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QUALIFICATION WORK

on the topic: **«RESEARCH ON REGULATION OF INTERNET PHARMACIES AND E-COMMERCE OF MEDICINES»**

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ANNOTATION

The qualification work highlights the current problems of the implementation of online pharmacies and the main aspects of regulation as a general basis for solving these problems. An online pharmacy, internet pharmacy, or mail-order pharmacy is a pharmacy that operates over the Internet and sends orders to customers through mail, shipping companies, or online pharmacy web portal. The work presents an overview of the diversity of the legislative and regulatory framework, which reflects the specifics of e-pharmacies, as well as the challenges that the legal and regulatory framework aims to correct.

The qualification work is laid out on 52 pages, consists of an introduction, 3 sections, general conclusions, a list of used sources.

Key words: e-commerce, regulation, pharmaceutical market, internet pharmacy, heath care.

АНОТАЦІЯ

У кваліфікаційній роботі висвітлено актуальні проблеми впровадження інтернет-аптек та основні аспекти регулювання як загальної основи вирішення цих проблем. Інтернет-аптека, онлайн-аптека або аптека, яка здійснює замовлення поштою, - це аптека, яка працює через Інтернет і надсилає замовлення клієнтам через пошту, транспортні компанії або веб-портал онлайн-аптек. У работі представлено огляд різноманіття законодавчої та нормативно-правової бази, що відображає специфіку електронних аптек, а також виклики, які нормативно-правова база має на меті виправити.

Кваліфікаційна робота викладена на 52 сторінках, складається із вступу, 3 розділів, загальних висновків, списку використаних джерел.

Ключові слова: електронна комерція, регулювання, фармацевтичний ринок, Інтернет-аптека, охорона здоров'я.

CONTENT

ABBREVIATIONS

ANAM – National Health Insurance Agency

EMA – European Medicines Agency

EU-European Union

EC-European Commission

FDA – Food and Drug Administration

FIP - International Pharmaceutical Federation

GMP – Good Manufacturing Practice

ICESCR - International Covenant on Economic, Social and Cultural Rights

MENA - Middle East and North Africa

MP-Medical Products

NMRAs - National medicines regulatory authorities

NHS - National Health System

NDP - National Drug Policy

NEMLs - National Essential Medicines Lists

OPs – Online Pharmacy

OTC - Over-the-counter

PC - Pharmaceutical Care

POM - Prescription-only medicines

HTA – Health Technology Assessment

OECD – Organisation for Economic Cooperation and Development

RAs - Regulatory authorities

WHO - World Health Organization

INTRODUCTION

Relevance of a subject. The introduction of the Internet has revolutionized the world of shopping. Most purchases are made exclusively through online e-commerce platforms. E-commerce of medicines has been extensively spread worldwide. Many reasons influence consumers to purchase their medical needs through the Internet, including low cost, availability, accessibility, and time saving. However, most of these medicines are substandard and counterfeit. The pandemic has changed the way we buy and sell things. The medical industry is not an exception. More and more people (especially the elderly) don't want to leave their homes for no good reason and prefer to order goods online. According to Fortune Business Insights, the Global ePharmacy market size is projected to reach $177 billion by 2026. eCommerce penetration drives the industry forward, so the number of people who order medicine online will only grow. E-Pharmacies can reduce the cost of medicines and provide better service, accuracy, and efficiency in medication management. With online medication management service, drug stores will decrease their error rates and provide the right medications and dosage forms. Online medicine delivery reduces medical waste and decreases the risk of unused pills being disposed of into land or water supplies. The favorable regulatory framework, medical product innovations, high penetration in the emerging market, and growing pharmaceutical companies toward OTC drugs from Rx drugs are among the top trends driving the global online pharmacy market growth.

The online trade in medicines is clearly regulated on the basis of European legislation. Most EU Member States have made it possible for stationary pharmacies to sell OTC drugs online, and have defined a list of requirements that such pharmacies must comply with. In some countries, online sales of prescription drugs are allowed due to the developed system of electronic prescription, in particular, in Sweden, Estonia, Finland, Germany.

In this work, we examined the main problems of legalization and development of Internet sales of medicines in the world. They revealed the content of the term "Internet pharmacy" and the process of transition from the format of an online

showcase to the activities of an Internet pharmacy with the right to make an act of sale and purchase of medicines. We have identified the prerequisites for the growing need of the population in the online trade in medicines in the context of the development of the digital economy and the COVID-19 pandemic.

To achieve the put purpose the following **tasks** of the research were definite:

- to study of modern approaches to the regulation of pharmacy establishments;
- to investigation of the implementation of e-commerce in the pharmaceutical market;
- to analysis of the legal framework for the regulation of online pharmacies: world experience.

The subject of the study is administrative and legal regulation of epharmacies.

The objects of the study were:

- statistical and informational materials of health authorities;
- data from WHO, as well as other international organizations on the organization of the work of online pharmacies;
- legislative and normative acts regulating online pharmacy.

Methods of researches. The research used a system-overview, analytical and structural-logical methods of analysis.

The practical significance of the work. An analysis of the organization of online drug sales in the US and EU countries, made it possible to identify factors contributing to this situation in relation to developing countries.

Scientific novelty. Attractive and negative factors for customers when buying online medicines are highlighted.

Structure and volume. The qualification work consists of the introduction, three chapters, conclusions and the list of the studied literature. The total amount of the qualification work makes 52 pages of the text, including 10 tables and 10 drawings. The bibliography contains 63 names of the studied literature.

CHAPTER 1. SCIENTIFIC FOUNDATIONS OF STATE REGULATION AND CONTROL OF PHARMACEUTICAL ACTIVITIES.

1.1. Theoretical aspects of pharmaceutical regulation.

Regulations play an important and necessary role in our society. They are laws created by government agencies. The legislative branch passes laws known as statutes which form the legal basis for establishing new governmental agencies. Regulatory role of government involves regulation of various business and economic activities by directing the businesses with set of controls. These regulations aim to prevent concentration of power in few hands, localization of business few areas. These controls include general norms and standards.

State policy in health care is defined as the set of accepted national decisions or commitments to preserve and strengthen the physical and mental health of the population of the country as an essential component of national wealth through the implementation of population policy, institutional, economic, legal, social, cultural, research, prevention and health measures to preserve the gene pool of the nation, its humanitarian potential and taking into account the requirements of present and future generations in the interest of a specific person (individual) and society as a whole.

Drug regulation is a complex process in which a number of activities are carried out to ensure the safety, efficacy and quality of medicines, as well as the adequacy and objectivity of drug information. The ultimate goal of pharmaceutical regulation is to ensure and protect public health.

Due to their specificity, medicines cannot be considered by either state or commercial structures as an ordinary product. In particular, public authorities should be held responsible for regulating the production, import, export, storage, distribution, sale and supply of drugs - from innovative to long-used drugs, from locally produced drugs to those imported into the country by public or private organizations.

Over the years, individual countries, WHO and other international organizations have taken steps to improve the regulatory process at the national and

interstate levels [61]. These steps included the development of relevant norms, standards, organizational principles and guidelines. However, despite the efforts made, only a few countries have a well-established system.

The viability of regulatory systems in the pharmaceutical sector may be due to various factors, but the most significant are:

- political and socio-economic environment;
- drug policy and legislation;
- organizational structure of the regulatory system;
- strategies for regulation and enforcement;
- human and financial resources;
- level of corruption.

The theoretical aspects of pharmaceutical regulation refer to the fundamental principles guiding regulatory activities [63]. The main functions of the regulatory authorities in the pharmaceutical market fig.1.1.

functions	creating and maintaining systems that ensure compliance with pharmaceutical requirements at all stages: development, import, production, transportation, sale (trade), consumption, disposal etc.;
	authorizing (registering) medicinal products;
	monitoring (pharmacovigilance) market agents' activities in order to ensure safety and quality of medicinal products at all stages of their circulation;
	issuing licenses for business activities;
	developing pricing policies and reimbursement strategies.

Fig.1.1 Functions of the regulatory authorities in the pharmaceutical market.

The need to have access to safe and effective medicines is so important that it has been designated as a basic human right by the World Health Organization [63]. Drug regulation should ensure that only products of proven quality, safety and efficacy are available on the market.

Given its potential impact on public health, the development, manufacturing, marketing and sale of pharmaceuticals is a highly regulated business. The primary classical aim of regulatory activities is to protect the public from harmful medicinal products and ensure that those with a favorable benefit–risk balance is approved and made available. It is possible to single out the main aspects of the regulation of pharmaceutical sector [56].

Risk-benefit assessment is a key theoretical aspect of pharmaceutical regulation. Before a drug can be approved for use, regulators must assess its potential risks and benefits. This involves evaluating the drug's effectiveness in treating the targeted condition and weighing it against any potential adverse effects. The risk-benefit assessment is an ongoing process as regulators continuously monitor drugs for any adverse effects and update their risk-benefit profile.

Another important theoretical aspect is *evidence-based medicine*. Regulators rely on clinical trials and scientific data to make decisions about drug approvals and labeling. This ensures that decisions are based on objective, verifiable data rather than subjective opinions or biases. The evidence's totality, including positive and negative results, must be considered when evaluating a drug.

Transparency is also a crucial theoretical aspect. Regulators must be transparent about their decision-making processes, including the evidence used to make decisions and any conflicts of interest. This helps to build trust between regulators and the public and ensures that decisions are based on sound scientific principles. Patient safety and public health are guiding principles of pharmaceutical regulation. The primary goal is to protect patients from harm and ensure they have access to safe and effective medicines. Regulators must balance this goal with promoting innovation and developing new therapies.

One of the primary goals of pharmaceutical regulation is to ensure that drugs are safe for use by patients. To achieve this goal, regulatory agencies require pharmaceutical companies to conduct extensive preclinical and clinical trials to establish the drug's safety profile.

The regulatory framework also requires pharmaceutical companies to adhere to strict quality control measures during manufacturing to ensure that the drug is produced consistently and to the highest quality standards. Another critical aspect of pharmaceutical regulation is the assessment of the drug's efficacy. Regulatory agencies require pharmaceutical companies to demonstrate the drug's effectiveness through well-designed clinical trials. This ensures that patients receive medicines that have been shown to be effective and that provide the intended therapeutic benefit. In addition to safety and efficacy, pharmaceutical regulation also addresses issues related to access and affordability.

Regulatory agencies may take steps to promote competition in the pharmaceutical industry to ensure that patients have access to a range of affordable medicines. They may also work to ensure that medicines are accessible to patients in developing countries who may not have the financial resources to purchase expensive medications.

Another *crucial theoretical aspect of pharmaceutical regulation is the role of clinical trials.* Clinical trials are designed to gather data on the safety and efficacy of drugs before they are approved for use. The regulatory authorities require clinical trial data before approving a drug for use. Clinical trials are designed to minimize the risks to participants and to ensure that the data collected is accurate and reliable.

Pharmaceutical regulation also covers guidelines on the manufacturing and quality control of drugs. These guidelines aim to ensure that drugs are manufactured in a safe and controlled environment and meet quality standards. Manufacturing guidelines cover everything from the sourcing of raw materials to the final packaging and labeling of the product. Quality control guidelines are in place to ensure that the finished product meets the required standards and is safe for use.

The regulatory framework for pharmaceuticals is often complex, involving multiple regulatory bodies at national and international levels. For instance, in the United States, the Food and Drug Administration (FDA) is responsible for the regulation of pharmaceuticals, while in Europe, the European Medicines Agency (EMA) oversees the regulation of medicines [27]. Additionally, the International

Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) provides guidelines on pharmaceutical regulation that are accepted worldwide.

Moral considerations play a decisive role in pharmaceutical regulation. Ethical guidelines are in place to ensure that the rights and welfare of patients are protected during clinical trials and that drugs are marketed in an ethical manner.

1.2 The role and importance of pharmacies as health care institutions.

The practice of pharmacy, which can trace its antecedents back several thousand years, has for most of its history combined elements of a scientific or technical occupation with elements of the merchant's trade. In this century scientific and technical progress and the effects of new marketing techniques have had a tremendous impact on pharmacy. The basic functions of pharmacists have been radically affected and serious problems of adjustment have arisen due to changes originating within as well as without the pharmaceutical industry and which for the most part were beyond the control of pharmacists.

Increased complexity, in a field such as pharmacy, frequently creates problems which lead to the enactment of additional laws to protect the public weal. This has been true for pharmacy in this century. The number of potentially harmful drugs and medicines has grown tremendously and the control of their preparation and distribution has become the subject of several state laws.

Community pharmacy, also known as retail pharmacy, is the most common type of pharmacy that allows the public access to their medications and advice about their health. Traditionally known as a chemist, it is the healthcare facility that is responsible for the provision of pharmaceutical service to a specific community group or region.

Most community pharmacies have a commercial store with a combination of medicinal goods only available with a prescription and those with that can be purchased over-the-counter (OTC).

Community pharmacists are considered to be the most accessible health professional to the public, as they are available to provide personalized advice about health and medicine on a walk-in basis, without the need for an appointment.

Pharmacy is involved to some degree, in all the processes of getting drugs and medicines from their original sources to the ultimate consumer including [56]:

1. basic research in developing new products or improving existing ones;
2. collecting drugs from their original sources;
3. manufacturing crude drugs in bulk;
4. formulating bulk drugs into dosage forms at the point of manufacture;
5. and marketing.

These activities may be summarized or listed extensively.

The definition of a pharmacy differs from country to country, although most define it as a type of healthcare facility that provides certain services or fulfills a certain mission in relation to medicines. The main task of a pharmacy is to dispense medicines, usually through a registered pharmacist who has the education, skills and competence to provide professional services to the public.

The regulatory authorities of each country are responsible for the following functions related to pharmacies [2]:

- accreditation of the pharmacist's initial education;
- registration/licensing and relicensing of a pharmacist;
- specialization of community pharmacists;
- accreditation of continuing education;
- defining the rules and standards a community pharmacist must follow;
- ensuring that the pharmacist complies with the rules (through inspection and disciplinary action).

