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ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

Медицинские новости Грузии

საქართველოს სამედიცინო სიახლენი

GEORGIAN MEDICAL NEWS

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GMN: Georgian Medical News is peer-reviewed, published monthly journal committed to promoting the science and art of medicine and the betterment of public health, published by the GMN Editorial Board since 1994. GMN carries original scientific articles on medicine, biology and pharmacy, which are of experimental, theoretical and practical character; publishes original research, reviews, commentaries, editorials, essays, medical news, and correspondence in English and Russian.

GMN is indexed in MEDLINE, SCOPUS, PubMed and VINITI Russian Academy of Sciences. The full text content is available through EBSCO databases.

GMN: Медицинские новости Грузии - ежемесячный рецензируемый научный журнал, издаётся Редакционной коллегией с 1994 года на русском и английском языках в целях поддержки медицинской науки и улучшения здравоохранения. В журнале публикуются оригинальные научные статьи в области медицины, биологии и фармации, статьи обзорного характера, научные сообщения, новости медицины и здравоохранения. Журнал индексируется в MEDLINE, отражён в базе данных SCOPUS, PubMed и ВИНИТИ РАН. Полнотекстовые статьи журнала доступны через БД EBSCO.

GMN: Georgian Medical News – საქართველოს სამედიცინო სიახლენი – არის ყოველთვიური სამეცნიერო სამედიცინო რეცენზირებადი ჟურნალი, გამოიცემა 1994 წლიდან, წარმოადგენს სარედაქციო კოლეგიისა და აშშ-ის მეცნიერების, განათლების, ინდუსტრიის, ხელოვნებისა და ბუნებისმეტყველების საერთაშორისო აკადემიის ერთობლივ გამოცემას. GMN-ში რუსულ და ინგლისურ ენებზე ქვეყნდება ექსპერიმენტული, თეორიული და პრაქტიკული ხასიათის ორიგინალური სამეცნიერო სტატიები მედიცინის, ბიოლოგიისა და ფარმაციის სფეროში, მიმოხილვითი ხასიათის სტატიები.

ჟურნალი ინდექსირებულია MEDLINE-ის საერთაშორისო სისტემაში, ასახულია SCOPUS-ის, PubMed-ის და ВИНИТИ РАН-ის მონაცემთა ბაზებში. სტატიების სრული ტექსტი ხელმისაწვდომია EBSCO-ს მონაცემთა ბაზებიდან.

WEBSITE

www.geomednews.com

К СВЕДЕНИЮ АВТОРОВ!

При направлении статьи в редакцию необходимо соблюдать следующие правила:

1. Статья должна быть представлена в двух экземплярах, на русском или английском языках, напечатанная через **полтора интервала на одной стороне стандартного листа с шириной левого поля в три сантиметра**. Используемый компьютерный шрифт для текста на русском и английском языках - **Times New Roman** (**Кириллица**), для текста на грузинском языке следует использовать **AcadNusx.** Размер шрифта - **12**. К рукописи, напечатанной на компьютере, должен быть приложен CD со статьей.

2. Размер статьи должен быть не менее десяти и не более двадцати страниц машинописи, включая указатель литературы и резюме на английском, русском и грузинском языках.

3. В статье должны быть освещены актуальность данного материала, методы и результаты исследования и их обсуждение.

При представлении в печать научных экспериментальных работ авторы должны указывать вид и количество экспериментальных животных, применявшиеся методы обезболивания и усыпления (в ходе острых опытов).

4. К статье должны быть приложены краткое (на полстраницы) резюме на английском, русском и грузинском языках (включающее следующие разделы: цель исследования, материал и методы, результаты и заключение) и список ключевых слов (key words).

5. Таблицы необходимо представлять в печатной форме. Фотокопии не принимаются. **Все цифровые, итоговые и процентные данные в таблицах должны соответствовать таковым в тексте статьи**. Таблицы и графики должны быть озаглавлены.

6. Фотографии должны быть контрастными, фотокопии с рентгенограмм - в позитивном изображении. Рисунки, чертежи и диаграммы следует озаглавить, пронумеровать и вставить в соответствующее место текста **в tiff формате**.

В подписях к микрофотографиям следует указывать степень увеличения через окуляр или объектив и метод окраски или импрегнации срезов.

7. Фамилии отечественных авторов приводятся в оригинальной транскрипции.

8. При оформлении и направлении статей в журнал МНГ просим авторов соблюдать правила, изложенные в «Единых требованиях к рукописям, представляемым в биомедицинские журналы», принятых Международным комитетом редакторов медицинских журналов - http://www.spinesurgery.ru/files/publish.pdf и http://www.nlm.nih.gov/bsd/uniform_requirements.html
В конце каждой оригинальной статьи приводится библиографический список. В список литературы включаются все материалы, на которые имеются ссылки в тексте. Список составляется в алфавитном порядке и нумеруется. Литературный источник приводится на языке оригинала. В списке литературы сначала приводятся работы, написанные знаками грузинского алфавита, затем кириллицей и латиницей. Ссылки на цитируемые работы в тексте статьи даются в квадратных скобках в виде номера, соответствующего номеру данной работы в списке литературы. Большинство цитированных источников должны быть за последние 5-7 лет.

9. Для получения права на публикацию статья должна иметь от руководителя работы или учреждения визу и сопроводительное отношение, написанные или напечатанные на бланке и заверенные подписью и печатью.

