Chapter 17

DEVELOPMENT OF DIGITAL TECHNOLOGIES IN PHARMACY: REGULATORY AND LEGAL BASIS FOR ENSURING THE ACTIVITY OF INTERNET PHARMACIES IN UKRAINE AND EU COUNTRIES[1]

Krychkovska A. M., Zayarnyuk N. L., Hrabovych B. A.
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INTRODUCTION

Features of the development of the world economy, such as: the intensity of interstate movement of goods, the development of international trade, the globalization of the Internet and the evolution of IT technologies, as well as the growth of health care costs and the aging of the population, all contribute to the digital transformation of the health care system. The COVID-19 pandemic has shown the need to ensure the availability of vital drugs, the introduction of remote retailing of drugs and the development of Internet pharmacies (e-pharmacies). The advantages of e-commerce of medicines are convenience for patients, the possibility of expanding the assortment and the use of various mobile applications. Legislation has a significant influence on the formation of the dynamics of the e-pharmacy market in Ukraine.

The purpose of the work was to review the regulatory and legal regulation of electronic trade in medicinal products in Ukraine and EU countries.

Pharmacists have always been and are now those workers in the medical field who provide primary medical care directly to the patient. But the remote sale of medicines, including via the Internet, is already an absolute necessity of reality. In response to this challenge, Ukraine adopted the Law of Ukraine No. 904 dated 17.09.2020 "On Amendments to Article 19 of the Law of Ukraine "On Medicinal Products" regarding electronic retailing of medicinal products"[2], which allows the remote sale of non-prescription drugs medicines.

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[2] Про внесення змін до статті 19 Закону України "Про лікарські засоби" щодо здійснення електронної роздрібної торгівлі лікарськими засобами. Документ 904-IX, чинний, поточна редакція – Прийняття від 17.09.2020

However, based on the European experience, it is impossible to simply apply the legal provisions of one country to another. Such a process requires a comprehensive analysis of advantages and disadvantages, adaptation to the local context and coordination with the national legal framework. An analysis of the provisions regulating possible alternative forms of drug supply (non-prescription drugs, prescription-only drugs, prescription drugs, and the sale of drugs on the Internet) is presented in a new report by the World Health Organization (WHO)[3].

The consumer turns to the Internet primarily for information about medicines. First of all, resources that provide the patient with useful, reliable, up-to-date information are given priority. Next, the consumer will look for the product he needs: where it can be purchased and how much it will cost (price aggregators, pharmacy websites) and how to make it more convenient (mobile applications, delivery services). These needs are provided, for example, by the content resource "Compendium" (https://compendium.com.ua/uk/) and the drug search service in pharmacies "Tabletki.ua" (https://tabletki.ua). Consulting companies predict that by 2024 the revenue of the global e-pharmacy market will reach $52.51 billion. The market is expected to grow at a CAGR of 11.57% during 2024-2028, leading to a projected market size of $81.37 billion by 2028. The number of users is projected to grow to 30.92% by 2028, with an average revenue per user of $28.69[4]. In Ukraine, the share of e-commerce in the field of pharmacy is estimated at 7.4%. Taking into account the development of this direction, in 5 years this indicator may increase to 15%[5]. The development of e-pharmacies is an important factor for sustainable development and adequate provision of medicines to the country's population[6].

1. Digital technologies in pharmacy: electronic pharmacy system and European experience

In today's digital environment, personal data protection is one of the most important issues, especially for e-pharmacies where sensitive medical information is collected and processed. Ensuring the security of personal data

[3] The legal and regulatory framework for community pharmacies in the WHO European Region. https://iris.who.int/bitstream/handle/10665/326394/9789289054249-eng. (дата звернення: 30.05.2024).

[4] Statistics. Online Pharmacy – Worldwide. https://www.statista.com/outlook/hmo/digital-health/digital-treatment-care/digital-care-management/online-pharmacy/worldwide (дата звернення: 30.05.2024).

[5] Онлайн-реалізація та доставка лікарських засобів: перспективи та правила гри. Аптека № 25 (1296) 28 Червня 2021 р. https://www.apteka.ua/article/600010 (дата звернення: 30.05.2024).

[6] Дуліба Є.В. Адміністративно-правове регулювання електронної торгівлі лікарськими засобами в Україні. Юридичний науковий електронний журнал. 2021. №2. С. 169-172. DOI: 10.32782/2524-0374/2021-2/39 (дата звернення: 30.05.2024).

requires a comprehensive approach and the use of modern technologies. First of all, Internet pharmacies must comply with the requirements for the storage and processing of personal data established by the legislation on the protection of personal data. This includes keeping data in a secure environment, restricting access to this data to authorized persons only, and using encryption technologies to protect information from unauthorized access. In addition, it is important to establish mechanisms to control access to personal data so that only authorized employees have access to confidential information. These mechanisms may include the use of authentication systems with multi-level identity verification, auditing of user actions to identify potentially suspicious actions, and limiting access rights according to the principle of "least privilege". Data security breach response procedures also include identifying system weaknesses and remediating them, as well as training staff on data security and incident prevention measures. Given the constant development of technology and the increase in the number of cyber threats, the protection of personal data in Internet pharmacies is an important component of successful.

Data encryption in electronic pharmacy systems is an important measure to ensure the security and confidentiality of information. The use of strong encryption algorithms, such as AES (Advanced Encryption Standard) or RSA (Rivest-Shamir-Adleman), allows you to reliably protect data from unauthorized access[7] [8]. Encryption can be applied to various types of data, including customer personal data, medical records, financial information and other sensitive data. Proper management of encryption keys is also an important component. Encryption keys must be stored in a secure location and accessible only to authorized persons. Regular change of keys and periodic updating of encryption algorithms allows you to maintain a high level of data security. Encryption is also used to protect data during its transmission over the Internet. The use of SSL/TLS protocols ensures data encryption between the user and the server, which prevents interception and misuse of information during transmission[9]. In addition, it is also important to implement authentication and authorization mechanisms to control access to encrypted data. The use of two-factor authentication, biometric technologies and other methods of identity verification help prevent unauthorized access to sensitive information. Therefore, data encryption makes it possible to ensure the safety

[7] Dworkin M., Sonmez Turan M. and Mouha N. Advanced Encryption Standard (AES), Federal Inf. Process. Stds. (NIST FIPS), National Institute of Standards and Technology, Gaithersburg, MD, 2023. URL: https://doi.org/10.6028/NIST.FIPS.197-upd1(date of access: 30.05.2024).