There are different types of the pharmacies. They range from minor, individually owned pharmacies in the remote rural towns to large chains in main shopping malls and supermarkets.

The types of these pharmacies organizations also depend on the regulations in that area. For example, in the United States pharmacies in large chains independently

owned pharmacies. This is in contrast to many of the countries in Europe that limit pharmacies to be owned by the registered pharmacist, who is restricted to owning less than the certain number of pharmacies, making large chains impossible [3,15,56].

For instance, community pharmacies are defined in Spain as “private health establishments of public interest, subject to health planning which must provide [a series of services]” (79: article 1), outlining 10 essential services that pharmacies must deliver. In Serbia the definition is “a health care facility where pharmaceutical care is provided at primary level” (37: article 100; in France it is “an institution in charge of the dispensing of medicines as well as other products [mentioned in another article] as well as compounding” (26: article L5125-1) [26,37,56].

In Germany pharmacies are defined as in charge of ensuring the proper supply of medicines to the public in the public interest (47: article 1); in the Netherlands as a premises (or several premises) in which medicines are prepared, dispensed and kept in stock for the purpose of dispensing, or are only dispensed and kept in stock for this purpose (80: article 1.) [4,56].

The definition in Slovenia is “a public health service, which ensures the permanent and uninterrupted care of the population and health care providers with medicinal products and the pharmaceutical treatment of patients” (32: article 5). Its purpose is to ensure “the quality and effective supply of medicines and other products to support treatment and health preservation and to advise on their safe, proper and effective use for patients and health care professionals” [3,32,50].

In Finland, a pharmacy is defined as “an operating unit providing pharmaceutical services, including the retail sale, distribution and preparation of pharmaceutical products, as well as counselling and other services related to pharmaceutical products” (36: article 38); in Lithuania as a legal entity “performing pharmaceutical activity including the acquisition, storage, sale (dispensing) of medicinal products to the ultimate consumer, the provision of pharmaceutical services and/or compounding and quality control of extemporaneous medicinal products” (81: article 2.51) [3,25,55,56].

1.3 A systematic review of modern approaches to the regulation of pharmacy establishments.

The past several decades has been a time of rapid globalization in the development, manufacture, marketing, and distribution of medical products and technologies. Increasingly, research on the safety and effectiveness of new drugs is being conducted in countries with little experience in research regulation. Additionally, biopharmaceutical companies seeking global markets need to submit applications for approval of a given product to the regulatory authorities of many different countries, each of which could introduce scientific requirements discordant with those of the manufacturer's home market. Differing data requirements across countries may necessitate additional clinical trials and animal studies, increasing the cost of potentially important medicines and slowing patient access to them. In many developing countries, regulatory capacity is insufficient to ensure a smooth process for new drug approval. Even after drugs are approved, international differences in systems to monitor the ongoing safety and quality of approved drugs slow recognition of any safety or manufacturing problems affecting public health. For reasons such as these, demand has been increasing for globally harmonized, science-based standards for the development and evaluation of safety, quality, and efficacy of medical products. The goal of such standards is to improve the efficiency and clarity of the drug development and evaluation process and, ultimately, to promote and enhance product quality and the public health.

Weak regulators threaten national and regional health security. Stronger regulatory capacity has benefits for the public and private sectors system-wide by improving treatment outcomes, reducing treatment costs, reducing antimicrobial resistance, reducing the availability of substandard and counterfeit medical products, and speeding up new drug applications. National medicines regulatory authorities (NMRAs), vary in capacity and need to work together to provide effective regulation and maximize use of resources. Regulatory collaboration and harmonization can improve operational efficiency and speed up market access for medicines of public health importance and new, advanced therapies.

The pharmaceutical market without state intervention and without state regulation cannot make production economically safe, ensure the realization of socio-economic human rights in the distribution of medicines, eliminate structural and regional inconsistencies in the supply of medicines and guarantee proper quality indicators of drugs that have entered circulation. Appropriate mechanisms are necessary to ensure effective state management of the pharmaceutical market fig. 1.2 [39].

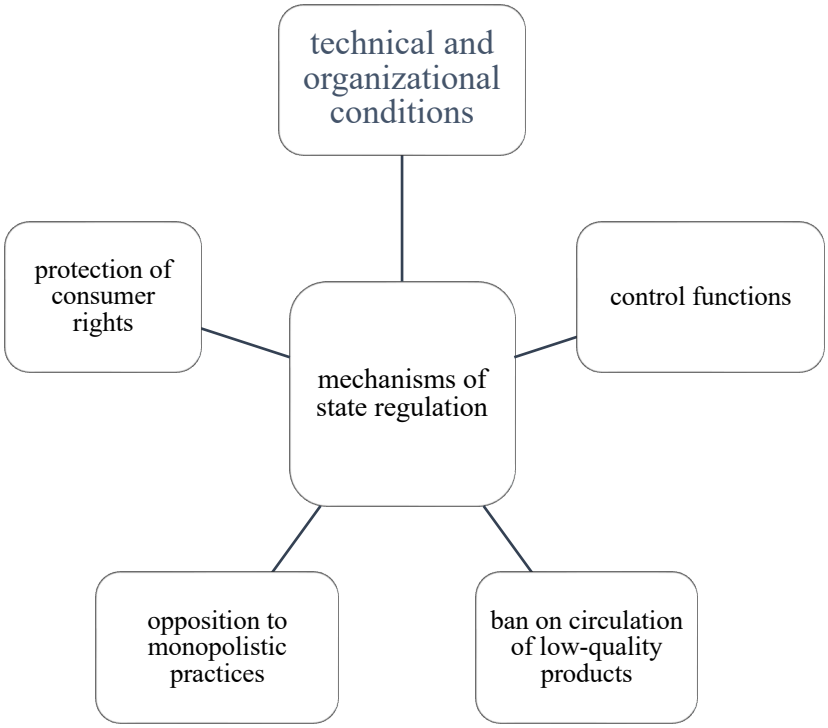


Fig.1.2 Mechanism of state regulation of the pharmaceutical sector.

Medicines are safely used every day to treat diseases, but there have been enough adverse events and even large-scale human disasters over the years to prove that medicines also carry risks. Daily adverse events may or may not be reported but evidence of harm can lead to regulatory change. It is often high-profile tragedies that bring about stricter regulation [3]. NMRAs, such as the US Food and FDA developed from the initial moves to control the development and sale of medicines following such incidents. This concept subsequently became established in most developed countries and it is a form of regulation that differentiates medicines from

other consumer goods. The regulation and enforcement systems for pharmacies vary greatly across countries, in terms of the type of regulators and their functions.

The three common pillars of medicines regulation are quality, safety, and efficacy fig.1.3 [30,44,56].

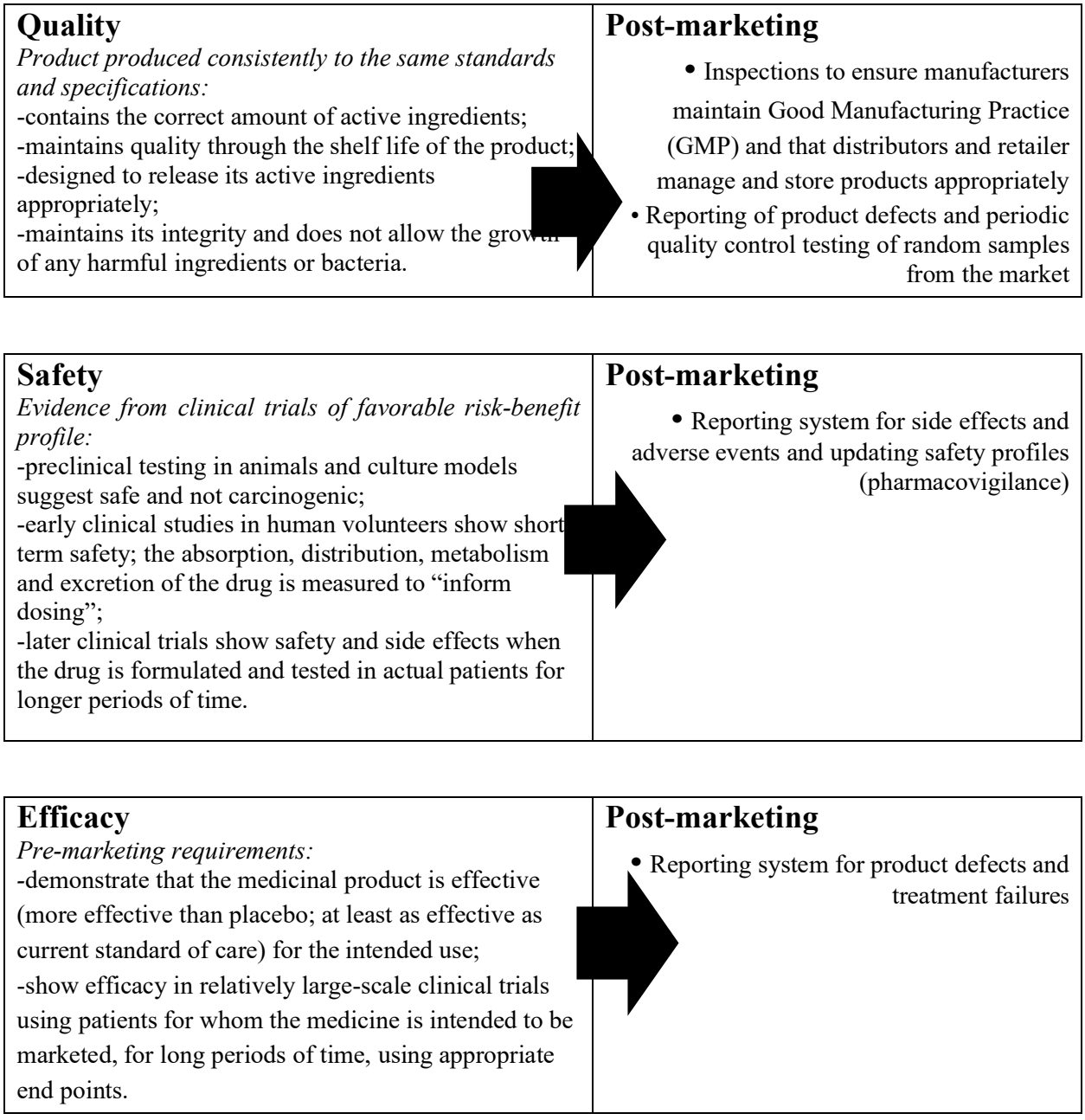


Fig.1.3 Medicines Regulation.

Only medicines that can satisfy these three criteria should be allowed onto the market. Companies wishing to sell a pharmaceutical or other regulated health care commodity are required to submit evidence in the form of a dossier to the NMRA

that their product meets the requirements of each of these criteria for marketing authorization to be granted.

Conclusions to the I Chapter

Based on the analysis of sources, it can be concluded that the processes in the pharmaceutical sector, which are constantly transforming, require thorough legal regulation. Among the means of regulatory influence of the state on the functioning of economic entities in the pharmaceutical industry, state assignments and orders, patenting and licensing activities, quotas, certification and standardization, the use of pricing regulation, the provision of benefits, as well as targeted innovations, are important.

A variety of forms and methods provides certain opportunities for business entities in the pharmaceutical industry. A single basic legislative act in the field of pharmaceutical relations does not exist in different countries. Nevertheless, the basic principles of regulation are used in all countries of the world economy. Pharmacies are a key unit of the pharmaceutical sector and their main function is to provide the population with quality, affordable and safe medicines. It is worth noting that ensuring the availability and physical availability of safe, effective and high-quality drugs for patients with minimal regulatory costs for both the state and business is an indicator of the effectiveness of the functioning of the pharmaceutical market.

CHAPTER 2. ASSESSMENT OF THE CURRENT STATE OF ONLINE PHARMACY AND OF THE E-COMMERCE OF MEDICINES IN WORLD.

2.1 Study of the implementation of e-commerce in the pharmaceutical market.

The Internet in its current state appeared in 1992. It was developed to ensure the interaction of remote computers as a decentralized geographically distributed network with many alternative storage points and ways of distributing information. The subsequent development of a number of programs that provide various types of network interaction, operating systems and navigator programs made it possible to use the possibilities of the new environment to the fullest extent.

Internet use is a part of everyday life, in which 80% of individuals in the European Union (EU) accessed the internet daily and two out of three Europeans (66%) ordered goods or services over the internet for private use as recorded in 2021 [21].

Today's Internet is the beginning of the e-commerce era. The information concept of the Web is beginning to fade into the background. In the first place is the use of the Internet in the commercial activities of enterprises. One of the main components of this process is trade, and trade not only in information products as the closest to the digital nature of the Internet, but also in traditional goods, including the pharmacy assortment.

Online markets allow you to conduct all the same entrepreneurial activities: look for suppliers and buyers, pay bills, draw up contracts, but do it all via the Internet, from one point. Naturally, special rules and regulations are being developed for this, unique software is being created, but the main idea is that e-commerce systems are available to everyone and everywhere where the Internet is.

The basic concepts of doing business on the Internet are "electronic business" and "electronic commerce". Electronic business is any business activity that uses the capabilities of global information networks to transform internal and external communications in order to create profit. The most important component of e-business is e-commerce [12,28,57].

There are 5 main forms that characterize this area of activity. Each of them has already become extremely popular and is used all over the world.

The main areas include:

1. Internet trading, absolutely any online store: in social networks, on the website, marketplaces.

2. Electronic Data Interchange (EDI), including simple information sites.

3. Internet banking and provision of insurance services through the network.

4. Automated systems for collecting, processing and storing data.

5. Marketing in the form of collecting information that can be used to build a customer base.

E-commerce is used in retail, wholesale trade. The development of electronic commerce using the Internet increases efficiency and makes significant changes in the organization of trade in goods and especially services. Traditional cost management, based on the analysis of the means used, is increasingly giving way to customer relationship management. In this environment, providers are focusing on retaining customers by offering value-added services while at the same time trying to better adapt to the disappearance of boundaries.

