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QUALIFICATION WORK

on the topic **«ANALYSIS OF THE LICENSING AS A FORM OF STATE REGULATION OF PHARMACEUTICAL ACTIVITIES»**

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ANNOTATION

The qualification work considers approaches to the legal regulation of pharmaceutical activities. Generalizes approaches to the licensing process, investigates the conditions that apply to various types of pharmaceutical activities. A questionnaire survey of 5th-year students at the National University of Pharmacy was conducted.

The qualification work consists of the introduction, three chapters, conclusions and the list of references.

Key words: pharmaceutical activity, regulation, licensing, pharmacy, medicine, respondents.

АНОТАЦІЯ

У кваліфікаційній роботі розглянуто підходи до правового регулювання фармацевтичної діяльності. Узагальнено підходи до процесу ліцензування, досліджено умови здійснення різних видів фармацевтичної діяльності. Проведено анкетне опитування студентів 5 курсу НФаУ.

Кваліфікаційна робота складається зі вступу, трьох розділів, висновків та списку використаної літератури.

Ключові слова: фармацевтична діяльність, регулювання, ліцензування, фармація, ліки, респонденти.

CONTENTS

ABBREVIATIONS

EU – European Union

EMA – European Medicines Agency

KSA – Kingdom of Saudi Arabia

MENA – Middle East and North Africa

MP – Medical Products

NPhaU – National Pharmaceutical University

UAE – United Arab Emirates

WHO – World Health Organization

INTRODUCTION

Relevance of a subject. Pharmaceutical activity around the world plays an important role in providing the population with high-quality, effective, affordable medicines, which includes such areas as: industrial production, manufacturing in pharmacies, sales, quality control, registration, inspection, etc. A necessary element of pharmaceutical activity is the regulation of the sphere of circulation of medicinal plants, which is necessary for the modern life of the welfare state. An urgent issue is the search for the formation of legal mechanisms, limiting state intervention in the sphere of interests of pharmaceutical market entities while ensuring an increase in the efficiency of public administration in the interests of social justice, improving the quality of life of the population.

Licensing is one of the forms of administrative and legal regulation in the field of economic management, within which a direct impact is exerted on the sustainable development of a particular entrepreneurial activity. Licensing is understood as a means of state regulation of economic activities aimed at ensuring security and protection of economic and social interests of the state, society, rights and legitimate interests, human life and health.

The licensing structure in pharmaceutical activities is a set of one or more regulations established by national or regional authorities to guarantee the safety, efficacy and quality of a pharmaceutical product and services. Licensing in this area is a means of regulatory influence of the state on the activities of business entities and control over compliance with licensing requirements related to various types of activities.

The purpose of the work is to study the feasibility of practicing the licensing structure of pharmaceutical activities in the world and its impact on the quality and efficiency of pharmacy institutions. The main purpose of the qualification work is to describe the licensing process based on the practice of European countries and Middle East and North Africa (MENA) countries.

The purpose of the qualification work is to study the importance of licensing

as one of the methods of regulating the pharmaceutical sector. To achieve this goal, the following **tasks** must be completed:

- to identify the features of state regulation of pharmaceutical activities;
- to analysis of norms and licensing requirements for pharmaceutical activities in international practice;
- to analysis of the structure of pharmaceutical licensing in MENA countries;
- to organize and conduct a sociological survey of public opinion of students on the issue of choosing a profession as a pharmacist and their attitude to the method of licensing pharmaceutical activities.

Research objects: data from special literature, as well as the legislative and regulatory framework governing the issues of state regulation of pharmaceutical activities in the world, in particular licensing requirements in Ukraine and MENA countries; scientific publications in this area; questionnaires of students with pharmaceutical education.

The subject of the study: the licensing process as one of the important methods of state regulation of pharmaceutical activities.

Methods of research was used a logical, historical, graphic and method of system analysis.

The practical value of the work: this work offers a vision and a roadmap for the licensing process in Europe and Morocco, with the recommendations.

Scientific novelty. For the first time, a comparative analysis of requirements for licensing pharmaceutical activities in a few countries around the world, including Morocco, was conducted, as well as a sociological survey of pharmacists on issues of licensing pharmaceutical activities.