[8] Rachmawati, D., & Munthe, Y. R. Implementation of Rivest Shamir Adleman Cryptographic Algorithms and Techniques of Steganography First of File for Message Security. Journal of Physics: Conference Series. 2018. Vol. 1090, No. 1, P. 012-062.

[9] Що таке SSL/TLS та як проапгрейдитися до версії TLS-протоколу 1.3. URL: https://vps.ua/blog/ukr/ssl-tls-protocols-details/(дата звернення: 30.05.2024).

and confidentiality of medical information and personal data of customers of e-pharmacies. Since the introduction of online payment systems in e-pharmacies, new requirements have appeared regarding the protection of financial transactions and the confidentiality of financial information of customers. One of the key aspects of the security of financial transactions is the use of secure payment gateways and payment processing services. These gateways ensure that financial data is encrypted as it travels over the network, preventing attackers from intercepting sensitive information. An additional security step is to introduce two-factor authentication to confirm the identity of clients during ongoing financial transactions: via SMS notification with confirmation codes or installation of mobile applications for generating one-time passwords. Regular audits and security checks of payment systems allow you to identify possible vulnerabilities and risks and take measures to eliminate them in time. In addition, it is important to provide customers with information on payment security and recommendations for protecting their financial data when using e-pharmacy services. The security of financial transactions in electronic pharmacy systems requires a comprehensive approach, which includes the use of secure payment gateways, the implementation of two-factor authentication and systematic security audits to ensure reliability and trust when conducting financial transactions in e-pharmacies. The main purpose of the audit is to ensure compliance of the security system with the requirements of standards and legal norms, identify and assess threats to information security, evaluate the effectiveness of security measures and develop recommendations for further security improvement. In the security audit process, it is important to check the availability and effectiveness of applied technical, organizational and procedural security measures: system access, data encryption, use of anti-virus software, control of access to financial transactions, etc. During the audit, special attention is paid to the identification of possible security threats and risks. This could be the loss or leakage of confidential information, unauthorized access to the system, attacks by attackers and other similar scenarios. After the security audit is completed, a report is generated that records the identified problems, shortcomings and recommendations for improving the security system. This report allows system administrators and e-pharmacy management to be aware of potential risks and take the necessary measures to improve security and information protection[10].

The privacy and security policy is a key element of Internet pharmacies and their interaction with customers. First of all, the privacy policy should define what types of information are considered confidential and personal.

[10] Kuzma Joanne, Dobson Kate, Robinson Andrew. An Examination of Privacy Policies of Global On-line E-pharmacies. European Journal of Research and Reflection in Management Sciences. 2016. No 4. 23-28.

This may include personal customer information (such as name, address, phone number, email, health information, etc.), financial information, medical records, and any other sensitive information. The rules and procedures for storing and processing confidential information include technical protection measures (for example, data encryption, access control, regular security audits), organizational measures (for example, mandatory training of personnel on data security, establishment of information access policies) and procedural measures (eg access rights management, use of secure data transfer methods). Also, an important component of the policy is the regular review and updating of privacy and security provisions so that they meet current standards and requirements. In addition, it is important to provide information to customers about privacy and security policies so that they have a clear understanding of how their data is handled and protected. This contributes to maintaining the trust of customers and creating a positive impression of working with an e-pharmacy[11].

Each country has its own laws, rules and regulations governing the advertising of medicines on the Internet. For example, in the USA, such legislation includes the Federal Food, Drug, and Cosmetic Act (FD&C Act), which regulates the advertising of drugs and requires their authenticity and safety[12]. In the European Union, Directive 2001/83/EC is in force, which sets requirements for the advertising of medical products, including advertising on the Internet. These requirements include the mandatory registration of advertising before its start, the prohibition of the use of certain words or terms that may mislead consumers, as well as the obligation to indicate the source of information about the drug. «Shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties»[13]. It is also prohibited to provide medical advice without appropriate qualifications. State control bodies supervise compliance with the rules for advertising medicines on the Internet. In case of violations, various sanctions may be applied, including fines, removal of advertising or revocation of the license to advertise a certain drug. The development and implementation of common standards and approaches contributes to the provision of a unified and effective system of control over drug advertising on an international scale.

[11] Quo Matters. Supply Chain. Internet Pharmacies are an Often-Overlooked Part of the Medicines Supply Chain. May 23, 2023. URL: https://qualitymatters.usp.org/(date of access: 30.05.2024).

[12] Federal Food, Drug, and Cosmetic Act. URL: https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act (date of access: 30.05.2024).

[13] Directive 2001/83/EC. URL: https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32001L0083 (date of access: 30.05.2024).