10. В конце статьи должны быть подписи всех авторов, полностью приведены их фамилии, имена и отчества, указаны служебный и домашний номера телефонов и адреса или иные координаты. Количество авторов (соавторов) не должно превышать пяти человек.

11. Редакция оставляет за собой право сокращать и исправлять статьи. Корректура авторам не высылается, вся работа и сверка проводится по авторскому оригиналу.

12. Недопустимо направление в редакцию работ, представленных к печати в иных издательствах или опубликованных в других изданиях.

При нарушении указанных правил статьи не рассматриваются.

REQUIREMENTS

Please note, materials submitted to the Editorial Office Staff are supposed to meet the following requirements:

1. Articles must be provided with a double copy, in English or Russian languages and typed or compu-ter-printed on a single side of standard typing paper, with the left margin of **3** centimeters width, and **1.5** spacing between the lines, typeface - **Times New Roman** (**Cyrillic**), print size - **12** (referring to Georgian and Russian materials). With computer-printed texts please enclose a CD carrying the same file titled with Latin symbols.

2. Size of the article, including index and resume in English, Russian and Georgian languages must be at least 10 pages and not exceed the limit of 20 pages of typed or computer-printed text.

3. Submitted material must include a coverage of a topical subject, research methods, results, and review.

Authors of the scientific-research works must indicate the number of experimental biological species drawn in, list the employed methods of anesthetization and soporific means used during acute tests.

4. Articles must have a short (half page) abstract in English, Russian and Georgian (including the following sections: aim of study, material and methods, results and conclusions) and a list of key words.

5. Tables must be presented in an original typed or computer-printed form, instead of a photocopied version. **Numbers, totals, percentile data on the tables must coincide with those in the texts of the articles.** Tables and graphs must be headed.

6. Photographs are required to be contrasted and must be submitted with doubles. Please number each photograph with a pencil on its back, indicate author's name, title of the article (short version), and mark out its top and bottom parts. Drawings must be accurate, drafts and diagrams drawn in Indian ink (or black ink). Photocopies of the X-ray photographs must be presented in a positive image in **tiff format**.

Accurately numbered subtitles for each illustration must be listed on a separate sheet of paper. In the subtitles for the microphotographs please indicate the ocular and objective lens magnification power, method of coloring or impregnation of the microscopic sections (preparations).

7. Please indicate last names, first and middle initials of the native authors, present names and initials of the foreign authors in the transcription of the original language, enclose in parenthesis corresponding number under which the author is listed in the reference materials.

8. Please follow guidance offered to authors by The International Committee of Medical Journal Editors guidance in its Uniform Requirements for Manuscripts Submitted to Biomedical Journals publication available online at: http://www.nlm.nih.gov/bsd/uniform_requirements.html
http://www.icmje.org/urm_full.pdf
In GMN style for each work cited in the text, a bibliographic reference is given, and this is located at the end of the article under the title "References". All references cited in the text must be listed. The list of references should be arranged alphabetically and then numbered. References are numbered in the text [numbers in square brackets] and in the reference list and numbers are repeated throughout the text as needed. The bibliographic description is given in the language of publication (citations in Georgian script are followed by Cyrillic and Latin).

9. To obtain the rights of publication articles must be accompanied by a visa from the project instructor or the establishment, where the work has been performed, and a reference letter, both written or typed on a special signed form, certified by a stamp or a seal.

10. Articles must be signed by all of the authors at the end, and they must be provided with a list of full names, office and home phone numbers and addresses or other non-office locations where the authors could be reached. The number of the authors (co-authors) must not exceed the limit of 5 people.

11. Editorial Staff reserves the rights to cut down in size and correct the articles. Proof-sheets are not sent out to the authors. The entire editorial and collation work is performed according to the author's original text.

12. Sending in the works that have already been assigned to the press by other Editorial Staffs or have been printed by other publishers is not permissible.

Articles that Fail to Meet the Aforementioned Requirements are not Assigned to be Reviewed.

ავტორთა საყურადღებოდ!

რედაქციაში სტატიის წარმოდგენისას საჭიროა დავიცვათ შემდეგი წესები:

1. სტატია უნდა წარმოადგინოთ 2 ცალად, რუსულ ან ინგლისურ ენებზე,დაბეჭდილი სტანდარტული ფურცლის 1 გვერდზე, 3 სმ სიგანის მარცხენა ველისა და სტრიქონებს შორის 1,5 ინტერვალის დაცვით. გამოყენებული კომპიუტერული შრიფტი რუსულ და ინგლისურენოვან ტექსტებში - **Times New Roman (Кириллица)**, ხოლო ქართულენოვან ტექსტში საჭიროა გამოვიყენოთ **AcadNusx.** შრიფტის ზომა – 12. სტატიას თან უნდა ახლდეს CD სტატიით.

2. სტატიის მოცულობა არ უნდა შეადგენდეს 10 გვერდზე ნაკლებს და 20 გვერდზე მეტს ლიტერატურის სიის და რეზიუმეების (ინგლისურ, რუსულ და ქართულ ენებზე) ჩათვლით.

3. სტატიაში საჭიროა გაშუქდეს: საკითხის აქტუალობა; კვლევის მიზანი; საკვლევი მასალა და გამოყენებული მეთოდები; მიღებული შედეგები და მათი განსჯა. ექსპერიმენტული ხასიათის სტატიების წარმოდგენისას ავტორებმა უნდა მიუთითონ საექსპერიმენტო ცხოველების სახეობა და რაოდენობა; გაუტკივარებისა და დაძინების მეთოდები (მწვავე ცდების პირობებში).