Structure and volume. The work is presented on 52 pages and consists of 3 chapters, general conclusions and a list of references, which consists of 34 sources. The results of the study are illustrated by 9 tables and 16 figures.

CHAPTER 1. ESSENCE AND BASIC PRINCIPLES OF STATE REGULATION OF PHARMACEUTICAL ACTIVITY

1.1. General characteristics, methods and functions of state regulation

Regulation is a key concept in economics that refers to the rules and guidelines established by authorities, often governments, to control or supervise the behavior and operation of businesses and industries.

Regulation is a vital mechanism in maintaining economic stability and promoting free competition against monopolistic behavior. Regulation is distinct in that many tools are employed in conjunction with it including [11]:

- legislative regulation, which defines industry standards in laws and policies;
- administrative regulation, in which regulatory bodies issue licenses, conduct inspections, etc.;
- economic and financial regulation, which includes price controls, antitrust laws, and subsidies;
- and finally, social and ethical regulation, which assists in creating laws that protect consumers, environments, and worker safety.

The regulatory landscape has changed significantly in recent years. With new trends such as digital governance, blockchain oversight, and data protection systems, changes are needed to support efficiency, transparency, and equitable growth across all sectors [20].

Having studied the relevant literature, one can identify the main methods of regulation that are used in the pharmaceutical sector.

State regulation of entrepreneurial activity is understood as the activity of the state represented by its bodies, aimed at ensuring public interests by using means of influencing entrepreneurial relations and the behavior of business entities. Governments create laws, regulations and guidelines relating to the pharmaceutical environment.

Economic Regulation: pricing control reimbursement policies and taxation.

Social and Ethical Regulation manifest in fair access to medicines; Drugs Control and Conformance to bioethical standards.

Through its functions, regulation ensures the safety of medicines at all stages of their life cycle. Implementation of industry standards, issuance of licenses by government bodies for the production, distribution and retail trade of medicines, as well as monitoring of medicines are just some of them.

Management and control are legal forms of state regulation of the economy. The problem of the state's influence on the content and forms of economic market relations and its adequate legal support has been and remains central in pharmaceutical activities. Healthcare is one of the priority areas of state activity. The state forms health policy and ensures its implementation. The most important category of instruments of state regulation, through which the state requires the subjects of social relations to implement its decisions, is legislation. Regulation is enshrined in the legal framework of laws, decrees and orders that prescribe compliance with standards. Provisions on state regulation of the economy are provided for in the basic laws of many states, for example, in Article 92 of the Constitution of Ukraine, Article 131 of the Constitution of Spain of 1978, Article 70 of the Constitution of France of 1958 [1-8].

The main task of state regulation of economic activity is to create complex legal means, including the creation of a legal basis for economic relations that protects the interests of all participants in the process. This task is expressed in ensuring sustainable and dynamic development of the economy, meeting state needs for goods, works and services, ensuring employment of the population, security of the country, freedom of enterprise, protection of consumer rights, etc.

In the legal basis of state regulation, several functions can be distinguished.

First, the function of governance, in which the public interest is protected, and economic viability is encouraged to ensure the smooth running of industries.

Secondly, the function of control.

Thirdly, the function of applying administrative and economic sanctions.

Methods are understood as ways of state influence on the sphere of entrepreneurship, market infrastructure, non-profit sector of the economy in order to create or ensure conditions for their activities in accordance with national economic policy. Each method finds its implementation, application through a set of suitable tools. Methods of state regulation can be classified both by forms and means of influence, and by other instruments of influence [11]. The main methods and their classification are highlighted in table 1.1.