Licensing of advertising activities is an important stage in ensuring control over advertising of medicines on the Internet. State control bodies establish requirements for obtaining a license to conduct advertising campaigns for medicinal products. The requirements include the presentation of evidence about the effectiveness and safety of the advertised means, compliance of information on advertising materials with scientific data, compliance with requirements for objectivity and reliability of information. Before starting an advertising campaign on the Internet, the advertiser must go through the procedure of registration of advertising materials: submit an application for registration, present advertising materials for assessment of their compliance with legislation and control requirements. Registration enables regulatory bodies to keep records of advertising, monitor compliance with the rules, and take action in case of detection of unreliable or incorrect advertising. Legal norms establish requirements for the content and form of advertising materials for medicines on the Internet. Information for consumers includes the name of the drug, composition, action, indications and contraindications, dosage, side effects and other important data that can be useful for making an informed decision about the purchase and use of drugs. It is prohibited to make promises and guarantees that may create a false impression of the drug's effectiveness or safety in drug advertising. Licensing and registration of advertising materials imposes responsibility on the advertiser for compliance with legal norms and requirements for advertising medicines on the Internet. Failure to comply may result in fines, revocation of license, removal of advertisements and other sanctions by regulatory authorities. In virtual pharmacies and on the websites of drug advertisers, it is necessary to ensure that the information provided in the advertisement corresponds to the valid properties of the product. State control bodies have the right to take measures to stop and prevent wrongful claims in the advertising of medicines on the Internet: demand correction of false information, remove advertising, impose fines or sanctions on advertisers who have violated the rules. Some countries may make it mandatory to consult a specialist before purchasing certain medicines, especially if they require a prescription. This contributes to the correct use of medicines and reducing the risk of negative consequences for the health of consumers.

Access to non-prescription medicines is based on the combined action of two regulatory norms: the existence of a monopoly on the dispensing of non-prescription medicines in a pharmacy and the classification of medicines. In Austria, France, Belgium, Greece, Lithuania, Latvia, Estonia, Slovakia, Luxembourg, Cyprus and Malta, over-the-counter medicines can only be sold in pharmacies. Nicotine replacement therapy products can be purchased over the counter in Finland. The rules for the sale of herbal and homeopathic remedies differ. In some EU countries (notably Bulgaria, Croatia, Germany, Portugal, Romania and Switzerland), a small range of medicines is available

for retail sale outside pharmacies under certain conditions, but without strict market regulation[14].

Drug classification is usually based on a risk assessment that takes into account scientific evidence, as well as local health care system, literacy and culture factors that affect the potential use of over-the-counter drugs.

For example, in Switzerland there are five categories of drugs:

– A – only on prescription in a pharmacy;
– B – on the basis of a repeat prescription in the pharmacy;
– C – without a prescription in the pharmacy;
– D – without a prescription in a pharmacy or non-pharmacy outlets;
– E – available in non-pharmacy outlets.

The classification may or may not include the ability or impossibility for patients to choose medication independently, or certain restrictions, such as age as in Denmark, or requirements for the premises where the medication can be obtained (especially if the country has not granted a monopoly to pharmacies)[15].

In a very few countries, such as the Netherlands and Switzerland, medical professionals called "drug specialists" (drogists and droguistes/drogisten/droghisti, respectively) have the right to dispense over-the-counter medicines after undergoing special professional training.

If pharmacies have a monopoly on dispensing drugs, regulators may define the following classification for over-the-counter drugs:

– medicines that can be displayed for free access to them by buyers in the pharmacy sales hall;

– medicines that can be displayed in an area available for inspection by customers, but which can be obtained only from a pharmacy employee after providing advice on their use;

– medicines that cannot be displayed in the area available for inspection by customers, but which can be obtained from a pharmacy employee without a doctor's prescription after providing advice on the use of medicines (pharmacist-only medicines).

In situations where a pharmacy does not have a monopoly on dispensing drugs, regulators can limit access to over-the-counter drugs by defining the following:

[14] Oleszkiewicz, P., Krysinski, J., Religioni, U., & Merks, P. Access to medicines via non-pharmacy outlets in European countries – a review of regulations and the influence on the self-medication phenomenon. In Healthcare. 2021. Vol. 9, No. 2, P. 123. DOI:10.3390/ healthcare9020123 (date of access: 30.05.2024).

[15] The legal and regulatory framework for community pharmacies in the WHO European Region. World Health Organization. Regional Office for Europe. URL: https://dokumen.tips/documents/the-legal-and-regulatory-framework-for-community-pharmacies-in-2020-3-22-of.html?page=48 (date of access: 30.05.2024).

– is it possible to sell over-the-counter drugs in any premises or does the relevant person/institution have to have a permit for this from authorities (for example, drug specialists);

– categories of over-the-counter drugs that can be sold to all customers or only to customers who are 18 years of age (or older).

It is worth noting that the Council of Europe has long expressed concerns about the conditions for the provision of medicines and the harmonization of national legislation. The ability to purchase drugs with or without a prescription has implications for patient safety, patient drug availability, and responsible health care cost management.

Deciding on the prescription status and accompanying conditions of supply is one of the main areas of competence of national health authorities. In the member states of the Council of Europe, the conditions for the supply of medicines differ to a large extent, since the provisions are interpreted and implemented differently by the countries, and important additional classification criteria are not harmonized.

It should be noted that a critical situation of uncontrolled dispensing of drugs exists in Ukraine now, since prescription drugs can be purchased without a prescription in pharmacies, which is partly due to the state of war in the country. Sometimes even pharmacists can advise and dispense such drugs to the patient. This is a clear example of a situation where a legal norm exists, but is not implemented. The solution to this problem can only be the introduction of an electronic prescription for all prescription drugs. In the European region, the sale of over-the-counter drugs via the Internet began to develop around the year 2000. For example, in Sweden it has been allowed since 2002, and in Ireland and Spain – since 2006[16].

The sale of some medicines on the Internet is allowed by Directive 2011/62/EU in the EU. «Patients should only buy medicines from online retailers registered with the national competent authorities in the EU Member States, to reduce the risk of buying sub-standard or falsified medicines». The European Commission has introduced a common logo that appears on the websites of these registered retailers.At the same time, some countries have allowed online sales of prescription drugs, including Germany, Finland, Switzerland, Sweden and Estonia. It is clear that it is advisable to introduce an electronic prescription at the state level. However, public health considerations, economic and social factors should be taken into account, including factors such as: technical implementation of regulation of online sales; technical capabilities for monitoring compliance with regulatory requirements; potential risks for the existing pharmacy segment and its further development**.** Economic factors to consider include: the potential loss of

[16] Продаж лікарських засобів через інтернет – європейський досвід/ Аптека online, 15.02.2021. URL: https://www.apteka.ua/article/583752 (дата звернення: 30.05.2024).

government revenue from pharmacy taxes due to reduced turnover if foreign pharmacies are allowed to enter the market; potential job losses due to the concomitant closure of pharmacies; potential risks for national drug manufacturers, especially over-the-counter drugs. The number of social factors includes: the risks of selling falsified drugs and drugs of insufficient quality; access to prescription drugs without a doctor's prescription; risks to the patient's safety from illegally operating pharmacies and the impossibility of obtaining advice on the use of medicines; limited access to medicines in the event of an emergency due to a reduction in the density of the territorial distribution of pharmacies.