In terms of marketing, the pharmaceutical sector dominates all other sectors [57]. Through social media platforms and e-commerce websites, pharmaceutical companies market themselves online. Thus, customers can make online purchases. In today's world, online pharmacies have become an integral part of digital technologies.

The sale of medicines online has a rich history, especially in the USA, where Internet pharmacies appeared in early 1990s. Since then, many countries have developed their own Internet pharmacies and online medicine sales. Most distance selling is done by ordering the required medicine online and then delivering it [5].

Electronic commerce refers to any form of business transactions in which the interaction of the parties is carried out electronically instead of physical exchange or direct physical contact, and as a result of which the ownership or right to use a product or service is transferred from one person to another.

E-commerce combines a wide range of business operations, the main ones we have presented in the table 2.1[57].

Table 2.1

Main types of business operations in e-commerce

Business operations	**Example**
information exchange	
establishing contacts	between potential customers and suppliers
pre- and post-sales support	providing detailed information about products and services, documentation, answering customer questions, etc.
sale of goods and services	
electronic payment	including using electronic payment systems
distribution of products	including both delivery management and tracking for physical products and direct delivery of products that may be distributed electronically
the possibility of organizing virtual enterprises	groups of separate specialists or even independent companies to conduct joint commercial activities
implementation of business processes jointly managed by the company and its trading partners	

The emergence of the Internet has significantly reduced the cost of e-commerce due to the low cost of information transfer and led to the emergence of its qualitatively new forms.

There are a huge number of advantages of using online platforms, and each of them works to generate new profits for the company, but there are also the disadvantages of using the network, although all of them can be worked with, we have highlighted the main ones in (tabl.2.2).

Table 2.2

Advantages and disadvantages of online platforms.

Advantages	**Disadvantages**
• Opportunity to enter an expanded market at minimal financial cost. It does not matter how far apart the seller and the end consumer are, they will be able to find each other anyway. • The chain between the supplier and his client is significantly reduced. It does not require the involvement of intermediaries, which means that costs are reduced, but the original quality is maintained. In addition, it is easier to find your target audience. • By being able to always stay in direct contact with your customers, the productivity and competitiveness of companies increases. They can work around the clock, any day of the week and still not reduce the quality of service.	• Dependence on modern information and communication technologies, in other words, a stable high-speed Internet. • The absence of a well-developed legislative framework that allows regulating processes. • Loss of potential customers who do not like shopping online. For them, ordinary stores remain familiar. • The danger of loss of confidentiality when making transactions via the Internet. Buyers are at serious risk of losing their money, even with the constant development of security technologies. • An unresolved issue with the delivery of goods to the consumer, as well as the return of low-quality products.

As e-commerce and online pharmacies arose, the potential impact of the Internet on the world of health shifted from merely the spread of information to a real opportunity to acquire health services directly. Online pharmacies (OPs) rise complex issues in terms of patient-doctor relationship, consumer empowerment, drug quality, regulation and public health implications [52].

The main tasks that electronic pharmacies solve, we have identified in fig. 2.1.

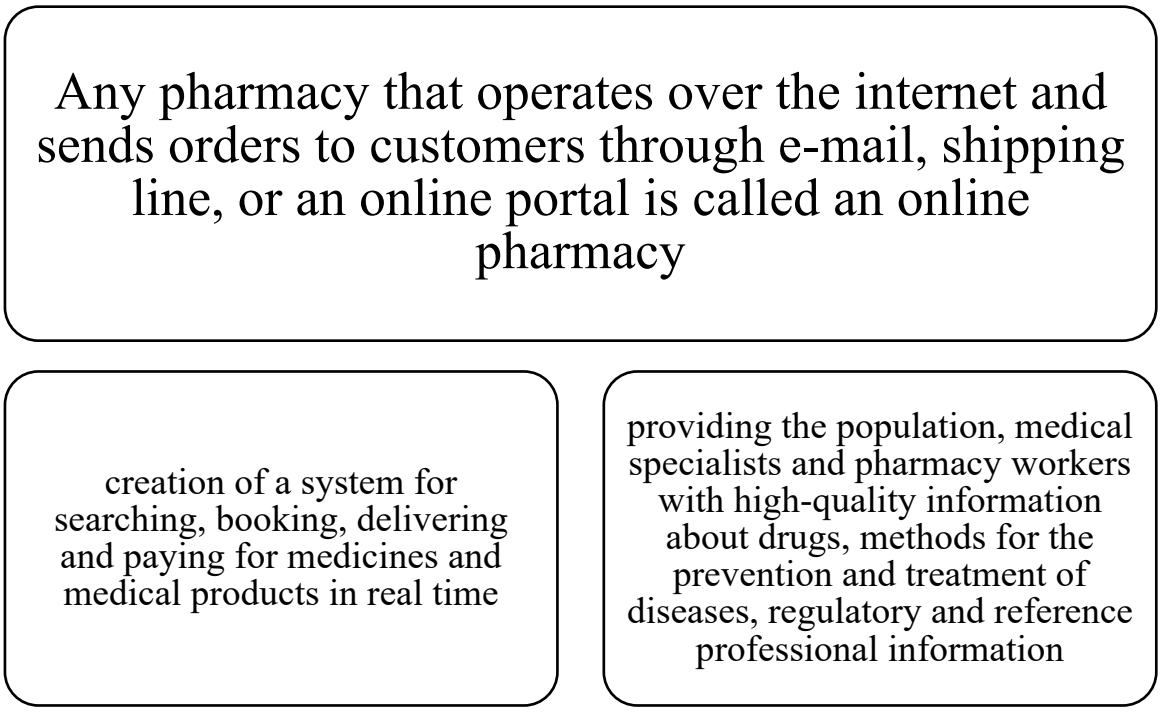


Fig.2.1 The main tasks that can be solved through an online pharmacy.

OPs have been a developing channel of the pharmaceutical supply since the beginning of the century. During the early development phase, due to the lack of national regulations and verification systems, low consumer experience, consumer trust, and a relatively low number of legitimate websites, the internet pharmacy market was considered a dubious channel of illegitimate sellers and a source for potentially counterfeit medications.

Today, online medicine purchase from legitimate and verified internet pharmacy websites has become an accepted practice among developed countries, especially experienced in major pharmaceutical markets in the United States, Germany and the United Kingdom. While initially the preserve of high-income countries, in the past decade e-market has been growing rapidly in low-income and middle-income country (LMIC) [5,19].

The global e-pharmacy market is currently worth around US$81.6 billion, and expected to grow to US$219.8 billion by 2028, at a CAGR of 20.1 % over the forecast period (2022 - 2028) fig.2.2. [8,19].

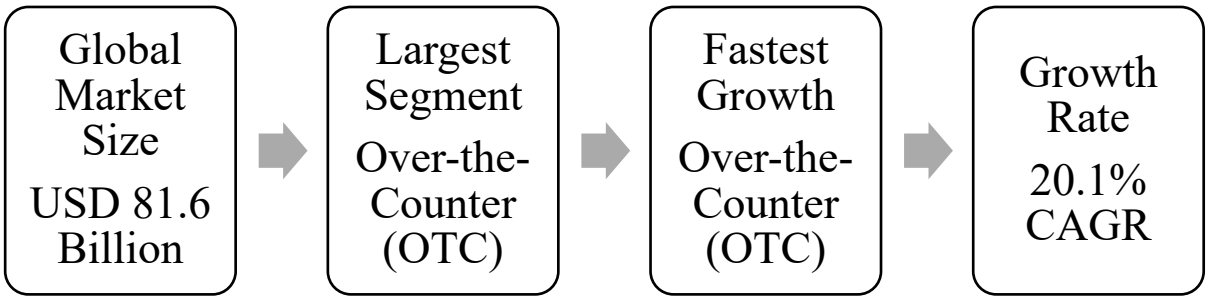


Fig.2.2 Structure of the e-pharmacy market.

Online purchase of pharmaceutical products has become a popular phenomenon and has been continuously spread almost all over the world since 1999 [47,48]. The rapid expansion of the e-pharmacy market has been largely uncontrolled and has been accompanied by significant public health challenges, such as the sale of prescription-only (POM) drugs without a prescription and inadequate provision of information to patients. In addition, non-health risks include consumer fraud and lack of data privacy. However, the benefits of e-pharmacies are clear, the main one is to provide potential x opportunities. to increase access to medicines. Buying medicines online can be quick, easy, convenient and private, and as internet and smartphone penetration increases, an e-pharmacy has the potential to improve access for the disabled, the elderly, and those living in rural areas [38,45,49].

The COVID-19 pandemic has accelerated the online purchase of goods and services, in which today's e-pharmacy is now an integral part of medical care in developed countries. Online pharmacies are utilizing different forms of technology to extend and enhance their site functionality, such as *video streaming on health topics* and *mobile apps* and *text reminders for ordering repeat prescriptions*. The inclusion of personal records of regular prescriptions also increases the involvement that a consumer might have with the online pharmacy.

The expansion of the Internet, the consumer experience of online shopping, the ease of mail shopping, and remote selling have contributed to the growth of the online pharmacy landscape. Changes in behavior aimed at seeking medical care, empowering patients and being open to self-diagnosis and self-medication, the

spread of the pandemic has further contributed to the development of the online pharmacy network (fig.2.3).

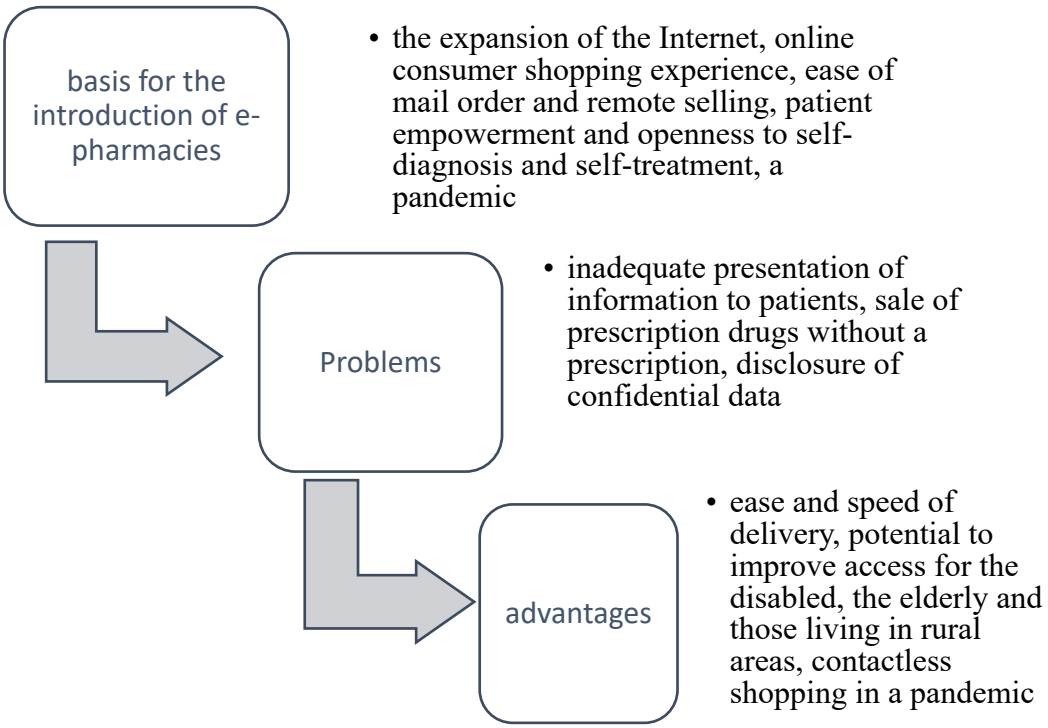


Fig.2.3 The main directions for the development of online pharmacies.

Global E-Pharmacy Key Market Trends [58]

One of the main trends that is driving the market is the increased demand and adoption of telemedicine. Individuals who have an affinity to IT are the ones who use telemedicine. With the help of this there is more transparency, awareness and access to several health care providers. This is one reason which is supporting the growth of the market.

Increasing penetration of e-commerce is another trend which is augmenting growth of the market. Some medicines are only available online and therefore patients prefer door step delivery of the medicines they easily cannot find. Millennials specially rely on online procurement of OTC drugs etc.

The rise of vitamin deficiencies among people is a factor that is boosting the growth of the market. Consumers are now aware of the importance of Vitamins and the need to include dietary supplements in their lifestyle, these factors will increase the demand for vitamins mainly through online platforms. Along with this the rise in the number of self-medication practices among the people is also deemed to

increase the sale of multivitamin products, because these products are easily available on ecommerce platforms, the e-pharmacy market will see significant growth.

2.2 Analysis of the place of online pharmacies on the World Wide Web.

The use of online services for the purchase of medicines - online pharmacies, is widespread in many countries. The main arguments used by adherents of this type of service are the opportunity to save time and money. However, despite all the benefits that online pharmacies offer their customers, there are certain risks. The positions of the governments of different countries on this issue differ significantly, as do their arguments.

The most promising and actively developing sector of the e-commerce market is the “consumer-pharmacy” sector, i.e. retail sales of pharmacy products to private individuals using the Internet. In many cases, virtual pharmacies are created on the basis of real pharmacy organizations that use a ready-made developed resource base (staff, warehouses, established contacts with suppliers, etc.). Internet pharmacies formed according to this principle carry out their functions in accordance with the legislation in force for real pharmacies.