Table 1.1

Classification of methods of state regulation of the economy [22]

Classification criterion	**Methods**
Impact content	• Economic; • Administrative; • Socio-psychological; • Institutional
Type of influence	• Direct; • Indirect
Nature of influence	• Restrictive; • Prohibitory; • Permissive; • Stimulating; • Recommendatory
Method of acceptance	• Legal; • Non-legal
Object of influence	• Sectoral; • Functional
Subject of influence	• Individual; • Collective
Level of influence	• National; • Local

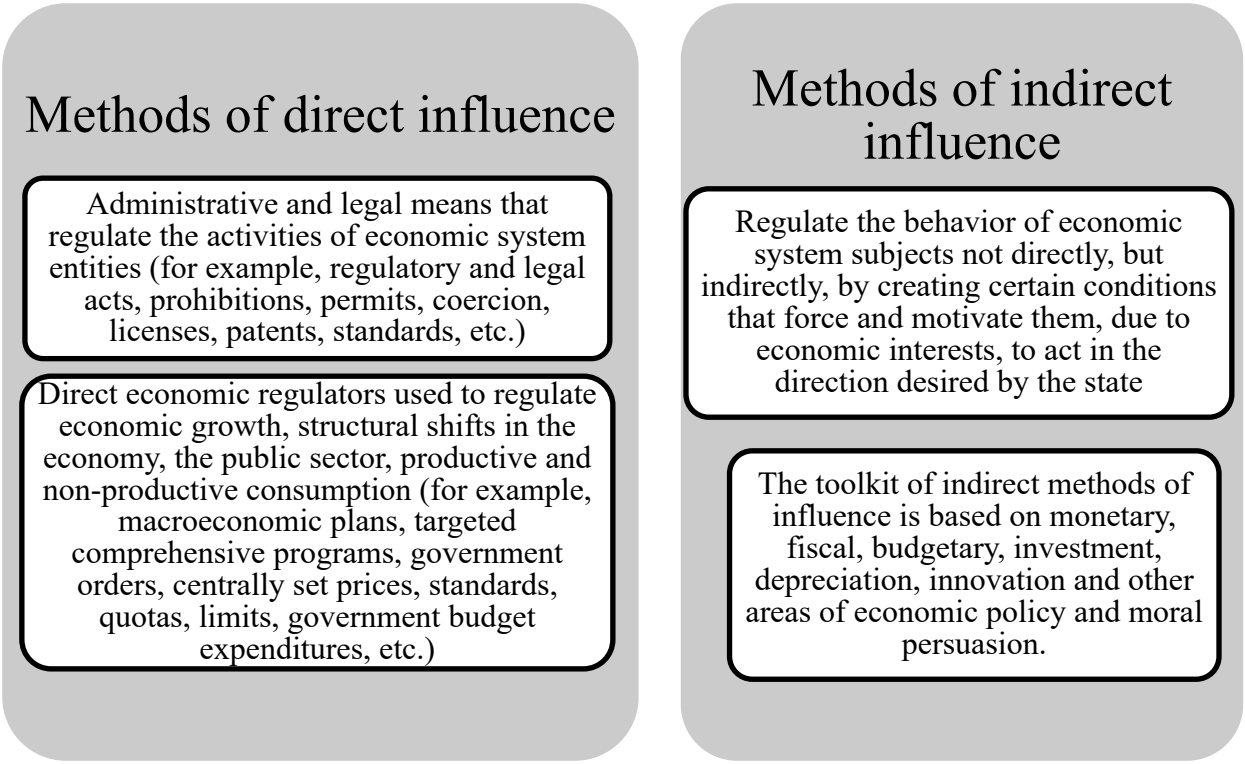

Fig.1.1. Methods of state regulation by forms of influence

The management function is carried out by direct (administrative) and indirect (economic) methods. The specificity of direct methods is that they are a set of mandatory requirements and orders of the state, and indirect methods allow the influence of the state on economic interests.

It can be noted that administrative methods significantly limit the freedom of economic choice, but there are areas of activity where administrative methods are quite effective (fig.1.1) [12,22].

Such areas of activity include the healthcare industry. Forms of state regulation of the economy, like all other elements of this system, are determined by the socio-economic goals and level of development of the country, the economic situation, government policy priorities, etc.

Direct intervention of the state is also the adoption of legislative acts designed to streamline and develop relations between market entities. This can also include the establishment of state or fixed prices, tariffs, the size of deviations in market prices, profitability standards, and trade markups.