4. სტატიას თან უნდა ახლდეს რეზიუმე ინგლისურ, რუსულ და ქართულ ენებზე არანაკლებ ნახევარი გვერდის მოცულობისა (სათაურის, ავტორების, დაწესებულების მითითებით და უნდა შეიცავდეს შემდეგ განყოფილებებს: მიზანი, მასალა და მეთოდები, შედეგები და დასკვნები; ტექსტუალური ნაწილი არ უნდა იყოს 15 სტრიქონზე ნაკლები) და საკვანძო სიტყვების ჩამონათვალი (key words).

5. ცხრილები საჭიროა წარმოადგინოთ ნაბეჭდი სახით. ყველა ციფრული, შემაჯამებელი და პროცენტული მონაცემები უნდა შეესაბამებოდეს ტექსტში მოყვანილს.

6. ფოტოსურათები უნდა იყოს კონტრასტული; სურათები, ნახაზები, დიაგრამები - დასათაურებული, დანომრილი და სათანადო ადგილას ჩასმული. რენტგენოგრამების ფოტოასლები წარმოადგინეთ პოზიტიური გამოსახულებით **tiff** ფორმატში. მიკროფოტოსურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალების შეღებვის ან იმპრეგნაციის მეთოდი და აღნიშნოთ სურათის ზედა და ქვედა ნაწილები.

7. სამამულო ავტორების გვარები სტატიაში აღინიშნება ინიციალების თანდართვით, უცხოურისა – უცხოური ტრანსკრიპციით.

8. სტატიას თან უნდა ახლდეს ავტორის მიერ გამოყენებული სამამულო და უცხოური შრომების ბიბლიოგრაფიული სია (ბოლო 5-8 წლის სიღრმით). ანბანური წყობით წარმოდგენილ ბიბლიოგრაფიულ სიაში მიუთითეთ ჯერ სამამულო, შემდეგ უცხოელი ავტორები (გვარი, ინიციალები, სტატიის სათაური, ჟურნალის დასახელება, გამოცემის ადგილი, წელი, ჟურნალის №, პირველი და ბოლო გვერდები). მონოგრაფიის შემთხვევაში მიუთითეთ გამოცემის წელი, ადგილი და გვერდების საერთო რაოდენობა. ტექსტში კვადრატულ ფჩხილებში უნდა მიუთითოთ ავტორის შესაბამისი N ლიტერატურის სიის მიხედვით. მიზანშეწონილია, რომ ციტირებული წყაროების უმეტესი ნაწილი იყოს 5-6 წლის სიღრმის.

9. სტატიას თან უნდა ახლდეს: ა) დაწესებულების ან სამეცნიერო ხელმძღვანელის წარდგინება, დამოწმებული ხელმოწერითა და ბეჭდით; ბ) დარგის სპეციალისტის დამოწმებული რეცენზია, რომელშიც მითითებული იქნება საკითხის აქტუალობა, მასალის საკმაობა, მეთოდის სანდოობა, შედეგების სამეცნიერო-პრაქტიკული მნიშვნელობა.

10. სტატიის ბოლოს საჭიროა ყველა ავტორის ხელმოწერა, რომელთა რაოდენობა არ უნდა აღემატებოდეს 5-ს.

11. რედაქცია იტოვებს უფლებას შეასწოროს სტატია. ტექსტზე მუშაობა და შეჯერება ხდება საავტორო ორიგინალის მიხედვით.

12. დაუშვებელია რედაქციაში ისეთი სტატიის წარდგენა, რომელიც დასაბეჭდად წარდგენილი იყო სხვა რედაქციაში ან გამოქვეყნებული იყო სხვა გამოცემებში.

აღნიშნული წესების დარღვევის შემთხვევაში სტატიები არ განიხილება.

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PROTECTION OF CONSUMER RIGHTS IN THE FIELD OF ELECTRONIC COMMERCE OF MEDICINES

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Abstract.

Background: The development of e-pharmacies has significantly expanded public access to pharmaceutical products. At the same time, the rapid growth of e-commerce, the globalization of digital services and the expansion of cross-border trade in medicines have created new risks for consumers. These include violations of the conditions of storage and transportation of medicines, distribution of low-quality or counterfeit products, increased cases of self-medication, uncontrolled or illegal interference by third parties in the delivery process, etc.

Aim: The purpose of the study is to analyze legal challenges and improve consumer protection mechanisms in the field of electronic commerce of medicines at the national and international levels.

Materials and methods: The study applies an interdisciplinary approach combining doctrinal legal analysis, comparative legal methodology, and empirical review of international regulatory practices. Legal acts, WHO and EU documents, FDA guidelines, and statistical data were examined to identify best practices for consumer protection in the field of e-commerce in medicines.

Results: The results of the study indicate that the legal regulation of relations in the field of electronic pharmaceutical services in the legislations of many countries is insufficient. It is emphasized that fragmented legal regulation, lack of harmonized international standards and insufficient supervision in the field of medicines circulation pose a significant threat to the health, safety and privacy of consumers.

Conclusions: It is concluded that effective consumer protection of digital services requires strengthening of regulatory requirements for e-commerce in medicines, in particular, introduction of clear rules for registration and licensing of online pharmacies, regulation of creation of relevant web resources, protection of personal data of consumers, etc. The author proposes a set of legal and institutional measures aimed at ensuring effective protection of the rights of consumers using the services of online pharmacies.