Forwarding prescription drugs is allowed, for example, in Germany. However, the potential risks to pharmacies and the healthcare system are predicted to be high. The share of online drug sales is increasing in the German market, but the number of pharmacies is decreasing. Importantly, when an online pharmacy dispenses medication to a patient registered in another country or jurisdiction other than its own country of registration, where it operates, it must generally comply with the laws of both jurisdictions. For example, it is the online pharmacy that is obliged to make sure that a specific drug is allowed to be sold on the market in both countries. Therefore, some countries are removing drugs from online sales. In Northern Ireland in particular, some prescription drugs are prohibited from being sold over the internet, even with a valid prescription. In countries that allow the sale of medicines online, this type of activity requires the permission of the sale's regulatory authority. This practice is characteristic of Germany, France, Switzerland and Estonia. Permits or regulatory notices may be subject to a fee and valid for a limited period (e.g. in Ireland €160 for 12 months).

Most of the requirements for dispensing and sending medications over the Internet are similar to those that apply to regular dispensing. However, there are a number of tools available to help patients identify legitimate and authorized online pharmacies. The list of registers of online medicine retailers is available on the website of the European Medicines Agency at https://www.ema.europa.eu/en/human-regulatory-overview. Each of the EU Member States, as well as Iceland, Norway and Liechtenstein, which are EEA Member States, provide their own list of authorized online pharmacies, which is kept up-to-date on its website. At the time of our visit (05/29/2024), only the website of Liechtenstein was unavailable. The lists are given in the language adopted in the country, in some cases in two languages: in Belgium – Dutch and French, in Cyprus – Greek and English. It is important to use a specially designed logo to confirm the legitimacy of the chosen online pharmacy. The legal basis for the generic logo is set out in European Commission Directive 2001/83/EC as amended by Directive 2011/62/EU on falsified medicinal products for human use and Implementing Regulation 699/2014 of 24 June 2014. All online drug stores registered in the EU must

have a logo. If you click on the logo, it will appear on the websites of all registered online stores. By clicking on the logo, you can go to the list of retailers in the country whose flag is displayed on the logo[17].

In addition to the general rules for purchasing medicines online, countries are introducing additional requirements. Thus, in France, sales should not exceed a monthly course of treatment, taking into account the recommended dose, or a full course of treatment for acute diseases. Consultation with a pharmacist is also necessary. In France, medications are not allowed to be dispensed unless the patient has access to a one-on-one consultation with a pharmacist, so this consultation cannot be done via voicemail. In most countries, pharmacies must be willing to provide advice after the medicine has been dispensed (usually after the patient has received the medicine). There are packaging requirements for drug delivery. Special requirements may be established so that the delivery does not affect the quality or effectiveness of the medicine, for example, the name of the person who ordered the drug, the order number, the name and contact information of the pharmacy, the business name of the license holder, the name of the person who checked the contents of the package, etc. Thus, in Belgium, there is a requirement to apply the following information to the medicine and put it together with it in the package: labeling of the medicine; information about the pharmacy; a warning that medicines cannot be returned (except for defective ones); a list of pharmaceutical care services after discharge; any information necessary for the responsible use of medicines. The package must contain a warning that the drug cannot be used if the package does not correspond to the order, if it is opened or damaged, or when there is a possibility that the drug may be defective. In addition, information on storage conditions, place of delivery, deadline for delivery and order number should be provided, as well as a reminder of the need to read the instructions. The sending pharmacy remains responsible for the medication until delivery is complete. The parcel is delivered to the recipient upon presentation of an identity document. Some countries set a standard (maximum) delivery time, usually 2–3 working days. In many countries, pharmacies are required to maintain their own website containing contact and registration details of the establishment, as well as information about the drug, trade name and international nonproprietary name of the drug, therapeutic indications, dosage form and number of dosage units, a link to the European Medicines summary of product characteristics Agency, photographs of packaging with the same image size for all drugs and, necessarily, the price of the drug and delivery fee. In France, at the regulatory level, it is stipulated that patients must have access to the "Personal Account"

[17] Buying medicines online. URL: https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/falsified-medicines-overview/buying-medicines-online (date of access: 30.05.2024).

– a section where data on all pre-orders and correspondence with pharmacists is stored. To create such an account, the patient must provide his full name, date of birth and email address. French pharmacies are also required to request specific patient data to approve each order and dispense a medicine. Data are collected using an online questionnaire, which includes age, weight, height, gender, current treatment, allergies, contraindications and, where appropriate, information about pregnancy or breastfeeding. In addition, in France, the patient can print out all correspondence with the pharmacist. The website domain name must not be promotional in nature, misleading to the patient as to its content, or whimsical.

The International Pharmaceutical Federation (FIP) conducted a global survey of opportunities for the sale of medicines over the Internet, which covered 73 countries and territories. Prescription drugs were found to be available online on the websites of conventional (physical) community pharmacies in 16 countries, and non-prescription drugs in 14 countries. Prescription drugs are available online and are not limited to physical community pharmacy websites in 11 countries, over-the-counter drugs – in 29 countries. Prescription medicines are not available/banned for online sale in 46 countries and over-the-counter medicines in 30 countries. «Some EU countries allow it, but some do not».