Direct intervention is carried out through the expansion of state ownership of

material resources, lawmaking and management of production enterprises. In all developed countries, there is a significant public sector of the economy. The state is the owner of enterprises here, has capital, and takes a share in the activities of enterprises.

Direct regulation is important for supporting domestic entrepreneurship and ensuring the competitiveness of national products on world markets. Thanks to its influence, market infrastructure is formed, monopoly is limited, developing small and medium businesses, encouraging innovative activities of enterprises.

There are also methods of government regulation that combine direct and indirect regulation, for example, the contract system, that is, the system of government orders and government purchases of products and services.

In our opinion, state regulation of economic activity includes the following types: regulation of conditions of economic activity; direct management of economic activity; control over economic activity. By determining the conditions of economic activity, the state also exercises control over their observance. Forms of state regulation of economic activity are fixed in legislative acts and other current legislation, as a rule, in relation to the relevant economic activity. General rules on state regulation of entrepreneurial activity may be provided for in a special law of the country.

1.2. Peculiarities of state regulation of pharmaceutical activity

"Legal regulation in society is one of the essential conditions for a stable legal order, as well as bodies, institutions and agencies that ensure the protection and protection from violation of those rights and legitimate interests of citizens and other persons that are enshrined in current legislation" [3,22,23].

Taking this into account, it should be understood that the pharmaceutical market is unique and differs from conventional markets in the complexity of regulation levels, the choice of adequate methods, and the establishment of mandatory requirements for all entities: manufacturers, intermediary structures, end

consumers, as well as the implementation of standards of good pharmaceutical practice, the specifics of which are subject to mandatory recording in European legislation. State regulation of the pharmaceutical market in the world necessarily includes administrative (institutional, organizational) and regulatory (legal, normative, source) components.

Administrative methods of regulation can be applied in areas that are not covered by the market but depend on it, and one such area is healthcare, and particularly the pharmaceutical sector.

Several methods of administrative regulation have been developed to regulate pharmaceutical activities, manifested in the European Medicines Agency (EMA) in Europe and the World Health Organization (WHO).

The main objectives of state regulation in the pharmaceutical sector are to ensure the health of the population. This is possible only through access to the market of quality medicines and medical standards, as well as in creating an environment for fair market practices, free from price manipulation.

Starting consumer trust through quality control, promoting economic stability through financial regulation, protecting the environment through sustainable regulation, protecting national production and controlling the supply chain in strategic industries. Having studied the literature, we identified several tasks of state regulation of the pharmacy sector (fig.1.2) [28].

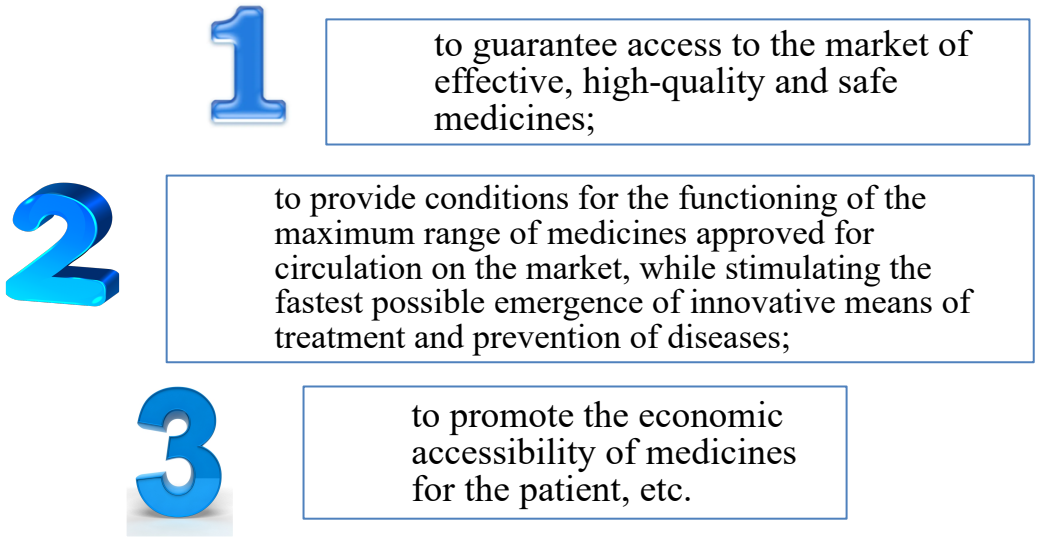

Fig.1.2. Main tasks of pharmaceutical sector regulation

For effective government regulation, the balance between innovation, accessibility, and security is a key operational aspect that requires constant adjustment to address the evolution of global challenges and technological development.