Key words. Business entities, economic activity, online pharmaceutical services, digital service, e-commerce.

Introduction.

In modern society, digitalization is becoming increasingly important. This also applies to the healthcare sector, where significant changes are taking place to simplify the realization of the right to healthcare, improve access to medicines, and provide online access to medical services [1].

These innovations have helped to increase the availability of medicines for citizens of many countries, in particular by minimizing physical contact between people, which is especially important during periods of special legal regimes and during pandemics. In addition, it has greatly simplified access to pharmaceutical care for people with disabilities, the elderly, refugees and internally displaced persons, war veterans and volunteers, and has helped to save time and reduce costs.

At the same time, online pharmacies have become not only a tool for convenient access to medicines, but also a new challenge in the field of consumer safety. After all, the expansion of digital services in the pharmaceutical sector has created the preconditions for new forms of consumer rights violations. These include the sale of low-quality or counterfeit products, non-compliance with personal data confidentiality requirements, legal liability issues, and lack of proper supervision. In addition, due to the lack of unified international standards for the operation of online pharmacies, there are significant difficulties with their legal regulation in the context of transnational trade.

In the context of Ukraine, these general global challenges are amplified by the incomplete and evolving regulatory framework governing pharmaceutical e-commerce. Although the legalization of electronic retail trade in medicinal products in 2020 marked an important step toward improving public access to medicines, the national legislation remains fragmented and internally inconsistent. As demonstrated by recent Ukrainian scholarship, including comprehensive administrative-legal research, the regulatory system still lacks a unified conceptual approach to licensing, supervision, and the distribution of powers among competent authorities [1]. Key practical problems persist, such as insufficient verification mechanisms for online pharmacies, the absence of clear and uniform requirements for website functionality and consumer data protection, and the continued circulation of unlicensed or illegally operating e-pharmacy platforms. Furthermore, Ukraine has not yet fully harmonized its domestic rules with EU regulatory standards, which complicates the introduction of effective cross-border safeguards and leaves consumers vulnerable to substandard or counterfeit medicines. Overall, the current state of pharmaceutical e-commerce regulation in Ukraine is characterized by legal uncertainty, institutional gaps, and the need for a more coherent and enforceable regulatory model.

The article carries out a comprehensive study of consumer protection mechanisms in the field of electronic commerce in medicines at the national and international levels. The emphasis is placed on legal threats arising in the digital environment, analysis of practices of developed and developing countries, and opportunities for harmonization of legal regulation. The purpose of the study is to formulate theoretical and practical

proposals for strengthening consumer rights guarantees in the field of electronic commerce in medicines.

Literature review.

The issue of consumer protection in the field of e-commerce of medicines is relatively new in modern legal science, although its relevance has grown considerably due to the digitalization of the pharmaceutical sector and the global challenges caused by the COVID-19 pandemic. These developments necessitate a thorough scientific analysis and comprehensive examination of the applicable legal regulation. Although individual studies are available, there remains an absence of in-depth research that systematically compares national legal mechanisms, evaluates their effectiveness, and identifies best practices for ensuring consumer protection in the digital pharmaceutical environment.

An analysis of current scientific works in the field of medicines circulation shows that research is mostly focused on specific aspects, such as: drug delivery during the COVID-19 pandemic [2], non-medical use of prescription drugs [3] (Novak et al, 2016), digitalization of pharmaceutical services [4], product quality risks [5], consumer behavior [6], service quality metrics [7], and regulatory uncertainty [8-9].

However, the legal aspects of protecting the rights of consumers of pharmaceutical services using electronic platforms for the sale of medicines have not yet received proper coverage in the scientific literature. Among the existing scientific works that became the theoretical and legal basis for this study and were used in its preparation, we should highlight the works of scholars who characterize the legal nature of such legal relations [10], analyze the existing mechanisms for protecting consumer rights in the provision of pharmaceutical services [11], the need to take into account the peculiarities of legal liability in this area is emphasized [12], the basic principles and features of electronic retail are defined [1], and the importance of guaranteeing consumers an adequate level of security is proved [13].

However, the rapid development of information technology and the increasing role of digitalization in the pharmaceutical sector require a review of the principles of its legal regulation. It is these circumstances that have necessitated a separate scientific study on the issues of consumer protection in the field of electronic commerce in medicines.

Materials and methods.

International sources and secondary legislation of the European Union (hereinafter - EU), official statistics (Statista, WHO, EC DG SANTE), academic publications, results of comparative analysis of the practice of online pharmacies in the United States, Canada, other developed and developing countries, legal journalism, reference books, publications on pharmaceutical topics in the media, etc. were used as materials for this study.

This study is interdisciplinary in nature and is based on a combination of doctrinal analysis of legal provisions, comparative legal approach, and empirical analysis of international consumer protection practice in the field of electronic commerce in medicines.

The study used the formal legal method to analyze the provisions of national legislation and international acts, including documents of the World Health Organization (hereinafter - WHO) and the European Commission, guidelines of the U.S. Food and Drug Administration (hereinafter - FDA), and the EU Directive on e-commerce; the comparative legal method to study the experience of legal regulation of e-commerce in medicines in different countries of the world (individual EU Member States, the United States, Canada, the United Kingdom, etc.). This made it possible to identify effective models of consumer protection for their possible further implementation in national legislation; induction and deduction, analysis and synthesis - to systematize empirical data and draw generalized conclusions; modeling - to formulate proposals for improving the legal mechanism for protecting consumer rights in the field of trade in medicines through the network of online pharmacies.