Today, e-pharmacies operate not only in most European countries, but also in the countries of North America (USA, Canada), the Asia-Pacific region (China, India, Japan, Australia). The e-pharmacy market is expected to be valued at USD 136,160.27 million in 2026.

2. Organizational and legal regulation of electronic trade in medicines in Ukraine: problems and prospects for the development of Internet pharmacies

Providing the population with medicines and increasing the level of their availability in Ukraine are integral components of the state policy in the field of health care, which is aimed at creating a patient-oriented system, as implemented in developed European countries. E-pharmacies offer comfort and accessibility, because a person only needs to place an order for medicines, and the e-pharmacy takes care of everything else, including the delivery of the order. In addition, e-pharmacies can offer customers some services that encourage people to use this method of purchasing drugs. These can be online pharmacist services, data on drug interactions, a list of symptoms, data on less expensive substitutes. The availability of such information enables the buyer to improve his choice.

The increase in the number of Internet users, expanded access to Internet services, the development of electronic commerce contributed to the introduction of electronic trade in medicines in the world, and also laid the foundations for the introduction of such trade in Ukraine.

In Ukraine, attempts have already been made to introduce remote trade and the sale of medicines using the Internet. In particular, the Order of the Ministry of Economy of Ukraine No. 103 dated 04/19/2007 "On approval of the Rules for the sale of goods to order and outside trade or office premises" approved the rules for the sale of goods to order and outside trade or office premises, which applied to business entities in the field trade, regardless of the forms of ownership, which are registered in accordance with the established procedure. In clause 1.3. of these rules, it was noted that the range of goods sold to order and outside of retail or office premises is determined by the business entity independently, except for goods whose sale is prohibited by law. A business entity that sells goods to order and outside of retail or office premises must obtain appropriate permits (licenses, trade patent, etc.)[18]. According to the Letter of the State Service of Ukraine on Regulatory Policy and Entrepreneurship Development No. 196/0/20-14 dated 11.01.2014, retail trade carried out by mail order firms or via the Internet includes retail trade activities when the buyer carries out his choice, based on advertisements, catalogs, website information or any other promotional products, and makes an order by mail, telephone or via the Internet[19]. Based on the understanding of the interpretation of the concept of "medicines" contained in the Law of Ukraine "On Medicinal Products" we can state the fact that electronic retail trade of medicines in a certain format already existed in Ukraine. According to the Law of Ukraine "On Medicinal Products", "a medicinal product is any substance or combination of substances (one or more APIs and excipients) that has properties and is intended for the treatment or prevention of diseases in humans, or any substance or a combination of substances (one or more APIs and excipients) that may be intended to prevent pregnancy, restore, correct, or alter physiological functions in humans by exerting a pharmacological, immunological, or metabolic action, or to establish a medical diagnosis. Medicinal products include: API, products in bulk; finished medicines (LP); homeopathic remedies; means used to detect pathogens, as well as fight against pathogens or parasites; medicinal cosmetics and medicinal additives to food products"[20]. However, with the adoption of the Law of Ukraine "On Licensing of Types of Economic Activities", and later also in the Licensing Conditions for conducting economic activities for the

[18] Про затвердження Правил продажу товарів на замовлення та поза торговельними або офісними приміщеннями. Документ z1181-07, чинний, поточна редакція – Редакція від 02.10.2020, підстава – z0905-20 URL: https://zakon.rada.gov.ua/laws/show/z1181-07#Text (дата звернення: 30.05.2024).

[19] Щодо здійснення торгівлі через інтернет-магазин/ Документ v0196773-14, поточна редакція – Прийняття від 11.01.2014 URL: https://zakon.rada.gov.ua/rada/show/v0196773-14#Text (дата звернення: 30.05.2024).

[20] Закон України “Про лікарські засоби”. Документ 2469-IX, чинний, Редакція від 17.09.2023, підстава – 3345-IX URL: https://zakon.rada.gov.ua/laws/show/2469-20#Text (дата звернення: 29.05.2024).

production of medicines, wholesale and retail trade of medicines, import of medicines (except for active pharmaceutical ingredients), approved by the Resolution of the Cabinet of Ministers of Ukraine according to No. 929 dated 30.11.2016, distance trade in medicines was declared prohibited, and trade was allowed exclusively through pharmacies [23].

However, the COVID-19 pandemic became the impetus for a new attempt to introduce electronic trade in medicines in Ukraine. The first changes in the direction of electronic trade in medicines were implemented by the Resolution of the Cabinet of Ministers of Ukraine No. 220 dated 23.03.2020 "On Amendments to the Licensing Conditions for Conducting Business Activities for the Production of Medicines, Wholesale and Retail Trade of Medicines, and the Import of Medicines (except active pharmaceutical ingredients)". However, the effect of this Decree did not extend to a significant part of drugs, in particular, prescription drugs. The next step was taken with the adoption of the Law of Ukraine No. 904-IX dated 17.09.2020 "On Amendments to Article 19 of the Law of Ukraine "On Medicinal Products", which established the legal regulation of electronic trade in medicinal products in Ukraine, giving the right to business entities, which have a license for the retail trade of medicinal products, to introduce e-pharmacies on the territory of Ukraine. The purpose of the adoption of this Law was to regulate legal relations in the field of distance trading of medicines and to ensure the protection of the end consumer from such risks as: non-compliance with the conditions of storage and transportation of medicines; violation of the drug circulation procedure, including the possibility of low-quality or falsified drugs reaching the patient; increase in the percentage of cases of self-treatment; lack of proper pharmaceutical care in relation to the consumer; uncontrolled and illegal intervention of conditional services and third parties in the process of drug delivery, who do not have the right to carry it out in Ukraine. However, the Law of Ukraine No. 904-IX dated September 17, 2020 does not refer to "electronic wholesale". Law of Ukraine No. 904-IX dated September 17, 2020 stipulates that in order to carry out electronic trade in medicines in Ukraine, economic entities must obtain a license for the retail trade of medicines and be included in the List of economic entities entitled to carry out electronic retail trade Such a list must be formed by the State Service of Ukraine for Medicinal Products and Drug Control (Derzhliksluzhba) and posted on the official website of this body with further maintenance and entry of information about such business entities, in particular: name of the business entity; addresses of the location and place of activity (with an indication of the pharmacies from which the medicine is delivered); the dates of the start of activities in the electronic retail trade of medicines; website addresses used for these purposes; electronic medical information system used for these purposes