Regulatory Frameworks in Various Countries: each country and region have its unique regulatory framework that governs pharmaceutical activity, which provides rules on drug approval, monitoring, and compliance. In the European Union, pharmaceutical firms may go for centralized approval through the EMA, allowing drug distribution throughout all member states [23]. Nevertheless, National regulatory agencies are essential players in drug pricing, monitoring, and post-market surveillance. The United States, on the other hand, follows a somewhat independent approach to regulatory systems, through the FDA, with a well-outlined drug approval process of rigorous clinical trials and process monitoring. State regulations govern licensing procedures that are very stringent so that only safe and quality pharmaceutical products reach the market [26,27,31].

The table 1.2 shows compare key regulatory bodies in different regions [20].

Table 1.2

Pharmaceutical regulatory bodies and their functions

Country/Region	Regulatory Body	Key Function
USA	FDA (Food and Drug Administration)	Drug approval, safety monitoring
Netherlands	MEB (Medicines Evaluation Board)	National drug approval and pharmacovigilance
Morocco	DMP (Direction du Medicament et de la Pharmacie)	Licensing and market authorization
EU	EMA (European Medicines Agency)	Centralized drug approval
Japan	PMDA (Pharmaceuticals and Medical Devices Agency)	Regulatory oversight and compliance

It is possible to determine the main functions of the regulatory (organizational and legal) policy of states related to the circulation of medicines, namely [22]:

- creation and maintenance of a system that ensures compliance with the requirements for the circulation of medicines at all stages: development, production, export/import, transportation, sale (internal trade, in particular with the participation of the end user/patient), consumption, disposal, etc.;
- licensing of types of economic activity in this area;
- admission to the market (registration) of medicines;
- monitoring of safety (pharmacological surveillance / control) and quality of medicines at all stages of circulation;
- pricing policy and reimbursement, etc.

An important aspect of the proper functioning of the global and domestic markets for pharmaceuticals is the provision, harmonization and unification of its regulatory and legal regulation.

To conclude on the safety and efficacy of the drug and to bring it to the market, a regulatory review is required by a national or regional regulatory authority using test data.

Each country has its own territory with large regulatory discrepancies, so the timing of drug approval may differ. These periods can be relatively fast in the United States and Japan, while in the EU it takes longer to register, confirming greater market access through centralized procedures. Some emerging markets, such as Morocco, require additional compliance measures that, due to their alignment with national regulatory requirements, make the already tedious approval process even longer.

Regulation is also influenced by drug pricing and reimbursement policies, respectively, control over the prices of medicines and devices differs significantly from one healthcare model to another. By establishing control over pricing, governments seek to balance the availability and profitability of pharmaceutical companies.

The social significance of medicines as essential goods determines the interest

and attention to the formation of prices for medicines on the part of world organizations: the UN (United Nations Organization), WHO, EU. To create a single internal market for medicines, most EU countries have adopted legislative acts to regulate prices for pharmaceutical products. The EU member states have decided on a coordinated policy of pharmaceutical pricing, trade ethics, control over the limitation of the range of medicines selected to meet the needs of national health care and insurance systems [28].

Today, there are two main pricing methods. State-regulated pricing is typical of European countries and Canada, while national health authorities negotiate prices with pharmaceutical companies. The second method uses a reference pricing system, which compares drug prices from abroad to determine a fair price. Generic drugs are strongly encouraged to reduce healthcare costs.