The first online pharmacies such as drugstore.com, *“PlanetRx.com”* and *“Yourpharmacy.com”* appeared in the US in the late 1990s [21]. Their example was followed by local pharmacies, creating Internet resources as an addition to their core business. The development of this business in Europe was slower. A relatively small number of EU countries strictly regulate the activities of online pharmacies through mandatory special registration, as a result of which such companies are forced to operate within the legislative framework of a particular country. Among them are Denmark, Germany, the Netherlands, Sweden, Switzerland and the UK [20,24,39].

Germany represents the largest online pharmacy market, accounting for approximately 56% of the market share in 2019. The UK and France are, respectively, the second and third largest remote retail medicine markets [2,31,58]. Scandinavian countries are also actively developing the online pharmacy market. For example, the total e-commerce market in Sweden is estimated to be at least EUR

9 billion as of 2021. Pharmaceutical e-commerce is estimated to be around EUR 500–600 million, which represents around 6% of the total e-commerce market [3]. In the UK, the number of online pharmacies increased almost by 7 times between 2009 and 2020 (from 56 to 390) [4,51]. China is considered one of the most advanced countries that has been actively developing distance selling of medicines for several decades. As of 2019, it is estimated that online sales of medicines in China amounted to yuan (RMB) 13.8 billion, 115 times more than in 2012 (RMB 0.12 billion) [42-46,51]. Because online pharmacies are so diverse, it's hard to single out the individual ones. According to consumer preferences, the regulatory environment and the legitimacy of their operations are key influencers. OPs can be classified according to several aspects, mainly for reasons of legality and patient safety. Based on this feature, we have identified three categories:

- regular pharmacies, which are online branches of local pharmacies,
- legitimate websites of authorized distributors that provide delivery services to patients from neighboring pharmacies,
- and illegal websites that are not controlled by government health authorities [22].

According to the organizational structure at the present stage, the following types of online pharmacies can be distinguished:

- a pharmaceutical company from the very beginning created as an Internet project, within which appropriate infrastructure has been built;
- an ordinary pharmacy creates its own website, expanding the circle of potential customers;
- the service was created on the basis of several pharmacies into a structure that concludes a cooperation agreement with several pharmacies, coordinating the process of ordering and delivering goods from them;
- the company creates an online pharmacy based on a network of pharmacies, and the delivery of medicines is carried out by a courier from the nearest pharmacy [1].

The last type of online pharmacies is the most unreliable and most of the products they sell are substandard and fake (counterfeit).

The global OPs market is segmented **by Drug** in Prescription Drugs and Over-the-Counter. **By Product** type the E-pharmacy Market is segmented by Skin Care, Dental, Cold and Flu, Vitamins, Weight Loss, Other. **Based on region** E-pharmacy Market is categorized into: North America, Europe, Asia- Pacific, South America, and Middle East and Africa (MEA) [13].

An online pharmacy may perform any or all of a number of functions. After analyzing the literature on the topic of online pharmacies, we have identified their main functions and focus (tabl.2.3).

Table 2.3

Types of pharmacies in accordance with their functions

Functions	**Typology of online pharmacies**
• the sale or supply of medicines, including repeat prescription services; • the sale or supply of other healthcare products; • providing information about medicines; • providing advice about symptoms; • hosting online support groups.	• *Send prescription:* an existing prescription, written by a licensed practitioner, is sent to the online pharmacy by post, fax or email. • *Online consultation and prescription:* customers have to register with the pharmacy site, and then complete an online questionnaire. Based on the submitted information, a doctor prescribes a treatment, and the online pharmacy sells the medicines to the patient. • *No prescription required:* regulated medicines are sold without prescription. The site states that responsibility for the selection and purchase of medicines rests with the consumer. • *OTC medicines:* pharmacies selling only non-prescription medicines, including vitamins, dietary supplements and homeopathic remedies.

Some online pharmacies share useful information about medicines and illnesses. It provides links to useful information, as well as important medical resources, universities, and government agencies. The advantages and disadvantages of online pharmacies at this stage of development of the pharmaceutical sector have become the subject of great discussions. In order to understand the topic, it is necessary to highlight and compare the main advantages and disadvantages of online pharmacies. At another stage of the research, we conducted an analysis of this direction and presented it in table 2.4.

Table 2.4

Perceived benefits and risks of purchasing medicines online.

Benefits/Advantages	**Risks/Disadvantages**
•Lower prices • Privacy / Anonymity • Convenience (e.g. housebound patients) • Medical Information • Available 24 hours a day, 7 days a week • Added value through functionality like personal medication profiles • Price comparison possible through online mediators • Regulated medicines available without prescription • Not limited by traditional pharmacy supplies Access and convenience, patients, oppose security. The cost of drugs is an issue for all parties.	•Unlicensed dispensing • Counterfeit drugs • Lack of protection of personal and financial information • Lack of pharmacy information (e.g. address) • Additional fees (e.g. shipping fee, account set-up fee) • Prices can change quickly • Inadequate safeguards to personal health • Sale of medicines that are dangerous if taken without medical supervision • Pharmacist not always immediately available online • Fears about the integrity of the medicines supplied • Damage through inadequate storage or delivery precautions • Fears about the qualification of the prescriber • Bypassing the health professional-patient relationship • Limited participation by third-party payers

Most legal stores that work with OPs have a drug verification process. These stores request a prescription from a personal doctor or drug delivery is applied after completing a questionnaire about the patient's health status. These questionnaires are approved by a doctor before being distributed.

A strategic and holistic approach may help regulatory authorities more effectively regulate online pharmacies and e-commerce of medicinal products. This proposed strategic approach involves a stepwise implementation of a framework that comprises (a) guidelines, advisories, and warnings; (b) legislation; and (c) enforcement activities (fig.2.4). Stepwise implementation grants companies buffer time to modify their in-house policies to align with directions set by the regulatory authorities with oversight power. The success of the approach lies in the collaboration of the authorities (domestic and international) with various organizations (accreditation organizations, Interpol, and private companies) [11,31].

Fig.2.4 Stepwise implementation framework to regulate medicinal product e-commerce.

Pharmaceutical companies can help regulators expedite the verification process by checking with their respective supply chain partners to confirm that medicines sold by individual online pharmacies are from a legitimate source. Upon satisfactory screening, Internet pharmacies will be issued country-specific accreditation stamps for their websites and added to the register of Internet pharmacies, which can be found on the regulator's website.

Certification standards are quite universal for all countries, we have identified those that are mandatory for all e-pharmacies [55,56]:

Licensure. A merchant must possess all necessary licenses, registrations, or permits to practice in all required jurisdictions.

Prescription validity. A pharmacy must dispense or offer to dispense prescription drugs only upon receipt of a valid prescription.

Legal compliance. A merchant must comply with all provisions of jurisdictional laws, including laws addressing regulatory agency approval of the prescription medication.

Privacy. All patients' data must be stored and transmitted according to jurisdictional patient information privacy and security laws.

Patient service. A website must provide customers with an accurate, readily accessible, and responsive phone number or another contact information allowing patients to contact or consult with a pharmacist.

Website transparency. Information and offers on a website should not deceive patients as to any material detail regarding the practice, its staff, prescription drugs, or payment transactions.

Conclusions to the II Chapter

After studying various sources dedicated to online commerce, it can be concluded that, with the growth of Internet penetration, the size of the global e-pharmacy market from the e-commerce segment will increase in terms of distribution channels. Advantages such as ease of access have contributed to the rapid expansion of online shopping in India, China and Germany, USA, etc. The

growing popularity of e-commerce and thriving retail business, which lead to an increase in overall sales, is also driving the growth of e-pharmacies.

The e-pharmacy sector has been rapidly growing in low-income and middle-income countries over the past decade, with the COVID-19 pandemic encouraging a further surge in online sales, and an associated rise in cybercrime.

Online medicine sales are linked to both public health concerns, such as sale of prescription-only medicines without a prescription, and sale of substandard and falsified medicines; and cyber-security concerns, including consumer fraud and lack of data privacy.

E-pharmacy may also present opportunities for enhancing access to medicines, particularly for those requiring regular medication for chronic conditions, or with problems accessing traditional pharmacy services.

Regulation of the sector has not kept pace with these rapidly evolving, dynamic markets which operate with ease across national boundaries, and present distinct regulatory challenges.

CHAPTER 3. SCIENTIFIC AND METHODOLOGICAL PRINCIPLES OF IMPROVING OF LEGAL REGULATION OF INTERNET PHARMACIES.

3.1 Analysis of the legal framework for the regulation of online pharmacies: world experience.

The Internet has changed people's lives, and along with its accessibility, the number of requests for medical information is increasing. Statistics show that within one year, 72% of Internet users in the US and 71% in Europe at least once searched for information related to health and obtaining various medical services or goods. This is confirmed by the growing market of online pharmacies in many countries, which have both a lot of obvious advantages and a number of disadvantages, more related to the issue of regulating their activities [35,52].

Such serious concerns about the activities of illegal Internet pharmacies are explained by the fact that illegal pharmaceutical practices are associated with a number of health risks for consumers [60].

However, despite the existing risks, the global Internet pharmacy market, led by North America and Europe, is actively developing. Various models of control over the sale of medicines via the Internet are being formed around the world. In many ways, the structure of these models depends on the regulatory, economic and cultural characteristics of a particular country.

In 2014, the US Food and Drug Administration, together with Interpol and 200 law enforcement agencies around the world, led a global action against illegal Internet pharmacies, which led to the arrest of 237 people and the closure of more 10,600 illegal websites [20,21]. A program to combat pharmaceutical crime has also been created, which is supported by large pharmaceutical companies.

WHO defines legitimate Internet pharmacies as “websites that comply with both the laws and regulations of the country in which the Internet pharmacy website operates and the destination where pharmaceutical products are delivered to the consumer” [21,47]. Pharmacies provide access to controlled substances (subject to the laws and regulations of each individual country or jurisdiction), which in

regulated systems require an original physician's prescription before they can be provided [33]. Some online pharmacies only require an online health evaluation or completing an “online questionnaire” to supply these medicines.

Lower-income countries might consider looking to the regulatory experience of their higher income counterparts, which have been grappling with e-pharmacy for longer [29]. However, there is no consensus in upper-middle and HICs on appropriate regulations. For example, in Thailand it is illegal to sell medicines online; whereas in the UK and Germany e-pharmacies are regulated as an extension of physical pharmacies and incorporated into existing regulatory frameworks. While the UK has a relatively permissive environment, Germany is more restrictive, only allowing the e-pharmacy sales from a few select countries [3,11,53]. International Pharmaceutical Federation in 2020 conducted an analysis of countries regarding the regulation of the online distribution of medicines, and provided information on the significance of each regulatory system. These rules can affect not only access to medicines, but also the degree of interaction between patients and pharmacists, how medicines are chosen and used, patient safety, and even treatment outcomes. The study involved 73 countries in each WHO region [31,60].

Table 3.1

Laws to regulate online pharmacies, by WHO region.

WHO region	**Africa**	**Eastern Mediterranean**	**Europe**	**The Americas**	**South-East Asia**	**Western Pacific**
Number of respondents	*13*	*4*	*35*	*8*	*3*	*10*
Countries (n) with laws and regulations for online pharmacies	*1*	*1*	*26*	*3*	*0*	*5*
Percentage	*3*	*3*	*72*	*8*	*0*	*14*

Overall, 49% of countries indicated that they had laws and regulations for online pharmacies, while 51% indicated that they had no such laws (tabl.3.1-fig.3.1).

Interestingly, 74% of European countries indicated the existence of laws for online pharmacies. Comparatively, 92% of countries in Africa and all countries in South-East Asia indicated there were no laws regulating online pharmacy operations [29-33].

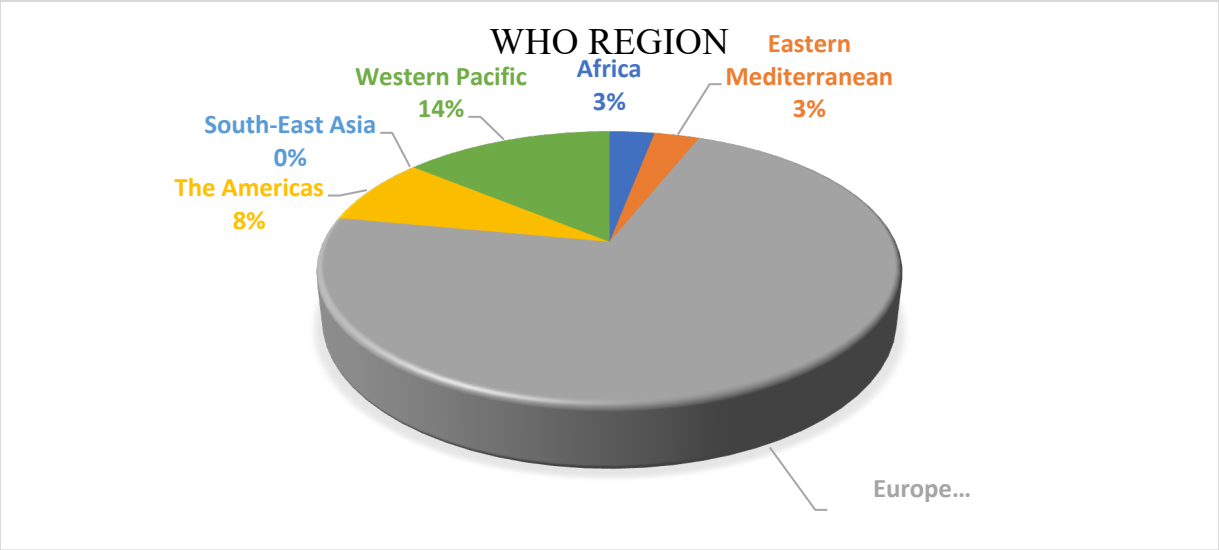


Fig.3.1 Laws to regulate online pharmacies, by WHO region.

Undoubtedly, e-commerce for medicines has many benefits for patients and the pharmaceutical industry, but it continues to attract the attention of regulatory authorities (RAs) around the world. Regulators must protect the public from the potential harm caused by illegal Internet pharmacies. Many countries face the question of whether existing laws can be amended to take into account the transnational nature of drug e-commerce.