(if available)[21]. In accordance with the Law of Ukraine "On Medicinal Products", the procedure for the electronic retail trade of medicines and their delivery to consumers is determined by the Licensing conditions for the conduct of economic activity in the retail trade of medicines. According to these conditions, entities that have a license to carry out business activities in the retail trade of medicines can carry out electronic retail trade, as well as organize the delivery of medicines to the end consumer. Prior to this, the Law of Ukraine No. 904-IX dated September 17, 2020 "On introducing changes to Article 19 of the Law of Ukraine "On Medicinal Products" stipulates that the subject of state control is the implementation of electronic trading for any medical purpose, you can create your own web site for electronic commerce. On such a site, in addition to the assortment of trademarks, there should be information about the contact details of the authorized service as a licensing body that controls product quality, as well as a logo that is displayed on the site and makes a reference to the page of the List of business entities that have the right to establish electronic distribution of goods, The peculiarity of the functioning of such a site also means that you can do without consulting a pharmacist during treatment. This provision of the Law has caused a lot of controversy due to the fact that often in Ukraine a pharmacist is a representative of a pharmaceutical distribution company and receives a large share of the sale of such products. The Law of Ukraine dated September 17, 2020 No. 904-IX "On Amendments to Article 19 of the Law of Ukraine "On Medicinal Products" defines medicines that are not subject to electronic retail trade, in particular: medicines that are dispensed to citizens according to doctors' prescriptions (with the exception of -recipe); medicines, the distribution of which, in accordance with the law, is carried out with a license to carry out activities related to the circulation of narcotic drugs, psychotropic substances and precursors; potent, poisonous, radioactive and immunobiological drugs. This Law also states that an important and mandatory condition for an enterprise engaged in e-commerce of medicines is the presence of its own delivery service or a concluded delivery agreement with delivery services, which during delivery will be able to ensure compliance with the storage conditions of medicines. This Law establishes that it is the enterprise that has a license to carry out business activities in the field of retail trade in medicines that is responsible to the end consumer for maintaining the quality of the medicine and compliance with the storage conditions determined by the manufacturer to the end consumer, including

[21] Постанова КМУ «Про внесення змін до Ліцензійних умов провадження господарської діяльності з виробництва лікарських засобів, оптової та роздрібної торгівлі лікарськими засобами, імпорту лікарських засобів (крім активних фармацевтичних інгредієнтів)». Документ 809-2023-п, чинний, поточна редакція – Прийняття від 04.08.2023. URL: https://zakon.rada.gov.ua/laws/show/809-2023-%D0%BF#Text (дата звернення: 29.05.2024).

when delivering the medicine sold remotely. A licensee conducting electronic retail trade of medicines must ensure protection and non-disclosure of confidential information, in particular personal data of medicine customers, in accordance with the Law of Ukraine "On the Protection of Personal Data"[22].

In the 2024 year, the Law of Ukraine dated September 17, 2020 No. 904-IX State Service of Ukraine has been developed and submitted to a large-scale discussion of the draft resolution to the Cabinet of Ministers of Ukraine "On making changes to the License Many minds promote government activity from the production of medicinal products, wholesale and retail trade medicinal products, import of medicinal products (except active pharmaceutical ingredients)"[23] The purpose of this project is to improve the requirements for providing the population with medicines and related goods using information and communication systems remotely (electronic retail trade of medicines), delivery of medicines to the end consumer. The requirements for electronic retail trade of medicinal products and their delivery to consumers are also being improved, in particular for the website of the licensee that has the right to carry out electronic retail trade of medicinal products. In particular, it is proposed to establish that a licensee who has the right to carry out retail trade in medicinal products may dispense medicinal products from pharmacies and their structural subdivisions upon the prior order of the consumer. The draft Resolution stipulates that the posting of offers for the sale of medicinal products based on the consumer's prior order may be carried out exclusively on the website of the licensee, which has the right to carry out electronic retail trade of medicinal products, and information about such a website is included in the List of business entities, which have the right to carry out electronic retail trade of medicinal products.

In addition, it is proposed to establish that the website, information about which is available in the List of business entities entitled to carry out electronic retail trade of medicinal products, can be used by several licensees for the organization of electronic retail trade of medicinal products. The draft Resolution regulates the procedure for placing information on the website, which is used to carry out electronic retail trade of medicinal products to licensees, including regarding the services of pre-ordering medicinal products by the consumer.

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[22] Закон України «Про захист персональних даних» Документ 2297-VI, чинний, поточна редакція – Редакція від 27.04.2024, підстава – 3585-IX URL: https://zakon.rada.gov.ua/laws/show/2297-17#Text (дата звернення: 29.05.2024).

[23] 22. Проєкт постанови КМУ «Про внесення змін до Ліцензійних умов провадження господарської діяльності з виробництва лікарських засобів, оптової та роздрібної торгівлі лікарськими засобами, імпорту лікарських засобів (крім активних фармацевтичних інгредієнтів)» Опубліковано 18.04.2024 о 16:00. URL: https://www.dls.gov.ua/projects_reg_acts/проєкт-постанови-кабінету-міністрів-12/(дата звернення: 30.05.2024).

In accordance with this project, in order to obtain a license for the electronic retail trade of medicinal products, the business entity must provide information on the availability of the material and technical base and qualified personnel necessary for conducting business activities in the electronic retail trade of medicinal products, a copy of the contract with the postal operator on the delivery of medicinal products to the final consumer, a copy of the agreement on the use of the website of the licensee who has the right to carry out electronic retail trade of medicinal products and information about which is included in the List of business entities entitled to carry out electronic retail trade of medicinal products (in the case absence of own website).