The research methodology allowed us to provide a comprehensive vision of the problem and formulate reasonable proposals for harmonizing the legal regulation of the circulation of medicines at the national and international levels.

Results and Discussion.

Market Expansion and Consumer Trends:

As is well known, the development of the Internet in the late 1990s led to the emergence of the first online pharmacies. Thus, one of the most famous online pharmacies that started operating in 1999 was Drugstore.com [14]. Its website offered customers a wide range of health and beauty products. In the late 1990s, Canada and some EU countries also began to allow online sales of medicines. The main goal was to facilitate the ordering of over-the-counter medicines.

The Covid-19 pandemic has exposed weaknesses in healthcare systems in many countries around the world [15]. Therefore, many countries have been forced to significantly accelerate the digitalization of the pharmaceutical sector, causing the evolution of consumer preferences and needs. As a result, the e-commerce market for medicines has grown significantly. For example, while in 2019 there was only one online pharmacy in Estonia, as of 2024 there were already six such pharmacies in the country [16].

Research on the online pharmacy market in Europe and prospects and forecasts for 2025 has shown that today there is a growing trend of online drug sales on this continent, mainly in Southern Europe, with Germany, France, Italy, and Spain [17] being the most prominent countries.

According to a Statista study, the global e-commerce market for medicines is constantly growing, and if in 2018 this market amounted to $26.03 billion, in 2023 it will reach $71.48 billion and by 2029 it is planned to grow to $130.46 billion [18].

According to global surveys conducted in 2023 in 18 countries, the highest percentage of consumers buying pharmaceutical products online was recorded in Sweden - 45%, followed by the United States - 32%, Germany - 30%, Austria - 29%, the United Kingdom - 24%; France - 16%, Spain - 14%, Finland - 12% [19]. It is worth noting that online pharmacies are the fastest growing segment in the Asian digital healthcare market, with China dominating the market [20].

Emerging Risks: Illicit Pharmacies and Counterfeit Pharmaceuticals:

It is worth noting that there is no internationally recognized regulatory act that would regulate the issue of electronic commerce in medicinal products. The analysis of international legal acts in the field of healthcare allows us to conclude that only Directive 2011/62/EU of the European Parliament and of the Council of 08.06.2011 [21] amending Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code on Medicinal Products for Human Use contains provisions on distance selling of medicinal products. Thus, Article 85c states that Member States should ensure that medicinal products are offered for distance selling to the public by means of information society services, with the indication that this provision does not limit national legislation prohibiting the offer of such distance selling of prescription

medicinal products. In addition, this article contains conditions imposed on each EU Member State, as well as on individuals and legal entities, for the electronic trading of medicinal products.

There is evidence in open sources that, according to a study conducted in 2021 by the International Pharmaceutical Federation, only 49% of 79 countries on different continents have legal regulation of the electronic commerce in medicines, while 51% of 79 countries do not have such regulation [22].

Today, there are countries in the world where electronic commerce in medicines is prohibited (Republic of Korea, Turkey, Cyprus, Serbia), where electronic commerce in OTC medicines is allowed only (most EU member states, Japan, Malaysia), and where electronic commerce in OTC and prescription medicines is allowed (USA, Canada, Germany, Great Britain, Estonia, Sweden, Australia). Depending on the legal regulation, e-commerce in medicines can be carried out by Internet pharmacies that operate simultaneously as a stationary pharmacy (Belgium, Finland, Norway, Iceland, France), Internet pharmacies that do not have a physical address (Denmark, Sweden), and online stores (Germany, Sweden, Denmark) [1].

Comparative Analysis of Global Regulatory Frameworks.

Licensing, Registration, and Verification Systems:

It is worth noting that most countries have the same requirements for e-commerce in medicines: clear rules are established for registration and licensing, website development, protection of personal data of customers, and delivery.

Ensuring the safety of patients using the services of online pharmacies is a challenge for both national healthcare systems in developed and developing countries. As e-commerce in medicines grows, the risks of illegal trade and circulation of low-quality or counterfeit medicines are increasing.

EU member states and many developed countries (USA, UK, Canada, Australia) have introduced strict legal regulations to prevent counterfeit medicines from entering the market through online pharmacies. These regulations include: accreditation systems that provide tools such as accreditation seals or website checks for legitimacy, the introduction of a common logo for legitimate online pharmacy providers, the need to display the registration number, name of the owner and head pharmacist, and physical address with corresponding phone numbers and email address, etc. For example, according to the WHO, 50% medicines purchased on websites that hide their real address are counterfeit [23]. That is why the United States launched the "pharmacy" domain initiative in 2014 to provide consumers around the world with a way to identify safe, legal, and ethical online pharmacies [24]. In addition, the FDA has developed the BeSafeRx program to help consumers identify legitimate online pharmacies [25]. The same practice exists in Canada [26]. In addition, there are registries of online pharmacies by state (USA) or province (Canada), where the buyer can check whether the pharmacy is licensed to operate [27,28].

The EU uses a common logo design for legal online pharmacies in accordance with the adopted Commission Implementing Regulation (EU) No 699/2014 [29], in accordance with Directive 2011/62/EU on counterfeit medicines [21]. According to the regulation, starting from July 1, 2015, all legal online pharmacies within the EU, as well as Norway, Iceland and Liechtenstein, must have a common European logo and be listed on the website of the EU member state where they are based. In addition, there must be a hyperlink between the website of the person authorized or entitled to supply medicinal products and the website containing the national list of business entities that may carry out electronic commerce in medicinal products.