This method is commonly used in the US, as pharmaceutical companies set their prices based on market demand and innovation. Patented drugs can be much more expensive, and this is where the conflict over access to essential medicines begins. The relationship between the pharmaceutical industry and the state is an important part of the management of the pharmaceutical sector in general, both at the national level and at the level of the European Union as a whole.

Some issues, such as aspects of the registration of medicines, are agreed upon and are the same everywhere. In other respects, however, the regulation of the pharmaceutical industry in different countries depends on whether the interests of healthcare or industry are more considered.

Conclusions to the I Chapter

In accordance with the results of the analysis of data from specialized literature, it can be stated that state regulation is the state's intervention in the economy with the aim of general coordination of the economic process and stabilization of economic development in accordance with the developed guidelines.

Differences have been established between the types of regulation:

administrative, legal, social and economic.

It has been determined that the role of the state is to regulate competition and is implemented through the development of industrial policy, within the framework of which methods and forms of influence on business activity are determined to increase their competitiveness.

Taking into account the above, it is necessary to conclude that the legislative consolidation of the legal regulation of pharmaceutical activities is necessary in each country, this is due to the objective need for the transition from the subordinate to the legislative level of legal regulation achieved in European countries.

European Union directives are binding on the territory of all Member States and are an important source of improvement in legal regulation.

In the European Union, the legal regulation of pharmaceutical activities is carried out in order to ensure a high level of protection of human health, to contribute to the functioning of the single pharmaceutical market.

CHAPTER 2. STUDY OF INTERNATIONAL EXPERIENCE REGARDING FORMS OF STATE REGULATION OF PHARMACEUTICAL ACTIVITIES

2.1. Licensing as a form of state regulation of pharmaceutical activity

In the pharmaceutical activity, regulation is an important and fundamental strategy used to control unauthorized entities in the industry, including pharmacy. The main goal is to ensure that only accredited companies and qualified individuals are allowed to engage in the development, production, marketing, distribution or any other drug-related activity.

The legitimacy of these measures increases public confidence, realizing that the safety of drug consumption increases despite the existence of lower-quality drugs that can be harmful to consumers.

The license refers to the authority or legal documents required to carry out any activity in the pharmaceutical sector. It is a broad term that includes entities such as pharmaceutical plants, chemists, importers, distributors, and pharmacist professionals, such as pharmacists.

Licensing is a process characterized by a clear approach to determining the powers and limits of influence of organizations, companies and institutions [12,13].

Licensing is the process of passing the procedure for obtaining a license for types of economic activity subject to increased control by the state or special bodies. The task of this process is to thoroughly check a business entity or other organization for whether it is sufficiently qualified, responsible and knowledgeable to provide certain services or manufacture certain goods. Such services or goods by default have an increased risk of negative impact on the environment and public health. Insufficient qualification of an entity dealing with the supply of medical products, pharmaceutical services or high-risk work can lead to inevitable consequences, losses and, in some cases, even casualties.

In fact, on the one hand, a license is a permit, evidence that the licensee has

received an exclusive right. On the other hand, licensing also implies the obligation that the licensee undertakes to comply with exclusive requirements when performing the work specified in the license or providing services, manufacturing goods. In Figure 2.1, we identified the main components of the licensing process [4].