In order to organize and carry out the electronic retail trade of medicines, the licensee is obliged to approve written standard working methods (standard operating procedures), which describe, in particular, work on receiving, registering, forming, storing, delivering orders for medicines, providing consultations, and as well as dispensing medicines to the end user. Also, the licensee is obliged to ensure compliance with these rules. In order to organize the electronic retail trade of medicines, the licensee appoints at least one person who accepts and completes orders, provides advice when ordering medicines through the website. The person(s) entrusted by the business entity with the responsibilities of accepting, filling drug orders, and providing advice when ordering a drug must be in employment with the licensee and meet the qualification requirements.

The licensee provides initial and periodic training of its personnel, who are involved in the processes of organization and implementation of electronic retail trade of medicines in accordance with the duties of the personnel. At the request of the consumer during the acceptance and completion of the order of medicines, the responsible person is obliged to provide appropriate advice, to inform the consumer about the indications for the use of the medicine ordered by the consumer, its retail price, expiration date, conditions of release, storage conditions, interaction with other drugs, analogues within one international non-proprietary name of drugs, return conditions, payment conditions, delivery conditions. The formed order is packed by an employee of the licensee in transport packaging, which must ensure the protection of medicines from external influences and the storage conditions of medicines specified by the manufacturer, during their transportation with the possibility of monitoring unauthorized interference with the transport packaging. In the event that medicines require different conditions of storage and/or delivery, such medicines are packed in different transport packages. The delivery of the ordered medicines is carried out by the licensee exclusively from the pharmacy establishment of such a licensee, information about which is

available in the List of business entities entitled to carry out electronic retail trade of medicines[24].

The customer has the right to refuse the delivered medicines upon receipt and has the right to demand a refund from the licensee who sold such medicines in the event of: damage to the primary and/or secondary packaging of the medicine; the expiration date of the medicinal product has expired; a ban on the sale and use of medicines has been published by the authorized body; the delivered order does not correspond to the ordered quantity or composition, name, dosage, release form, price. The consumer has the right to return it to the licensee's delivery service employee who made the delivery, without paying for the delivered goods and/or delivery services and/or to demand proper execution of the order.

The development of e-pharmacies in Ukraine has its own problems and prospects. The study of the state of e-pharmacies by the digital agency UAMASTER showed that the number of Ukrainians who started ordering medicines online doubled in 2020.This is obviously due to the COVID-19 pandemic. Currently, more than 40% of customers of pharmacy chains place orders on the Internet, and their number is increasing. UAMASTER investigated online pharmacies in Ukraine from February to April 2021 using the SimilarWeb service. The traffic leader was "Social Pharmacy" (https://1sa.com.ua/) with 4.9 million sessions per month. The second place in this period was held by "Apteka dobroho dnya") with an indicator of 4.2 million sessions per month. "Apteka 911" (https://apteka911.ua/) in terms of the number of sessions it took the third position in the category with an indicator of 3.8 million sessions per month, although it was during this period that it changed the domain zone. The leader among price aggregators by all indicators was tabletki.ua: more than 6 million sessions per month, session duration 4:57 minutes and 6.86 page visits per session. YouTube is the most popular social network for attracting traffic: liki24.com receives 67.15% of its traffic from YouTube, 14.95% from Facebook, 11.30% from Vkontakte and 6.6% from other sources; tabletki.ua receives 54.73% of referral traffic from YouTube, 17.93% from Facebook, 6.42% from Vkontakte, the rest from others[25].

In many localities in Ukraine, the number of traditional pharmacy stores is important, as they offer a wide range of products and services. This may be the reason for high competition for e-pharmacies. Traditional pharmacy

[24] Закон України «Про затвердження Ліцензійних умов провадження господарської діяльності з виробництва лікарських засобів, оптової та роздрібної торгівлі лікарськими засобами, імпорту лікарських засобів (крім активних фармацевтичних інгредієнтів» від 30.11.2016. URL: https://zakon.rada.gov.ua/laws/show/929-2016-%D0%BF#Text (дата звернення: 30.05.2024).

[25] Дослідження УАМАСТЕР: інтернет-аптеки у 2021 році. URL: https://blog.uamaster.com/research-online-farmacies/ (дата звернення: 30.05.2024).

services can provide specialized services such as medical consultations, customization of health parameters, and the creation of individual prescriptions, etc.. Some traditional pharmacy practices already provide great brand recognition and customer confidence. This may be a disadvantage for e-pharmacies in a competitive environment, but they will be responsible for preserving the trust of clients through the online platform. One of the advantages of Internet pharmacies can be a more competitive price proposition for medical goods and services that is equal to traditional pharmacy rates. Some traditional pharmacy companies are also actively developing their online sales channels and working with Internet pharmacies or creating other online platforms.

The prospects for the development of e-pharmacies are connected with their unique capabilities[26]. Online pharmacies can:

– expand assortment with a wider range of products: liqueurs, vitamins, cosmetics, dietary supplements, sanitary and hygienic products, medical supplies and other health care products;

– provide consultation services with physicians, such as pharmacists, doctors and other medical specialists;

– develop virtual prescription programs that allow clients to obtain an electronic prescription from a doctor and obtain necessary medical care online;

– expand the service of home delivery and manual methods;

– organize promotions, discounts, special offers and loyalty programs that stimulate purchases and customer satisfaction;

– develop mobile applications for manual procurement of medical goods and services, obtaining consultations and virtual prescriptions, and enhancing other functions to facilitate interaction with clients;

– use proprietary intelligence to analyze customer data, recommend products and services, personalize propositions, and manage inventory;

– combine with medical services and telemedicine platforms for consultation with doctors, diagnostics via additional video communication and remote monitoring of patients;

– using blockchain technology to save medical data, transactions and other critical information flows;

– install partnerships with clinics to provide medicine delivery services to patients, carry out loyalty programs and promotions for patients;

– consider the possibility of developing a network of pharmacy points in conjunction with medical facilities.