There is a notable degree of uniformity around the world in terms of legislation regarding the regulation of online pharmacies. After analyzing the world experience of selling medicines on the Internet, we identified 3 main principles that determine the legality of an online pharmacy:

1. When selling prescription drugs, an online pharmacy does not detect the presence of a prescription (physical or otherwise) - usually, on such illegal websites, users are asked to fill out only an online form or questionnaire.

2. Online pharmacies are generally required to be licensed in the jurisdiction in which they operate. To regulate this principle, some jurisdictions cooperate with each other on the basis of mutually beneficial terms (EU member

states). In the US, online pharmacies can only operate in the state in which they are registered. The exception is the state of Pennsylvania, which recognizes the pharmacy license of any other US.

3. It is generally prohibited to import prescription drugs from one country directly to a patient in another country. Of course, there are exceptions to this general principle. For example, Germany allows Internet pharmacies registered with the national competent authorities of a limited number of other countries to send prescription medicines to German residents, provided that these Internet pharmacies comply with German law.

According to the global policy regarding Internet pharmacies, the main requirement is the presence of a legal framework that strictly defines the rules, duties and responsibilities before the law of all pharmaceutical market participants. In general, in EU countries, the online sale of medicines is regulated by Directive 2001/83/EC [14]. But each EU member state has its own national legislation on the classification and delimitation of prescription/over-the-counter drugs, where the red line identifies concerns about the health and safety of patients tabl.3.2 [1,24,46].

Table 3.2

The main legislative framework on the basis of which OPs operate in the EU

Legal background	**Description**
EU Directives 2000/31/EU "On some legal aspects of information services, in particular, electronic commerce, in the internal market"	Directive on electronic commerce
EU Directive 2001/83 EU "On the Community code relating to medicinal products for human use"	European-wide level of regulation of Internet pharmacies. Article 85 Fair competition between local pharmacies and OPs.
Council of Europe Convention "On counterfeiting medical products and similar involving threats to public health"	Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products
Directive 97/7/EC of the European Parliament and of the Council of 20.05.97	The Directive applies to distance contracts between a professional and a consumer, for the provision of a service or goods.

One of the main examples of national consumer protection procedures is the establishment of a specific logo when opening an e-pharmacy. Consumers should only buy medicines from online pharmacies registered with the national competent authorities in the EU Member States in order to reduce the risk of purchasing substandard or counterfeit medicines. To this end, the European Commission has developed a special logo that is placed on the websites of registered online pharmacies [17,18,51].

The logo leads to the website of the national competent authority, which lists all legal online pharmacies/retailers. The national websites are listed by the European Medicines Agency. By simply clicking on the logo, an online drug buyer will be directed to the pharmacy's entry on this national list [29-34].

The logo can only be trusted if, after selection, the customer is redirected to the record of this pharmacy in the list of legal online pharmacies and retailers registered in this EU country on the national web page.

In order to harmonize the functioning of the common logo, the EU Commission adopted the main requirements:

I. the technical, electronic and cryptographic requirements for verifying the identity of the common logo;

II. general logo design.

For example, the General Pharmaceutical Council of the United Kingdom has a procedure for registering online pharmacies, during which eligible pharmacies are issued with an electronic logo with a green cross and a unique registration number [39,42-46].

The logo consists of a national flag in the middle left side of the logo which corresponds to the EU country where the pharmacy or retailer is registered or authorised. Only national flags of EU countries or those of Norway, Iceland and Lichtenstein feature [24,25,42-46].

The legal framework for the common logo is set out in European Commission Directive 2001/83/EC as amended by Directive 2011/62/EU on falsified medicines for human use and by the Implementing Regulation 699/2014 on 24 June 2014 [14].

An analysis of the legal framework that reflects the requirements for the e-pharmacy logo is given in tabl. 3.3.

Table 3.3

The legal framework for the common logo in EU.

Legal background	**Description**
Directive 2011/62/EUEN of 8 June 2011 amending Directive 2001/83/EC (the Falsified Medicines Directive) [14]	The Directive gave the European Commission a legal basis to establish the design of a common logo as well as the technical, electronic and cryptographic requirements for verification of its authenticity.
Commission Implementing Regulation, No 699/2014 of 24 June 2014 [7]	As of 1st of July 2015, all online pharmacies or retailers legally operating in the EU should display the logo.

If the identification of legitimate e-pharmacies in the EU is carried out using the “common EU logo”, then digital pharmacies in the US and Canada are accredited and work with the certification mark of the Canadian International Pharmaceutical Association [9,21]. To be accredited, US e-pharmacies must apply for a "pharmacy" domain, which is an easy way to communicate quality to customers via a web address. In addition, search engines such as Google, Yahoo! and Bing now require the "pharmacy" domain in order to use their advertising services [19].

The US National Association of Pharmacy Councils operates the Verified Online Pharmacy Site Program under which consumers of VIPP accredited pharmacies can search for them online and they are also identified by a logo [6,45].

In addition to the requirements for the logo of pharmacies, there are also requirements for the site, where all information about their activities is located. The next stage of our work was the study of the organization of the websites of online pharmacies.

We have identified the main conditions for the existence of websites of the EU countries. Each Member State must establish a website providing at least the following [56,62]:

a) information on national legislation applicable to the offering of medicines for sale to the public at a distance through information society services, including information that there may be differences between Member States regarding the classification of medicines and the conditions for their supply;

b) information about the purpose of the common logo;

c) list of persons offering medicinal products for remote sale to the public through information society services, as well as their website addresses;

d) background information on the risks associated with medicinal products illicitly supplied to the public through information society services.

In developed countries, where e-commerce in the field of pharmacy business is very common, accreditation of online pharmacies is of great importance for consumer safety. Accreditation systems can help improve information balance and offer consumers security assurances. For example, these systems provide tools such as accreditation seals or website checkers that check the legitimacy of online pharmacies. However, many consumers are unaware of the existence and purpose of accreditation systems, and some illegal online pharmacies may use fake accreditation stamps on their websites to fool unsuspecting consumers.

It should be noted that while there are national and international regulations and laws regarding Internet pharmacies, effective regulatory oversight and enforcement is often difficult to ensure. Thus, it is the responsibility of pharmacists to provide information about signs that an online pharmacy website is unsafe in order to advise patients. They also must educate consumers on safer practices for purchasing medicines online, such as how to differentiate between authentic and inauthentic accreditation seals.

Analyzing the world experience of regulating online pharmacies, at the next stage of our work, we formulated in the tabl. 3.4 the main requirements by country.

Table 3.4

Accreditation organizations for online pharmacies.

Accreditation Organization Countries	**Countries of Operation**	**Comments**
National Association of Boards of Pharmacy (NABP) [44]	US and Canada	-Operates an FDA-endorsed voluntary accreditation program, i.e., VIPPS. To earn VIPPS accreditation, online pharmacies must comply with US laws, be physically located in the US, and meet listed criteria to ensure quality standards.-Launched the ".pharmacy" domain initiative in 2014 to provide consumers worldwide with a way to identify safe, legal, and ethical online pharmacies.
General Pharmaceutical Council (GPhC) [39,43]	Great Britain	-Operates a voluntary accreditation scheme for online pharmacies to help assure Great Britain consumers when purchasing medicines online. -Issues the common EU logo to legitimate online pharmacies operating in Great Britain.
Regulatory authorities (Ras) of EU member states [17,18,	EU member states	-Under FMD, EU-based online pharmacies must display the common EU logo on their websites-Online pharmacies must register with their respective national RA and comply with relevant laws to obtain the common EU logo. -By clicking the national flag under the logo, consumers are directed to the RA website to verify the company's identity.
LegitScript [35]	International	-Third-party certification service helps consumers verify the legitimacy of online pharmacies.-Certification is recognized by many RAs worldwide, including those of Japan and Italy.
PharmacyChecker [49]	International	-Offers PharmacyChecker Verification Program to verify the legitimacy of online pharmacies. -Provides miscellaneous services like price comparison of medicines among different online pharmacies.

From this it can be concluded that, in the USA there are two major verification programs for online pharmacies implemented by the National Association of Boards of Pharmacy (NABP) and LegitScript. Getting a certification seal is a mandatory procedure (if an online pharmacy has no certification, Google doesn't allow it to advertise its products). Certification shows customers that online pharmacy operates in compliance with the FDA and FTC requirements.

The EU has introduced a common logo for legally operating online pharmacies/retailers in EU countries as one of the measures to fight against falsified medicines. The logo vouches for the authenticity of the websites and guarantees the safety of the products. This logo links to the website of the national competent authority listing all legally operating online pharmacies/retailers. An online retailer needs just to register the business with authorities. Then, if the business meets standards and requirements, complete an application form to get the logo.

The "pharmacy" domain scheme complements national accreditation systems to verify the legitimacy of online pharmacies. It was launched by NABP in 2014 to provide consumers worldwide with a way to identify safe, legitimate, and ethical online pharmacies. As the owner of the "pharmacy" domain, NABP determines which pharmacies to host on the domain and requires that they demonstrate legitimacy. Regulatory Authorities may audit NABP periodically to ensure its reliability and fairness in implementing this scheme.

3.2 Evaluation of the effectiveness of visits to online pharmacies by the world population.

There are no laws that directly regulate or prohibit the online sale of medicines in 66% of the world's countries. Therefore, prescription-only and over-the-counter drugs can be sold on e-commerce platforms by anyone [32]. As a result, regulators in these countries hope that consumers themselves will remain vigilant when purchasing medicines online.

Regulators that allow the online sale of prescription-only drugs can use the official accreditation system and online registries to direct consumers to legitimate sites, while regulators that ban the online sale of prescription-only drugs may make

it clear that no one is allowed to sell them via email [20,33]. Additional restrictions may apply to the sale of prescription drugs over the Internet (tabl.3.5). For example, while China allows the online sale of over-the-counter drugs, it prohibits their sale on third-party e-commerce platforms, including its own Tmall.com.

At the next stage, we analyzed approaches to the sale of prescription and over-the-counter drugs in several countries through online pharmacies [9,20,21,40 - 43].

Table 3.5

Approaches of RA worldwide to control medicinal product online sales.

Country	**Online Sale of Medicines POMs**	**Online Sale of Medicines OTC**	**Comment**
US	Yes	Yes	State-licensed online pharmacies can sell medicinal products online
Canada	Yes	Yes	Licensed brick-and-mortar pharmacies can sell medicinal products online.
Germany	Yes	Yes	Licensed brick-and-mortar pharmacies must register with the relevant RA, obtain a mail order permit, and display the EU common logo to sell medicinal products online
Great Britain	Yes	Yes	Online pharmacies must register with GPhC and have a physical location in Great Britain to sell POMs.
The Netherlands	Yes	Yes	OPs must register with the relevant RA and display the common EU logo issued by the RA to sell drugs online.
Australia	Yes	Yes	Brick-and-mortar pharmacies operating in Australia can sell medicinal products online as long as they adhere to all applicable laws and practice standards.
China	No	OTC medicines only	A bill to allow the sale of POM via online pharmacies has been delayed due to safety considerations. The sale of OTC medicinal products on third-party e-commerce platforms is prohibited due to safety considerations.

Continuation of table 3.5

Japan	No	specific OTC medicines only	The online sale of specific OTC medicines such as fexofenadine and loratadine is prohibited. Other OTC drugs can be sold online. Purchasing prescription drugs from overseas online pharmacies is prohibited.
South Korea	No	No	Medicinal products can only be sold at physical stores registered with the RA.
India	Law is unclear	Law is unclear	Although the RA bans the online sale of medicinal products, the prohibition is not legislated.
Singapore	No	specific OTC medicines only	The RA employs a "buyers beware" approach to warn consumers of the risk involved in purchasing medicinal products online.
Brazil	Yes	Yes	OPs with Brazilian registration are authorized to fulfill online orders and sell prescription drugs. In Brazil, it is not possible to open and register an online pharmacy without an existing retail pharmacy.
Spain	No	Yes	The sale of an OTC can be carried out only after the client has been provided with appropriate professional advice. availability of a special questionnaire in which patients must enter their personal data so that pharmacists can fulfill their pharmacovigilance duties
Ireland, Italy, Turkey Thailand	No	Yes	The sale of prescription drugs over the Internet is prohibited. Personal importation of drugs and delivery of prescription drugs by mail are also prohibited.
Ukraine	POMs by e-Rx, except for controlled ones	Yes	The online pharmacy must be in the state list of online pharmacies on the website of the State Medical Service. website must necessarily contain the information defined by the Law.
Malaysia	No	Yes	The RA employs a "buyers beware" approach to warn consumers of the risk involved in purchasing medicinal products online.

Without legislation, regulators cannot establish legal liability for online pharmacies or require them to commit to quality assurance or undergo periodic reviews. Relevant legislation empowers regulators to implement well-defined frameworks to protect public health.

The growing internet penetration and the high prevalence of chronic diseases in developed countries have increased the popularity of online pharmacies in recent years. Online pharmacies are the most trending developments in several developing and developed countries in Europe. As the trend from offline to online is growing, there is major growth potential for healthcare companies to grow in southern European countries such as France, Germany, Italy, and Spain. Germany is the fastest-growing regional market due to the high-speed internet availability and increased awareness of online over-the-counter benefits. France and Italy are highly established markets that contribute to significant shares in the European market.

In our study, we paid attention to how the number of visits to online pharmacies has changed in recent years and what are the main reasons for their changes.

New government health initiatives are spurring online drug sales as consumers seek to improve their health, and this will drive up the cost of over-the-counter drugs. In addition, the growth of the online pharmacy market in the world is greatly influenced by [19]:

- emergence of new diseases such as Covid-19,
- the growing penetration of the Internet,
- the introduction of electronic prescriptions (ePrescription adoption in the consumer healthcare eCommerce industry may create an accelerated growth as consumers and patients vouch for convenience and quicker means to obtain their required medication),
- the improvement of virtual payments and
- the aging of the population.