There is also a requirement that the website of the EU Member State (the website of the supervisory competent authority responsible for monitoring pharmacy activities) is linked to the website of the European Medicines Agency, which contains all information about authorized online pharmacies that operate in the EU. The presence of a pharmacy in the register proves its legitimacy and guarantees that the institution is authorized, providing better safety guarantees for consumers who purchase medicines online [29].

EU member states, as well as the United States and Canada, maintain registers of business entities authorized to conduct business activities in the electronic commerce of medicines. For example, in Austria, such a register contains a list of pharmacies that can sell medicines by mail, their addresses, as well as their website addresses and the date of their start of operation [30]. Similar information is also contained in the German register, which lists not only pharmacies but also other sellers of medicines that have official permission to sell medicines online [31].

Each country sets forth in its legislation certain requirements for websites of business entities engaged in electronic commerce of medicines. For example, in France, the domain name of the website must not mislead the patient about the content of the website, nor contain links to pharmaceutical company websites or discussion forums and other public discussion spaces. In addition, the website must contain a system for alerting the pharmacist when the ordered quantity of medicines exceeds the dose specified for each active ingredient in accordance with the regulations [32].

Thus, the sale of medicines by online pharmacies is directly related to the issue of protecting the rights of consumers who purchase medicines via the Internet.

In general, the issue of consumer protection in the era of e-commerce is extremely relevant at the international level. In particular, the United Nations General Assembly Resolution No. 70/186 "Protecting the rights of consumers" [33] emphasized that member states of this organization should work to strengthen consumer confidence in e-commerce by continuing to develop transparent and effective policies to protect their rights, ensuring a level of protection that is not lower than that provided in other forms of trade.

In addition, the resolution states that EU Member States should implement the following guiding principles in their policies: consumer access to basic goods and services; protection of vulnerable and socially disadvantaged consumers; ensuring consumer safety and health; consumer access to reliable information that will allow them to make informed choices in accordance with individual desires and needs; availability of effective consumer dispute resolution and redress mechanisms; protection of the confidentiality of personal data of consumers [33].

Despite the existence of verification or accreditation systems, consumers continue to have problems verifying the authenticity of online pharmacy websites that appear in search engine results, as the illegal pharmaceutical industry is growing alongside the legal industry. For example, a group of researchers tracking 136 online pharmacy websites over a 4-year period found that the physical location information provided often did not match the actual domain registration zone, and a significant number of online pharmacies were illegal websites [34].

According to the WHO, approximately 1 in 10 medicines in low- and middle-income countries are substandard or counterfeit [35]. For example, in the United States, a survey of 10,000 online pharmacies conducted by the National Association of Boards of Pharmacy (NABP) found that 9,938 online pharmacies did not comply with patient safety and pharmacy practice standards or US state and federal laws. Another survey conducted among doctors in the UK showed that 25% of patients who reported a side effect from a drug bought it from an online pharmacy [3]. In 2021, the Alliance for Safe Online Pharmacies (ASOP Global Foundation), a charitable non-profit organization dedicated to combating the growing public health threat posed by illegal online sales of medicines, conducted a study that found that 95% of the approximately 35,000 online pharmacies worldwide operate illegally and do not adhere to pharmacy practice standards [36].

Of course, measures are being taken at the global level to combat illegal online pharmacies that distribute counterfeit and fake medicines, but this phenomenon has not been completely eradicated.

For example, in 2021, a large-scale operation was carried out, coordinated by Interpol. It involved law enforcement agencies, customs services and healthcare institutions from 92 countries. As a result of this operation, 113020 web links were closed or removed, including websites and online platforms that engaged in illegal trade in counterfeit medicines and medical devices [37].

Both legal and illegal online pharmacies exploit consumer vulnerabilities, which are typically determined by a combination of demographic, psychosocial, personal, systemic, and situational factors [38]. For example, reviews of an online pharmacy from other consumers are a potential means of increasing transparency before purchase. However, such reviews can be unreliable, as sellers sometimes artificially increase their ratings or lower the ratings of competitors by posting fake reviews. Online pharmacies may implement persistent advertising strategies aimed at convincing patients to self-diagnose their illnesses, purchase medicines they may not need, or offer medicines without a prescription from a doctor, which may expose people to risks associated with taking inappropriate medicines.

Today, there are online pharmacies that operate without a proper license and do not comply with the requirements of the legislation regulating the circulation of medicines, selling prescription drugs without a valid prescription or medical supervision. Many of these sites offer uncertified drugs that may be ineffective or even dangerous due to unknown composition, incorrect doses of active ingredients, or impurities. For example, studies on the use of non-medical prescription drugs in Denmark, Germany, the United Kingdom, Spain, and Sweden have shown that opioids (4.1%), potent psychoactive drugs (stimulants) (7.6%), and sedatives (2.7%) were available without a prescription in online pharmacies [3]. Another study found that 120 out of 136 online pharmacy websites distributed various prescription drugs without requiring a prescription, and 52 of these pharmacies did not ask for any medical information from customers [34].

The uniqueness of the Internet, including its wide reach, relative anonymity, and ease of creating new websites or removing old ones, creates new challenges for enforcement, as online consumer protection is equivalent to the guarantees of a traditional pharmacy. An effective online enforcement process requires identifying and monitoring websites that potentially violate the law and taking appropriate action to bring those responsible to justice. However, an obstacle is the fact that most drug sales websites consist of many related sites and links, making investigations much more complex and resource-intensive [39].