[26] Технології в інтернет-аптеці: інновації та перспективи. Райан Ріенер, 10.11.2023. URL: https://www.nikopoltoday.com/article-6798/ukraina-tehnologii-v-internet-apteci-innovacii-ta-perspektivi/ (дата звернення: 30.05.2024).

Internet pharmacies can cooperate with medical institutions to conduct joint medical events that contribute to education and popularization of a healthy lifestyle among the population. Cooperation with medical institutions allows e-pharmacies to develop specialized programs and services for specific groups of patients, such as patients with chronic diseases, the elderly, children, etc. Partnerships with medical institutions can facilitate R&D and clinical trials, giving e-pharmacies access to the latest medical technologies and developments. which can significantly improve efficiency and user interaction.

CONCLUSIONS

The regulatory and legal regulation of electronic trade in medicines in Ukraine and EU countries, as well as in other countries of the world, is considered. It has been established that today e-pharmacies operate in most EU countries (France, Great Britain, the Czech Republic, the Netherlands, Germany, Italy, Spain, the Republic of Poland and others), North American countries (USA, Canada), countries of the Asia-Pacific region (China, India, Japan, Australia).

In general, differences at the level of the legal framework reflect the peculiarities of the development of pharmacies and the health care system in individual EU countries and the world. It has been established that the procedure for dispensing and sending medicines via the Internet in most EU countries has requirements similar to those applied to dispensing in the usual manner. In some countries, additional requirements are provided, which are usually described in a separate special section "Rules for the proper dispensing of medicines" in accordance with the regulatory legislation of each individual country.

Many countries include regulations on planning the optimal network of pharmacies to ensure universal access to medicines for consumers and professionals in the field of pharmacy. Similarly, some countries allow the implementation of alternative forms of dispensing drugs, and the range of such options is quite large.

The conducted analysis of the regulatory and legal regulation of electronic trade in medicines in Ukraine proves that a number of adopted legislative acts laid the foundation for the legal regulation of electronic trade in medicines in Ukraine, giving the right to a business entity that has a license for retail trade in medicines to implement e-pharmacies in the territory of Ukraine.

In general, the introduction of an e-pharmacy in Ukraine is an important step to ensure the availability of medicines for every citizen. Many issues have already been resolved in the state: settlement of the issue of delivery of medicines to end users in terms of ensuring the quality of medicines, protection of the end user from violating the rules of dispensing and delivery of drugs, as well as from falsified medicines, settlement of the issue of

bringing a person to administrative and criminal liability for violation of the rules release and delivery,

In the future, it is necessary to form an effective state policy in Ukraine to ensure the development of the functioning of e-pharmacies using international experience in this field and with the aim of ensuring the proper quality of public service.

SUMMARY

The development of modern digital technologies (digitalization) has provided a vector impetus for the sustainable development of all branches of the national economy in general and, in particular, medicine and pharmacy. The monograph analyzes the principles of legal regulation of electronic trade in medicines in Ukraine, as well as the peculiarities and differences of domestic legislation from regulations of other countries of the world. The evolution of IT technologies contributed to the improvement of the personal comfort of all people and the emergence of e-pharmacies in the world. The recession of the world economy, the worldwide spread of the COVID-19 pandemic affected the need to ensure the availability of vital medicines and became the basis for the introduction of remote retailing of medicines. In Ukraine, this process was facilitated by such disappointing circumstances as the aggression of the russian federation and the establishment of martial law in the country. The first chapter of the monograph "Digital technologies in pharmacy: the electronic pharmacy system and the European experience" examines the regulatory and legal basis of the functioning of the electronic sale of medicines in European countries and other parts of the world. The rules and regulations for providing information about medicines in electronic trade, as well as requirements for accompanying documents and protection of consumer (patient) rights when receiving ordered medicines, were considered.

In the second chapter of the monograph "Organizational and legal regulation of the electronic trade in medicines in Ukraine: problems and prospects for the development of Internet pharmacies" the legislative and regulatory acts on the electronic trade in medicines in retrospect and currently in force are elaborated, the differences of the domestic rules of the electronic trade in medicines are determined, analyzed disadvantages and development prospects of this direction of public service by pharmacy institutions.

It was established that the analysis of the administrative and legal regulation of electronic trade in medicines in the country allows us to conclude that a number of adopted legal acts laid the foundation for the legal regulation of electronic trade in medicines in Ukraine. The introduction of an e-pharmacy in Ukraine became an important step to ensure the availability of medicines for every citizen. The domestic legal framework contains decisions on a number of issues: regulation of the delivery of medicines to end users in terms of ensuring the quality of medicines, protection of the end user from violating

the rules of dispensing and delivery of medicines, as well as from falsified and counterfeit medicines, regulation of the issue of bringing a person to administrative and criminal liability for violation of dispensing and delivery rules, settlement of the issue regarding the specifics of the use of payment transaction recorders during the delivery of medicines to the consumer.

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Information about the authors:
Krychkovska Aelita Myronivna,
https://orcid.org/0009-0006-0783-7059
Candidate of Pharmaceutical Sciences,
Associate Professor at the Department of Technology of Biologically Active Compounds, Pharmacy and Biotechnology,
Lviv Polytechnic National University
12, Stepana Bandery str., Lviv, 79013, Ukraine

Zayarnyuk Nataliya Leonidivna,
https://orcid.org/0000-0002-5507-5873
Candidate of Pharmaceutical Sciences,
Associate Professor at the Department of Technology of Biologically Active Compounds, Pharmacy and Biotechnology,
Lviv Polytechnic National University
12, Stepana Bandery str., Lviv, 79013, Ukraine

Hrabovych Bohdan Andriiovych,
https://orcid.org/0009-0000-4603-4597
Student of group FR-41 at the Institute of Chemistry and Chemical Technologies,
Lviv Polytechnic National University
12, Stepana Bandery str., Lviv, 79013, Ukraine