In 2022, a group global study was conducted: "electronic pharmacies around the world", in which 94 countries participated. This report identifies significant opportunities for retailers and consumer health product manufacturers to use e-commerce to meet the needs of new online shoppers fig.3.2 [19].

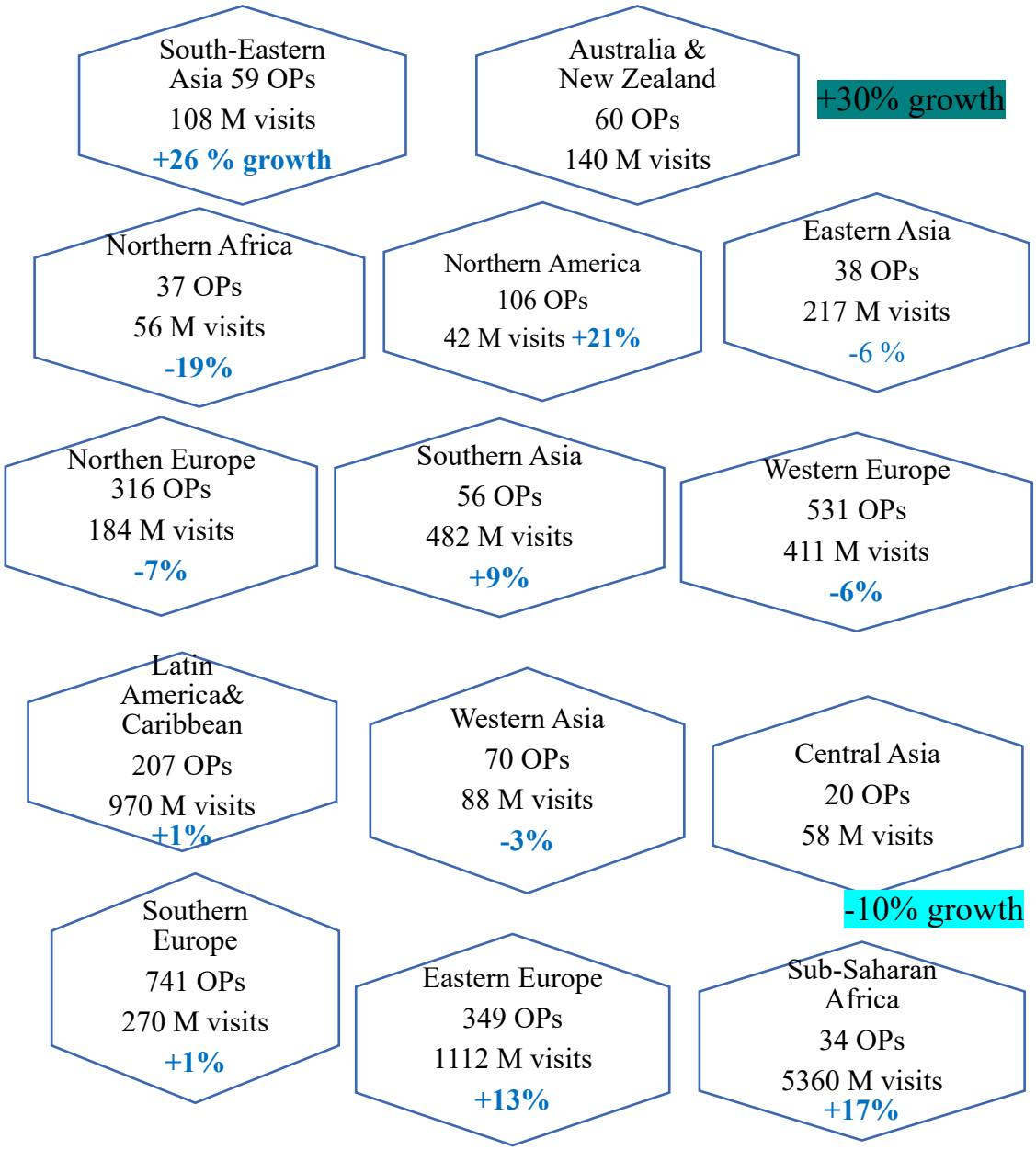


Fig.3.2 Online traffic of ePharmacy by geographical region in 2022 and how it compares to 2021.

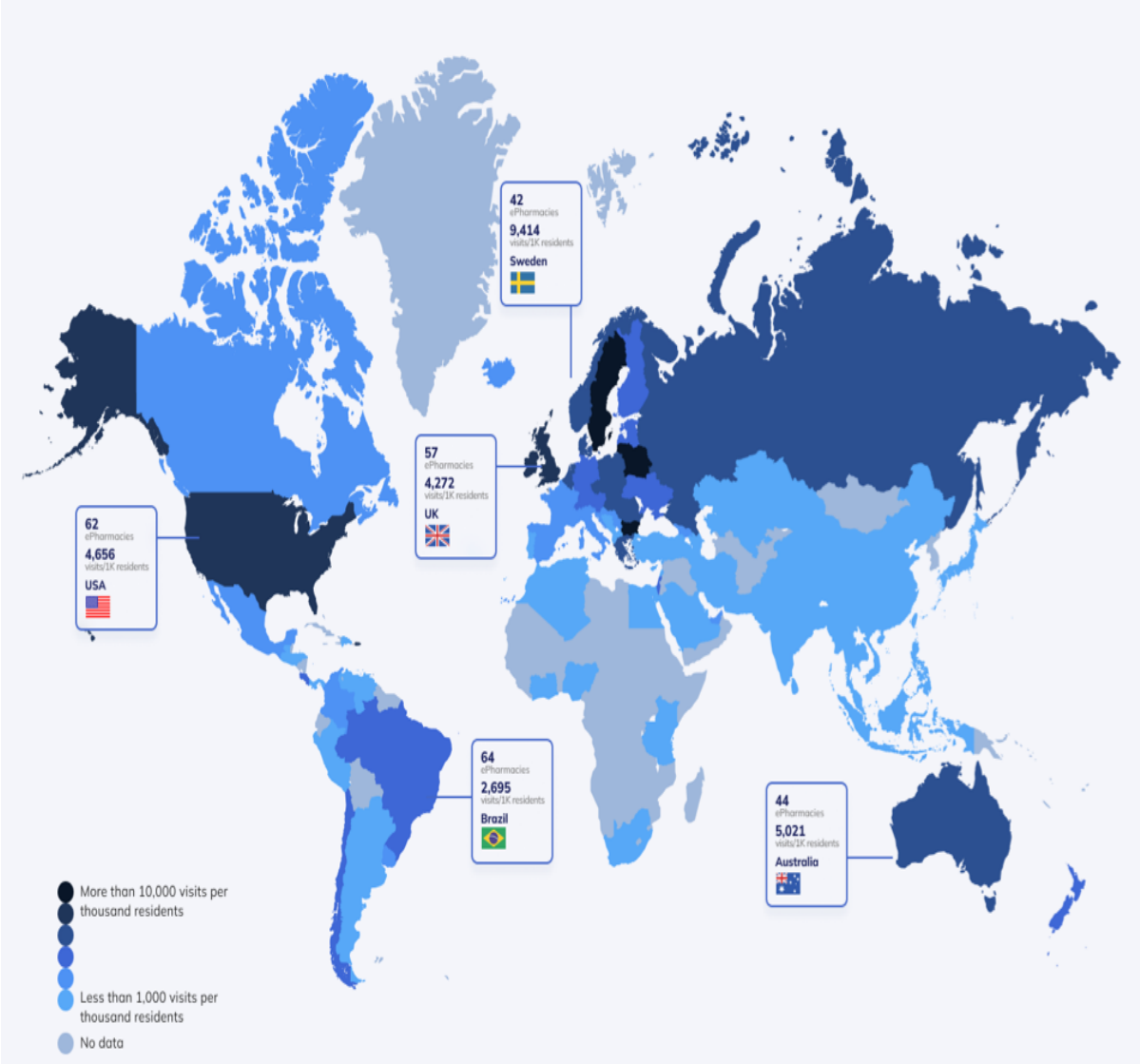
Even as the global pandemic subsides, the population continued to visit online pharmacies in 2022, with 5.8 billion online visits recorded in 94 countries in the first 6 months of 2022 [56]. 53 out of the 94 countries permit the online ordering of prescription medicine. 87 out of the 94 countries permit the online ordering of non-prescription medicine. The only countries prohibiting it are Algeria, Cyprus, Greece, Morocco, Iran, UAE and Turkey [11].

Australia with New Zealand was the region with the highest growth, as online visits grew by +29.9%, followed by Southern Asia with a +25.7% increase and Sub-Saharan Africa with a +17.1% increase. On the contrary, Northern America, which up until this point had been the region leading the pack, recorded a 20.7% drop in growth. This decrease was driven by a massive drop in online visits in leading American retailers like Rite Aid (-51.2%), Walgreens (-29.3%) and CVS Health (-21.2%) in the first semester of 2022, according to Similar Web. The same applies to other regions like Northern Africa, with Chefaa (-44.4%) and Vezeeta (-13.9%), Northern Europe, with Superdrug (-22%) and Boots (-8.7%), and Western Europe, with Medpex (-13.6%) and DocMorris (-11.6%) [58,59].

Sweden was the leading country with 9,416 visits to online pharmacies per 1,000 residents, followed by 6,702 visits per 1,000 residents in Bulgaria, 6,297 visits per 1,000 residents in Norway, and 5,021 visits per 1,000 residents in Australia, leaving the US in the 6th place with 4,656 visits per 1,000 residents and the UK in the 8th place with 4,272 visits per 1,000 residents (fig.3.3) [13].

Brazil had the most Tier 1 online pharmacies (pharmacies with more than 5M average visits per month in S1 2022) with 6 total for the whole year, followed by India and USA with 5 each, and the UK and Mexico with 3 each.

Apollo Pharmacy, based in India, is the world's fastest growing ePharmacy, with a +374% Y-o-Y visit growth rate in S1 2022 compared to the same period last year, followed by Hong Kong-based Mannings with +78% Y-o-Y visits growth rate. The remaining top 10 fastest growing ePharmacies in ascending order are: Dr. Max with +67% growth (Romania), Drogaraia with +51% growth (Brazil), Watsons with +50% growth (Philippines) and Shop Farmacia with +46% growth (Italy) [58,59].



epharmacy Data, Insights& Visualisation Convert Group

Fig.3.3 ePharmacies Visits per thousand residents across countries.

At the moment, quite a lot of developed countries have allowed online trade in medicines. The specifics of business models directly depend on the specifics of the legislation in each individual country.

Key events for online pharmacies in 2022 around the world include:

Amazon Pharmacy gains pace in the industry and the last-mile delivery becomes more essential than ever, the US based *NowRx* has partnered with the *Korean Hyundai Motor Group* to outpace Amazon by providing an out-of-the-box last-mile delivery service to its customers. *Brazilian-based RaiaDrogasil* is also partnering with *Uber* to strengthen its delivery services across Brazil. Additionally, *UK-based Pharmacy2U* also partnered with *Royal Mail* to distribute NHS prescriptions to patients in the UK (tabl.3.6) [8,10,58].

Table 3.6

Online pharmacies and main delivery sources

Online pharmacies	**Delivery service**
Amazon Pharmacy	Own sphere of logistics and delivery
NowRx	Uber
Hyundai Motor Group	Uber
RaiaDrogasil	Uber
Pharmacy2U	Royal Mail

It is becoming easier and easier to buy prescription drugs online and a quick internet search will turn up hundreds, if not thousands, of websites selling prescription drugs. While purchasing prescription drugs online may seem convenient and cheap, it may expose consumers to serious health risks as both legitimate and illegitimate outlets operate online.

The US pharmacy sector is worth $312.6 billion and the online pharmacy business is one of the major sectors that almost exclusively contributes to the rapid growth of the market. Indeed, according to Zion Market Research, the global online pharmacy business is an industry giant that is expected to grow at a 14.26 percent CAGR to reach $107.53 billion by 2025 [51].

This is an indication that the US population is experiencing demand for online pharmacy services. Considering these opportunities emerging in the online pharmaceutical sector, one can see why the biggest retailers like Amazon want to go deeper into the pharmacy industry [10].

At the last stage of our work, we conducted a study of the modern online drug sales market and identified popular online pharmacies in US by analyzing their offers.

BlinkRx

A digital pharmacy that provides your lowest prescription price, with free home delivery for select medications.

- No membership cost.

- Offers discounts on over 15,000 prescriptions.
- Offers free delivery nationwide for select medications.
- Online doctor visits available for some conditions.

Express Scripts Pharmacy

Express Scripts has pharmacists and customer service representatives available around the clock to answer health and insurance questions.

- Only available for those with Express Scripts benefits coverage.
- Works with a network of over 70,000 pharmacies.
- Free shipping is standard and overnight shipping is available on request.

Rx Outreach

is a fully licensed, nonprofit mail order pharmacy available to people who qualify based on their income, which needs to be at or below 400% of the federal poverty line. Individuals can check their eligibility online.

- No membership fees.
- Provides access to affordable medications for those who qualify.
- Provides some free medications each month on a first-come, first-serve basis.
- Medications can be shipped to your provider or to patients directly.
- Free standard shipping.

DiRx

doesn’t take insurance, and instead, focuses on keeping prices on generic medications as low as possible. There are no membership fees and standard shipping is free.

- No membership fees.
- Does not accept insurance, but accepts payment from HSA and FSA accounts.
- Carries over 1,200 common, generic medications.
- Free ground shipping.