Management of Prescription and Over-the-Counter Medications:

The differentiation between prescription (Rx) and over-the-counter (OTC) medicinal products is a fundamental element of regulatory oversight in the electronic commerce of medicines. This distinction is critical not only for determining the appropriate level of patient access but also for shaping mechanisms designed to protect consumers from the uncontrolled circulation of potent substances and to mitigate public health risks associated with irrational self-medication. Within the broader comparative context examined in this article, jurisdictions consistently apply more stringent regulatory measures to Rx medicines, while OTC products are subject to simplified – yet still essential – safeguards.

In Ukraine and many other jurisdictions, OTC medicines may be sold online under less stringent regulatory conditions because they are presumed to pose lower levels of risk. Nevertheless, their safe distribution still requires strict compliance with licensing obligations, proper storage and delivery standards, and age-verification mechanisms intended to prevent misuse. Simakova notes that even OTC products may present safety risks when transported without temperature control or when their online promotion encourages excessive or irrational consumption [40]. Comparative international practice, as discussed in Sections 3.1 and 3.2, reinforces this observation: several EU Member States and Canada employ automated monitoring systems that notify pharmacists when online orders exceed recommended dosages, thereby functioning as preventive safeguards against potential consumer harm.

Prescription medicines, by contrast, remain subject to considerably stricter regulatory regimes due to the heightened risks of illegal dispensing, circulation of counterfeit or substandard products, and the absence of necessary medical supervision. In numerous jurisdictions, including several EU Member States, the online sale of Rx medicines is either heavily restricted or entirely prohibited. Where such sales are permitted, they are governed by robust protective mechanisms

– secure e-prescription systems, mandatory pharmacist verification, reliable buyer identification, and full traceability of each dispensing transaction. Simakova emphasizes that Ukraine's current regulatory framework lacks an integrated e-prescription verification system specifically adapted for online pharmaceutical trade, which creates enforcement gaps and exposes consumers to significant vulnerabilities in the digital medicines market [41].

A persistent regulatory challenge concerns unlicensed online platforms that offer prescription medicines without medical consultation or a valid prescription. As demonstrated in the international studies discussed earlier, such platforms frequently obscure their physical location, circumvent national licensing requirements, and distribute medicinal products of uncertain or unverifiable quality. This issue is particularly acute in Ukraine, where illegal operators continue to exploit gaps in supervisory and enforcement mechanisms, thereby contributing to the circulation of falsified or substandard medicines in the digital pharmaceutical market.

Therefore, an effective regulatory framework for managing both OTC and prescription medicines in e-commerce must be differentiated yet harmonized across regulatory domains. For OTC products, priority should be placed on strengthened website verification requirements, enhanced consumer information standards, and appropriate delivery controls. For prescription medicines, essential safeguards include reliable authentication of prescribers, secure digital transmission and verification of electronic prescriptions, mandatory pharmacist oversight, and strict liability for illegal online dispensing. The integration of licensing requirements, technological safeguards, and comprehensive administrative supervision is necessary to ensure that expanding digital access to medicinal products does not compromise consumer safety or public health.

Guaranteeing Secure Transmission and Privacy:

One of the key issues of legal regulation in different countries is the delivery of medicines to the buyer. This aspect is an integral part of the process of purchasing pharmaceutical products from online pharmacies and requires special attention to ensure the safety and quality of the goods received. First, the delivery of medicines must be carried out in compliance with all necessary transportation conditions. Some medicines require a certain temperature regime, protection from light or moisture, and failure to comply with these conditions may result in a loss of their effectiveness or even danger to the consumer's health. Second, consumers have the right to timely delivery. Online pharmacies must ensure that the specified delivery times are strictly adhered to, especially when it comes to medicines that are needed for emergency treatment. Third, it is extremely important to ensure confidentiality during delivery. The packaging of medicines should be opaque and not contain any information that could reveal the contents of the order to unauthorized persons. At the same time, ensuring the confidentiality of a person is an extremely important aspect in the process of drug delivery.

Interesting in this context is the experience of Sweden, where § 9 of the Medical Products Agency's Regulation on Distance Selling in Outpatient Pharmacies states that the inpatient pharmacy is responsible for ensuring that the person receiving the medicines is the proper recipient. Therefore, when transferring a particular medicinal product to the recipient, the pharmacy employee is obliged to check the recipient's identity documents. If a representative receives the medicinal product, the latter must provide proof of his/her authority - a written power of attorney, which must contain the name of the representative and be signed by the person in whose name the medicinal product was prescribed [42]. Medicines may be left only in the consumer's mailbox. They are not allowed to be left at the front door, next to the mailbox, or in other places where they can be accessed by unauthorized third parties [43].

In Belgium, a parcel must be accompanied by an information sheet containing information about the pharmacy, labeling of medicines, a notice of non-return (except in cases of defects), a list of pharmaceutical care services provided after dispensing, and any other information necessary for the safe use of medicines [44].

Estonian legislation regulates in detail the requirements for the accompanying documents to be attached to the delivery of medicines. In particular, they must contain information about the customer's name, order number, pharmacy name and contact details, the name of the company holding the license, and the name of the person who checked the contents of the parcel. If the order includes a prescription drug, the prescription number is required. In addition, the accompanying documentation must contain a warning calling on the recipient to read the instructions for use before using the medicinal product [45].

