bit.ly/3nxtbvZ>.
12. Kabinet Ministriv Ukrainy. (2019). *Postanova vid 13 ber. 2019 r. № 255 «Pro zatverdzhennia pereliku likarskykh zasobiv ta medychnykh vyrobiv, yakі zakupovuiutsia na pidstavi uгод shchodo zakupivli iz spetsializovanymy orhanizatsiaymy, yakі zdiisniuiut zakupivli za napriamamy vykorystannia biudzhetykh koshtiv u 2019 rotsi za programoiu “Zabezpechennia medychnykh zakhodiv okremykh derzhavnykh prohram ta kompleksnykh zakhodiv prohramnoho kharakteru”»*. *zakon.rada.gov.ua*. Available at: <https://zakon.rada.gov.ua/laws/show/255-2019-%D0%BF#Text>.

Information about authors:

Podgaina M. V., Candidate of Pharmacy (Ph.D.), associate professor of the Department of Organization and Economics of Pharmacy, National University of Pharmacy of the Ministry of Health of Ukraine. E-mail: sm211@ukr.net. ORCID: <https://orcid.org/0000-0002-3949-1826>. Researcher ID E-6990-2019

Sliptsova N. A., applicant for higher education of the Department of Organization and Economics of Pharmacy, National University of Pharmacy of the Ministry of Health of Ukraine. E-mail: apteka111888111@gmail.com

Відомості про авторів:

Подгайна М. В., кандидатка фармац. наук, доцентка кафедри організації та економіки фармації, Національний фармацевтичний університет Міністерства охорони здоров'я України. E-mail: sm211@ukr.net. ORCID: <https://orcid.org/0000-0002-3949-1826>. Researcher ID E-6990-2019

Сліпцова Н. А., здобувачка кафедри організації та економіки фармації, Національний фармацевтичний університет Міністерства охорони здоров'я України. E-mail: apteka111888111@gmail.com

Сведения об авторах:

Подгайна М. В., кандидат фармац. наук, доцент кафедры организации и экономики фармации, Национальный фармацевтический университет Министерства здравоохранения Украины. E-mail: sm211@ukr.net. ORCID: <https://orcid.org/0000-0002-3949-1826>. Researcher ID E-6990-2019

Слепцова Н. А., соискатель кафедры организации и экономики фармации, Национальный фармацевтический университет Министерства здравоохранения Украины. E-mail: apteka111888111@gmail.com