Amazon Pharmacy

applies its Prime philosophy to its pharmacy offerings, with Prime members saving money on prescriptions and receiving free, two-day delivery. Amazon promises “no surprises” at the time of purchase and offers refills in 30-day and six-month supply options. Amazon has opened an online pharmacy, giving the chance to all customers in the United States to order medication on their phones and computers. Shoppers have to set up a profile on Amazon’s website and have their doctors send prescriptions there [10].

- No membership fees.
- Accepts most insurance plans.
- Offers Prime members savings of up to 80% without insurance.
- Offers free delivery (and free two-day delivery for Prime members).

BioPlus

focuses exclusively on those with chronic conditions needing specialty medications. The company offers specialty pharmacy support and a two-hour patient acceptance guarantee in order to avoid delays in receiving needed prescriptions.

- Offers personalized support for your treatment plan.
- Helps handle paperwork to expedite medications and treatment.
- Provides ongoing support for the management of chronic conditions.

SelectRX

is online pharmacy specializing in helping people living with chronic conditions and those who take multiple medications. SelectRX aims to help people manage their medications and demystify the process with personalized assistance.

- No membership cost.
- Automatic refills in conjunction with your doctor to ensure meds are up-to-date.
- Free in-home delivery each month.
- 24/7 support for your prescription.
- Offers free shipping.

Since COVID-19 has changed consumer behavior, e-pharmacies are viewed as a safe and convenient option. Digital payments and last-minute deliveries may also boost more revenue for pharmaceutical businesses and encourage price competition in the pharmacy industry, thereby making medications more affordable for consumers. Thus, with the access to both online and offline offerings, pharmacies are now able to provide more options to consumers to choose based on the requirements, availability and price.

Conclusions to the III Chapter

Online pharmacy companies use competitive pricing by providing the same product at an equal or lesser price to acquire new customers and a larger market share. Online pharmacies also have an opportunity to present their online platform as advertising space on rent, allowing different parties such as manufacturers, laboratories, clinics, hospitals to do their promotion on these websites. This is an excellent source for generating revenue.

Online pharmacy platforms are simple and convenient because they reduce the effort required to go to the pharmacy and help consumers know about the availability of over-the-counter products and medicines.

In 2022, there were 5.8 billion online pharmacy visits in 94 countries. 53 out of 94 countries allow online ordering of prescription drugs, and 87 out of 94 countries allow online ordering of over-the-counter drugs. The only countries where this is prohibited are Algeria, Cyprus, Greece, Morocco, Iran, UAE and Turkey.

The major players in the industry are Amazon Pharmacy, Cigna (Express Scripts), CVS Health, Giant Eagle, NowRx with the Korean Hyundai Motor Group, Walgreens Boots Alliance, Walmart, and Zur Rose Group.

New players like Amazon are entering the US ana other country, such as UK and India market by acquiring the online pharmacy channel of major players.

GENERAL CONCLUSIONS

1. E-commerce for medicines is becoming an integral part of healthcare systems. The expansion of e-commerce for medicines can provide benefits such as lower cost, convenience and consumer privacy. However, the shift from physical stores to online platforms also comes with health risks.
2. The e-pharmacy market consists of the sale of e-pharmacy services by entities (organizations, sole proprietorships, and partnerships) that are used by patients to order prescribed drugs using the internet. E-pharmacies are online pharmacies that allow customers to acquire medications without having to go to a physical location. Consumer convenience has improved as a result of these platforms, resulting in increased demand for the model around the world. Consumers can purchase medications or medication from an online pharmacy. The platform is intended for online pharmacy services, such as drug delivery. E-pharmacy allows patients to refill prescriptions and receive over-the-counter and specialized medications.
3. In the countries where e-pharmacies currently operate, there are laws in place to effectively regulate the e-commerce of medicines. National regulators initiate a national licensing system for all Internet pharmacies operating under their jurisdiction to ensure regulatory oversight. A mandatory verification or accreditation system is included in the licensing requirement to ensure that online pharmacies comply with relevant internationally recognized quality system standards.
4. Without legislation, regulatory authorities cannot stipulate legal responsibilities for online pharmacies or mandate that they take on quality assurance responsibilities or undergo periodic inspections. In contrast, relevant legislation empowers regulatory authorities to implement well-defined frameworks to safeguard public health. Regulatory authorities that allow prescription-only medicines online sales can use an official accreditation system and online registries to direct consumers to legitimate

sites, whereas regulatory authorities that prohibit prescription-only medicines online sales make it clear that no one is allowed to sell them via e-commerce.

5. Many regulatory authorities lack legislation to properly regulate online pharmacies. Strategic and holistic approach may help regulatory authorities regulate e- commerce of medicinal products more effectively. This approach - which incorporates a stepwise implementation of industry guidelines, advisories, and warnings; legislation; and associated enforcement activities - can address the current risks associated with illegitimate online pharmacies and illegal medicinal product e-commerce. Although compliance costs may increase with tighter e-commerce regulation of medicinal products, safeguarding public health should ultimately be the overriding concern of all RAs and stakeholders in general.
6. Digital health technologies and e-pharmacy services make use of computing platforms, networking, software, and sensors for health care and related applications that include mobile health (mHealth), health information technology (IT), wearable devices, telehealth, telemedicine, and personalized medicine. These technologies can be used for a variety of things, from general wellness to medical equipment.
7. The digital pharmacy market is expected to reach USD 211.9 billion by 2027 from USD 96.5 billion in 2022, at a CAGR of 17.0% during the forecast period. The growth of this market is driven by the growing consumer preference toward buying online medicines during and post COVID-19 pandemic, consolidation in the market and partnerships, and increasing geriatric population.
8. Major players in the e-pharmacy market are Walgreen Company, Express Scripts Holding Company, CVS Health Corporation, DocMorris N.V, OptumRx, PharmEasy, Tata 1mg, Netmeds, Amazon Inc., Axelia Solutions Pvt Ltd, Apex Healthcare Berhad, Apollo Pharmacy, Doctors Rowlands Phamacy, Optus Rx Inc., and Healthkart.

REFERENCES

1. Association Agreement between the European Union and Ukraine Association Agreement between the European Union and Ukraine. Government portal. Available at: https://www.kmu.gov.ua/en/yevropejska-integraciya/ugoda-pro-asociacyu.

2. Besançon L, Rockey P, van Zanten M. Regulation of health professions: disparate worldwide approaches are a challenge to harmonization. World Med J. 2012;58(4):128–36.

3. Better Regulation of Medicines Means Stronger Regional Health Security D. Ball, Susann Roth, J. Parry Published 30 April 2016 Medicine, Political Science.

4. Bundesgesetz über die Österreichische Apothekerkammer (Apothekerkammergesetz 2001) [Federal Act on the Austrian Chamber of Pharmacists], including amendments until September 2018 (in German). Vienna: Bundesgesetzblatt für die Republik Österreich; 2018: 14 June.

5. Brown J., Li C. (2014). Characteristics of online pharmacy users in a nationally representative sample. J. Am. Pharm. Assoc. 54, 289–294. 10.1331/JAPhA.2014.13169.

6. By Meng Jing (China Daily USA) http://usa.chinadaily.com.cn/epaper/2016-08/02/content_26317670.htm.

7. Commission Implementing Regulation (EU) No 699/2014 of 24 June 2014 on the design of the common logo to identify persons offering medicinal products for sale at a distance to the public and the technical, electronic and cryptographic requirements for verification of its authenticity. O. J. E. U. 2014, L 184/5–7.

8. Coherent Market Insights. Global ePharmacy Market.2020.

9. China FDA stops online med sales Updated: 2016 https://www.legislation.gov.uk/uksi/2002/2013/contents/made.

10. Christina Farr, Annie Palmer. Amazon jumps into the pharmacy business with online prescription fulfillment, free delivery for Prime members, NOV

17 2020 : https://www.cnbc.com/2020/11/17/amazon-pharmacy-free-prescription-delivery-for-prime-members.html.

11. Convert Group: The way Retailers and Brands collaborate through Data.2022. https://convertgroup.com.

12. Developing a digitally enabled pharmaceutical workforce. International Pharmaceutical Federation: The Hague, The Netherlands, 2021.

13. Digital Pharmacy Market by Drug (Rx, OTC), Product (Medicine, Personal Care, Vitamins & Supplements, Diabetes, CVD, Oncology), Platform (Apps, Websites), Business Model (Captive, Franchise, Aggregator), Geographic (Urban, Rural) - Global Forecasts to 2027.

14. Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products. O. J. E. U. 2011, L 174/74– https://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0074:0087:EN:PDF.

15. Dilipkumar A. Ode, Jigeshkumar D. Chauhan, Multidisciplinary subjects for research-VI, volume-2.

16. Eurostat (2020). Eurostat. Internet purchases - goods or services (2020 onwards). ICT usage in households and by individuals – E commerce. https://ec.europa.eu/eurostat/databrowser/view/ISOC_EC_IBGS/default/table?lang=en&category=isoc.isoc_i.isoc_iec.

17. European Commission. EU logo for online sale of medicines. 2021.

18. European Commission. “EU logo for online sale of medicines”. Accessed https://health.ec.europa.eu/medicinal-products/eu-logo-online-sale-medicines_en.

19. E-Pharmacy Global Market Report 2022 - Research and Marketsю accesses. https://www.researchandmarkets.com/reports/5659537/e-pharmacy-global-market-report-2022#rela1-5549995.

20. Fittler A, Bosze G, Botz L. Evaluating aspects of online medication safety in long-term follow-up of 136 Internet pharmacies: Illegal rogue online pharmacies flourish and are long-lived. J Med Internet Res. 2013;15(9):e199: http://doi.org/10.2196/jmir.2606.

21. FDA Consumer Health Information. The possible dangers of buying medicines over the Internet. http://www.fda.gov/ downloads/ForConsumers/ConsumerUpdates/UCM204943. pdf. Accessed June 11, 2015.

22. Fung CH, Woo HE, Asch SM. Controversies and legal issues of prescribing and dispensing medications using the internet. Mayo Clin Proc. 2004; 79:188–94.

23. Ganapathy N.” India's pharmacies do battle with online rivals”. PUBLISHED 12.07.2017 P., 5:00 ДП SGT https://www.straitstimes.com/asia/south-asia/indias-pharmacies-do-battle-with-online-rivals.

24. General Pharmaceutical Council (GPhC). Internet Pharmacy. Available at http://www.pharmacyregulation.org/ regulatingpharmacy/registration/ internetpharmacy/index.aspx Accessed 5 May 2011.

25. Guidance on Internet supply of non-prescription medicines. Dublin: Pharmaceutical Society of Ireland; 2015.

26. Health Portfolio Ministers Department of Health Ensuring Continued Access to Medicines during the COVID-19 Pandemic. Available online: https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/ensuring-continued-access-to-medicines-during-the-covid-19-pandemic.

27. Heads of Medicines agencies (HMA): official site. URL: https://www.hma.eu/ (date of access: 29.10.2022).

28. Ignjatović, D., Cogoljević, M. (2019). The importance of modern pharmacy marketing to conquer new markets through electronic pharmacy. International Review, 3-4, 121–125. doi: http://doi.org/10.5937/intrev1903121ihttps://eur-

lex.europa.eu/legalcontent/EN/TXT/PDF/?uri=OJ:JOL_2014_184_R_0004&qid=1403861374882&from=EN.

29. International Pharmaceutical Federation. The FIP Development Goals: Transforming Global Pharmacy.

30. International Pharmaceutical Federation: The Hague, The Netherlands, 2020.

31. International Pharmaceutical Federation. Digital health in pharmacy education. Developing a digitally enabled pharmaceutical workforce. International Pharmaceutical Federation: The Hague, The Netherlands, 2021.

32. International Standard Classification of Occupations [website]. Geneva: International Labour Organization; 2012 (https://www.ilo.org/public/english/bureau/stat/isco/, accessed 1 April 2019).

33. Internet pharmacies: Illegal rogue online pharmacies flourish and are long-lived. J Med Internet Res.2013;15(9):e 199.

34. Joint Nordic Report. Online pharmacy markets in the Nordics. 2021.

35. LegitScript Website https://www.legitscript.com.

36. Littlejohn, C., Baldacchino, A., Schifano, F., Deluca, P. (2005). Internet pharmacies and online prescription drug sales: a cross-sectional study. Drugs: Education, Prevention and Policy, 12 (1), 75–80. doi: http://doi.org/10.1080/0968763042000275326.

37. Long CS, Kumaran H, Goh KW, Bakrin FS, Ming LC, Rehman IU, et al. Online pharmacies selling prescription drugs: Systematic review. Pharmacy_2022.accesse_https://www.ncbi.nlm.nih.gov/pmc/articles/PMC903118.

38. Mackey TK, Nayyar G. Digital Hazard: An Overview of Global Threats to Public Health, Patient Safety, and Cybersecurity Posed by Illegal Online Pharmacies. British Medical Bulletin 2016;118): :110–26.

39. Murray R. Community pharmacy clinical services review. London: NHS England; 2016.

40. Ministry of Health of Japan “List of OTC drugs https://www.mhlw.go.jp/bunya/iyakuhin/ippanyou/hanbailist/.

41. Ministry of Health of Malaysia.” Buying Medicines Online: Beware.” https://www.pharmacy.gov.my/v2/en/website/waspada-belian-ubat-online.

42. National Association of Boards of Pharmacy NABP’s Verified Pharmacy Program.acsess https://nabp.pharmacy/programs/accreditations-inspections/verified-pharmacy-program/.

43. National Association of Pharmacy Regulatory Authorities (NAPRA) Online pharmacies https://www.napra.ca/resources/online-pharmacies/.

44. National Association of Boards of Pharmacy. Find a VIPPS online pharmacy. http://www.nabp.net/programs/ accreditation/vipps/find-a-vipps-online-pharmacy. Accessed June 11, 2015.

45. National Association of Boards of Pharmacy. VIPPS crite- ria. http://www.nabp.net/programs/accreditation/vipps/vipps- criteria. Accessed June 11, 2015.