It should be noted that in many countries, pharmacists play a key role in the process of placing orders and ensuring the delivery of medicines purchased through an online pharmacy. For example, in Sweden, it is the pharmacist who is responsible for actually verifying the age of the person placing the order, as in this country the sale of medicines is allowed only to persons over 18 years of age. Such verification is carried out by means of electronic identification or during payment transactions that require verification of the person and allow to confirm his/her age [46].

Enhancing the Roles and Responsibilities of Pharmacists:

As comparative analysis shows, many jurisdictions increasingly emphasize the expanded professional duties of pharmacists, recognizing their central role in ensuring the safety, accuracy, and quality of pharmaceutical services provided through online platforms.

In Germany, the pharmacist must ensure that the ordered medicines, if available, are dispatched within two working days at the latest (§ 11a sentence 1 No. 3 lit. a ApoG) [47].

In Belgium, the pharmacist is obliged to deliver medicines within two working days of receiving the order, unless otherwise agreed with the patient or his/her authorized representative, and to notify of any delay in delivery [44].

In Estonia, the delivery of medicines must be made within three working days after the order is confirmed, unless the customer has chosen a later delivery date or if compliance with the deadline is impossible for reasons beyond the control of the pharmacy service provider [48].

In France, the dispensing of medicines is only possible if the patient is able to interact with the pharmacist. At the same

time, such interaction cannot be carried out through automated answering services, as this makes it impossible for the pharmacist to provide personalized and timely recommendations to the patient [31].

Oversight, enforcement, and consumer education:

To ensure the security of e-commerce in medicines, regulatory authorities must not only have legally defined powers, but also sufficient resources to identify and prosecute offenders. For example, in Germany, the key regulatory authorities that oversee the activities of online pharmacies are the Federal Institute of Medicines and Health Services (BfArM) and the Federal Joint Committee (G-BA). These institutions define the list of licensed pharmacies, set requirements for their activities, and ensure quality control and compliance with data protection regulations [49,50].

In the United States, the FDA controls the safety and efficacy of medicines. The FDA regularly sends warning letters to website operators that violate U.S. drug laws. In particular, common violations of the rules for conducting business activities in the field of electronic commerce in medicines include the sale of unauthorized (unregistered) prescription drugs of unknown origin, the sale of prescription drugs without a proper prescription, the sale of prescription drugs without proper instructions for their safe use, etc. The FDA also maintains an open register of illegally operating Internet pharmacies that have received a warning of violations. This registry is available on the official website [51]. In addition, any person can file a complaint with the FDA if they believe that a particular website is selling medicines illegally [52]. In the UK, a similar complaint can be filed with the Medicines and Healthcare products Regulatory Agency, which regulates online pharmacies [53].

When studying international experience in the field of e-commerce in medicines, it is also advisable to pay attention to the educational activities of public authorities. By informing the public about the peculiarities of the functioning of online pharmacies and the risks associated with low-quality or counterfeit medicines, regulatory agencies contribute to the formation of an informed consumer choice. Educational initiatives are aimed, in particular, at teaching consumers how to recognize legitimate online pharmacies and safe medicines.

For example, back in 2000, the FDA launched an information campaign on safe ways to purchase pharmaceutical products online. The initiative included placing thematic advertisements on health-related websites, broadcasting public service announcements on national television channels, and creating a “safety checklist” for buyers that was distributed both online and through healthcare providers and consumer protection organizations [54]. The Dutch Ministry of Health, Welfare and Sport is also conducting an information campaign among the country's population about the risks of ordering medicines online. As part of this initiative, consumers are provided with clear guidelines on how to distinguish between legitimate online suppliers and fraudulent platforms [55]. In general, the official web resources of regulatory authorities in most countries contain recommendations designed to help consumers choose reliable and safe online pharmacies.

Conclusion.

Thus, the study of the experience of e-commerce in medicines in both developed and developing countries has shown that the emergence and development of this type of trade is largely due to economic and cultural characteristics. Legal regulation and the market of online pharmacies are at different stages of development, which is related to national approaches to the liberalization of the pharmaceutical market and regulation of online commerce. At the same time, ensuring the quality, safety and authenticity of medicinal products sold through online pharmacies and online stores remains a priority for each country where electronic commerce in medicinal products is carried out.

The analysis of the legal regulation of e-commerce in medicines in different countries of the world has made it possible to identify the best foreign practices that can be used to formulate proposals for improving the national legislation of the states in the field of consumer protection of medicines via the Internet, in particular:

1) To expand the list of business entities entitled to carry out electronic commerce in over-the-counter medicines, with the list of such medicines being enshrined in law (experience of Germany and Denmark).

2) Determine the list of medicines prohibited for sale through online pharmacies (experience of Belgium and Northern Ireland).

3) Introduce mechanisms for authentication of registered online pharmacies by creating a single domain space (the experience of the United States and Canada).

4) To strengthen the responsibility of pharmacists for the dispensing of medicines (experience of France, Belgium, Estonia).

5) Guarantee the confidentiality of customers' personal data (Swedish experience).

6) Conduct information campaigns to raise public awareness of the recognition of legal and illegal online pharmacies, as well as safe ways to purchase medicines online (experience of the EU and the US).

7) To ensure effective monitoring of the activities of Internet pharmacies for compliance with the requirements of the legislation in the field of circulation of medicines with bringing violators to justice (experience of the United States and the United Kingdom).

The implementation of these legal and institutional measures will help to increase transparency, quality control and accountability in the field of consumer protection of electronic pharmaceutical services.

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