46. National Association of Boards of Pharmacy (NABP). VIPPS. Available at http://www.nabp.net/programs/ accreditation/vipps/ Accessed 5 May 2011.

47. Orizio G, Merla A, Schulz PJ, Gelatti U. The quality of online pharmacies and websites selling prescription drugs: a systematic review. J Med Internet Res. 2011;13(3):e74.

48. Priyanka VP, Ashok BK. Regulation of e-pharmacies in India: bringing new dimensions to the pharmaceutical sector Pharmaceutical regulatory issues 2016;5.

49. PharmacyChecker Website https://www.pharmacychecker.com.

50. Pharmaceutical practice and the FIP sections [website]. The Hague: International Pharmaceutical Federation; 2016 (https://www.fip.org/pharmacy_practice, accessed 17 September 2018).

51. Research and markets. Online pharmacy market in Europe- industry outlook and forecast 2020-2025. 2020.

52. R. Miller, F. Wafula, C. Onoka, P. Saligram - BMJ global, 2021 - gh.bmj.com.

53. Statista. Number of distances selling pharmacies in England from 2008/09 to 2019/20. 2021.

54. Statista. Sales revenue of medicine through online retail pharmacies as end sales channel in China from 2011 to 2019. 2020.

55. Standards and guidance for internet pharmacy services in Northern Ireland. Belfast: PSNI; 2016.

56. The legal and regulatory framework for community pharmacies in the WHO European Region//report WHO//accesses https://apps.who.int/iris/bitstream/handle/10665/326394/9789289054249-eng.pdf.

57. Technology Market Research Reports by GlobalDatahttps://www.globaldata.com.

58. The data is based on the latest Convert Group 2022 Online Pharmacy Trends Report. https://www.epharmacydata.com/directory.

59. Website Traffic: Effortlessly Analyze Your Competitive Landscape. https://www.similarweb.com.

60. World Health Organization. A study on the public health and socioeconomic impact of substandard and falsified medical products. World Health Organization: Geneva, Switzerland, 2020.

61. World Health Organization. (1999). Effective drug regulation: what can countries do?: theme paper for discussion, Geneva 16-19 March 1999. World Health Organization. https://apps.who.int/iris/handle/10665/65025.

62. World Health Organization. Towards Access 2030: WHO Essential Medicines and Health Products Strategic Framework 2016–2030. Geneva: World Health Organization; 2017. https://www.who.int/medicines/publications/Towards_Access_2030_Final.pdf.

63. World Health Organization International Health Conference, New York; 1946. https://www.who.int/about/who-we-are/constitution.

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National University of Pharmacy

Faculty for foreign citizens' education
Department of social pharmacy

Level of higher education master's

Specialty 226 Pharmacy, industrial pharmacy
Educational program Pharmacy

APPROVED
The Head of Department
of Social Pharmacy

_____
Alina VOLKOVA
"28" of September 2022

ASSIGNMENT
FOR QUALIFICATION WORK
OF AN APPLICANT FOR HIGHER EDUCATION

Ayoub BAALI

1. Topic of qualification work: «Research on regulation of Internet pharmacies and e-commerce of medicines», supervisor of qualification work:
Lyubov TERESHCHENKO, PhD, assoc. prof.,

approved by order of NUPh from "06" of February 2023 № 35

2. Deadline for submission of qualification work by the applicant for higher education: April 2023.

3. Outgoing data for qualification work: authors' publications; media publications; official health sites; State Statistics Service of the world; sites of WHO, IFD, Internet, etc.

4. Contents of the settlement and explanatory note (list of questions that need to be developed): study of the problems of the development of electronic commerce of medicines in the conditions of political and socio-economic crisis; analysis of state regulation of Internet pharmacies in the world; study of new approaches in the regulation of Internet pharmacies in EU countries.

5. List of graphic material (with exact indication of the required drawings):
Tables – 10, schemes – 10.

6. Consultants of chapters of qualification work

Chapters	Name, SURNAME, position of consultant	Signature, date	
		assignment was issued	assignment was received
1	Lyubov TERESHCHENKO, associate professor of higher education institution of department of social pharmacy	30.09.22	30.09.22
2	Lyubov TERESHCHENKO, associate professor of higher education institution of department of social pharmacy	15.11.22	15.11.22
3	Lyubov TERESHCHENKO, associate professor of higher education institution of department social of pharmacy	23.12.23	23.12.23

7. Date of issue of the assignment: «_ 28_ » of September 2022.

CALENDAR PLAN

№ з/п	Name of stages of qualification work	Deadline for the stages of qualification work	Notes
1	Study of modern approaches to the regulation of pharmacy establishments	*October 2022*	**done**
2	Investigation of the implementation of e-commerce in the pharmaceutical market	*November-December 2022*	**done**
3	Analysis of the legal framework for the regulation of online pharmacies: world experience	*January-February 2023*	**done**
4	Registration of a qualification work according to the general requirements	*March 2023*	**done**
5	Preparation of the report and multimedia presentation in official protection of a master's thesis	*April 2023*	**done**

An applicant of higher education _____ Ayoub BAALI

Supervisor of qualification work _____ Lyubov TERESHCHENKO

ВИТЯГ З НАКАЗУ № 35
По Національному фармацевтичному університету
від 06 лютого 2023 року

нижченаведеним студентам 5-го курсу 2022-2023 навчального року, навчання за освітнім ступенем «магістр», галузь знань 22 охорона здоров'я, спеціальності 226 – фармація, промислова фармація, освітня програма – фармація, денна форма здобуття освіти (термін навчання 4 роки 10 місяців та 3 роки 10 місяців), які навчаються за контрактом, затвердити теми кваліфікаційних робіт:

Прізвище студента	Тема кваліфікаційної роботи		Посада, прізвище та ініціали керівника	Рецензент кваліфікаційної роботи
• **по кафедрі соціальної фармації**				
Баалі Аюб	Дослідження регулювання Інтернет-аптек та електронної торгівлі лікарськими засобами	Research on regulation of Internet pharmacies and e-commerce of medicines	доцент Терещенко Л. В.	доцент Юрченко Г.М.

Підстава: подання декана, згода ректора

Ректор

Вірно. Секретар

Ф А2.8-47-110

ВИСНОВОК

Комісії з академічної доброчесності про проведену експертизу

щодо академічного плагіату у кваліфікаційній роботі

здобувача вищої освіти

№ 112282 від « 12 » квітня 2023 р.

Проаналізувавши випускну кваліфікаційну роботу за магістерським рівнем здобувача вищої освіти денної форми навчання Баалі Аюб, 5 курсу, _____ групи, спеціальності 226 Фармація, промислова фармація, на тему: «Дослідження регулювання Інтернет-аптек та електронної торгівлі лікарськими засобами / Research on regulation of Internet pharmacies and e-commerce of medicines», Комісія з академічної доброчесності дійшла висновку, що робота, представлена до Екзаменаційної комісії для захисту, виконана самостійно і не містить елементів академічного плагіату (компіляції).

Голова комісії,

професор **Інна ВЛАДИМИРОВА**

1%

29ж%

Ф А 2.2.1-32-353

REVIEW

of scientific supervisor for the qualification work of the master's level of higher education of the specialty 226 Pharmacy, industrial pharmacy

Ayoub BAALI

on the topic: « Research on regulation of Internet pharmacies and e-commerce of medicines »

Relevance of the topic. The pandemic has changed the way we buy and sell medicines. More and more people do not want to leave the house without good reason and prefer to order goods online. According to Fortune Business Insights, the global e-pharmacy market is expected to reach $177 billion by 2026. The penetration of e-commerce is driving the industry forward, so the number of people ordering medicines online will only grow. According to the global policy regarding online pharmacies, the main requirement is the presence of a legal framework that strictly defines the rules, duties and responsibilities before the law of all participants of the pharmaceutical market.

Practical value of conclusions, recommendations and their validity. In recent years, the global e-pharmaceutical market has shown significant progress due to favorable demographic and economic factors, as well as the strengthening of the e-pharmacy regulatory system. Despite the obvious relevance of the problems studied in this qualification work, it can be noted that this topic is insufficiently covered both in scientific and journalistic publications. Thus, the research direction of Ayoub BAALI's qualification work is relevant and has practical significance.

Assessment of work. During his qualification work, Ayoub BAALI studied and analyzed a significant amount of literature and regulatory legal acts on the topic. The analysis carried out confirms the relevance of the research and puts forward the need for their implementation.

General conclusion and recommendations on admission to defend. On structure this work meets the requirements to qualification work in "Pharmacy" and can be presented to protection to EK of NUPh.

Scientific supervisor _____ Lyubov TERESHCHENKO

«06» of April 2023

Ф А 2.2.1-25-356

REVIEW

for qualification work of the master's level of higher education, specialty 226 Pharmacy, industrial pharmacy

Ayoub BAALI

on the topic: «Research on regulation of Internet pharmacies and e-commerce of medicines»

Relevance of the topic. Online pharmacies have been an emerging pharmaceutical supply chain since the turn of the century. During the initial development phase, due to the lack of national regulations and verification systems, low consumer experience, and few legitimate websites, the e-pharmacy market was considered a dubious channel for illegal sellers and a source of counterfeit medicines. Today, buying drugs online from legitimate and trusted e-pharmacy websites has become a common practice in developed countries, especially in the major pharmaceutical markets in the US, Germany, and the UK.

Theoretical level of work. The qualification work is a theoretical generalization and solution of the problem, which is designed to justify the effective development of online pharmacies and e-commerce in the pharmacy sector in modern conditions.

Author's suggestions on the research topic. As a result of the study, it was concluded that the availability and quality of pharmaceutical care for all segments of the population is increased through the introduction of e-commerce in the pharmaceutical sector; by improving the system of state regulation of online pharmacies.

Practical value of conclusions, recommendations and their validity. These studies have shown that, taking into account the world experience in relation to Internet pharmacies or distance selling of medicines, countries that are just adopting this experience need to be very careful in creating a legislative framework with the involvement of representatives of the professional sector.

Disadvantages of work. Ayoub BAALI qualification work, submitted for review, made a good impression, primarily due to its content and the relevant current standards of research results. It is necessary to note some according to the text there are grammatical errors.

General conclusion and assessment of the work. On structure the specified work conforms to requirements to qualification work in "Pharmacy" and can be presented to protection to EC of NUPh.

Reviewer _____ Gennadiy YRCHENKO

«13» of April 2023

Ф А2.5-32-231

ВИТЯГ
з протоколу засідання кафедри соціальної фармації
№ 12 від «20» квітня 2023 року

ПРИСУТНІ: зав. каф. доц. Волкова А. В., доц. Кубарєва І.В., доц. Овакімян О.С., доц. Болдарь Г.Є., доц. Корж Ю.В., доц. Терещенко Л.В., доц.Гавриш Н.Б., доц. Калайчева С.Г., ас. Пилюга Л.В., ас. Сєврюков О.В., ас. Сурікова І.О., ас. Тарасенко Д.Ю., ас. Ноздріна А.А.

ПОРЯДОК ДЕННИЙ: Про представлення до захисту в Екзаменаційній комісії кваліфікаційних робіт.

СЛУХАЛИ: завідувачку кафедри доц. Волкову А. В. з рекомендацією представити до захисту в Екзаменаційній комісії кваліфікаційну роботу здобувача вищої освіти спеціальності 226 Фармація, промислова фармація Аюб БААЛІ на тему: «Дослідження регулювання інтернет-аптек та електронної торгівлі лікарськими засобами».

Науковий керівник: к. фарм. н., доцент кафедри СФ Терещенко Л.В.
Рецензент: к. фарм. н., доцент кафедри ОЕФ Юрченко Г.М.

ВИСТУПИЛИ: доц. Корж Ю.В., доц. Волкова А. В., доц. Болдарь Г.Є., висловили рекомендації до кваліфікаційної роботи Аюб БААЛІ

УХВАЛИЛИ: Рекомендувати до захисту в Екзаменаційній комісії кваліфікаційну роботу здобувача вищої освіти Аюб БААЛІ на тему: «Дослідження регулювання інтернет-аптек та електронної торгівлі лікарськими засобами».

Завідувачка каф. СФ, доцент _____ Аліна ВОЛКОВА

Секретар, асистент _____ Альміра НОЗДРІНА

Ф А2.2.1-32-042

НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

ПОДАННЯ
ГОЛОВІ ЕКЗАМЕНАЦІЙНОЇ КОМІСІЇ
ЩОДО ЗАХИСТУ КВАЛІФІКАЦІЙНОЇ РОБОТИ

Направляється здобувач вищої освіти Аюб БААЛІ до захисту кваліфікаційної роботи за галуззю знань 22 Охорона здоров'я
спеціальністю 226 Фармація, промислова фармація
освітньою програмою Фармація
на тему: «Research on regulation of Internet pharmacies and e-commerce of medicines».

Кваліфікаційна робота і рецензія додаються.

Декан факультету _____ / Світлана КАЛАЙЧЕВА /

Висновок керівника кваліфікаційної роботи

Здобувач вищої освіти Аюб БААЛІ під час виконання кваліфікаційної роботи вивчив і проаналізував значний обсяг літератури та нормативно правових актів по темі. Проведений аналіз підтверджує актуальність досліджень і висуває необхідність їх проведення.

Керівник кваліфікаційної роботи _____ Любов ТЕРЕЩЕНКО

«06» квітня 2023 р.

Висновок кафедри про кваліфікаційну роботу

Кваліфікаційну роботу розглянуто. Здобувач вищої освіти Аюб БААЛІ допускається до захисту даної кваліфікаційної роботи в Екзаменаційній комісії.

Завідувачка кафедри
соціальної фармації _____ Аліна ВОЛКОВА

«20» квітня 2023 р.

Qualification work was defended

of Examination commission on

« ___ » _____ 2023

With the grade _____

Head of the State Examination commission,

DPharmSc, Professor

_____ / Oleh SHPYCHAK /