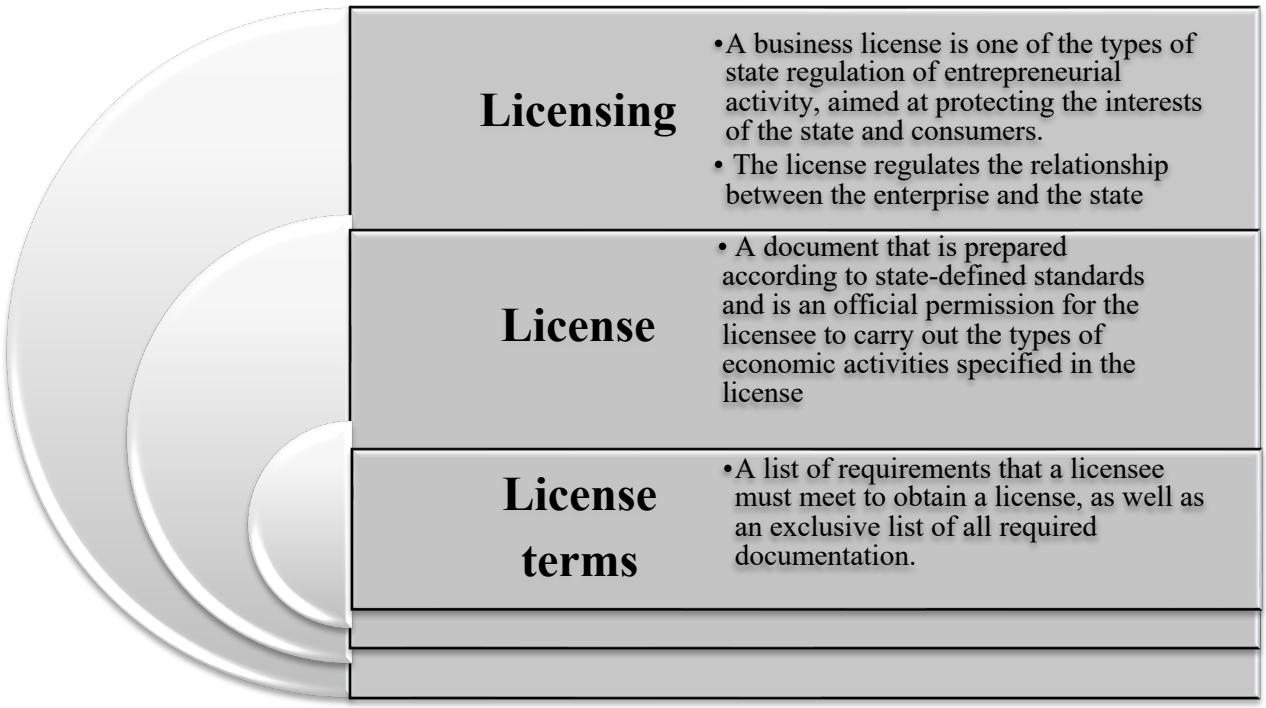

Fig.2.1. General licensing concepts

The main purpose of licensing is to assess the possibility of pharmaceutical organizations providing various types of qualified drug care and to issue a state permit (license) for the right to engage in pharmaceutical activities.

Tasks of licensing certain types of activities [5,9,11,18,19]:

- prevention, detection and suppression of violations by a legal entity, individual entrepreneur of the requirements established by law.
- compliance of the license applicant with these requirements is a prerequisite for granting a license, their compliance by the licensee is mandatory when carrying out the licensed type of activity.

State policy in the field of licensing is based on:

- the principle of a unified state licensing system;
- the principle of territoriality, according to which the license applies to

the administrative territory of the licensing authority that issued it;

- the principle of compliance with the law;
- the principle of priority of consumer protection;
- the principle of publicity and openness.

Licensing can be defined as management activities carried out through control and accounting functions. The content of state control can be considered as an integral part of public administration activities and control as an independent management process.

Control in relation to licensing of pharmaceutical activities has specific features. It can be of a preventive nature and expressed legal nature, as it is a set of administrative and legal means that establish and fix at the legislative level the mechanism for licensing entrepreneurial activity.

For the government to control and regulate the pharmaceutical sector, licensing is an essential tool for them. Licensing by a government, after ensuring that all legislation and codes concerning such a subject are followed, provides society with safe and effective medicine. The licensing process can vary, but its aim is the same, namely, to safeguard public health and afford certain standards to industry.

In the absence of a license, firms or professionals are not allowed to work in accordance with the law. Many aspects of a functioning licensing system can be depicted as a process.

The stages of the licensing process are developed in accordance with the generally structured procedure of each country. They begin with an application, where the person or company identifies the scope of the pharmaceutical activity and provides documentary evidence of regulatory compliance. The next stage consists in checking by state authorities the compliance of the institution with the necessary standards. If these conditions are met, the organization receives permission to implement this activity. After this phase, regular inspections will take place to ensure ongoing compliance, prevent any violations, and ensure consistently high-quality standards [22].

We have depicted the licensing process in the figure 2.2.

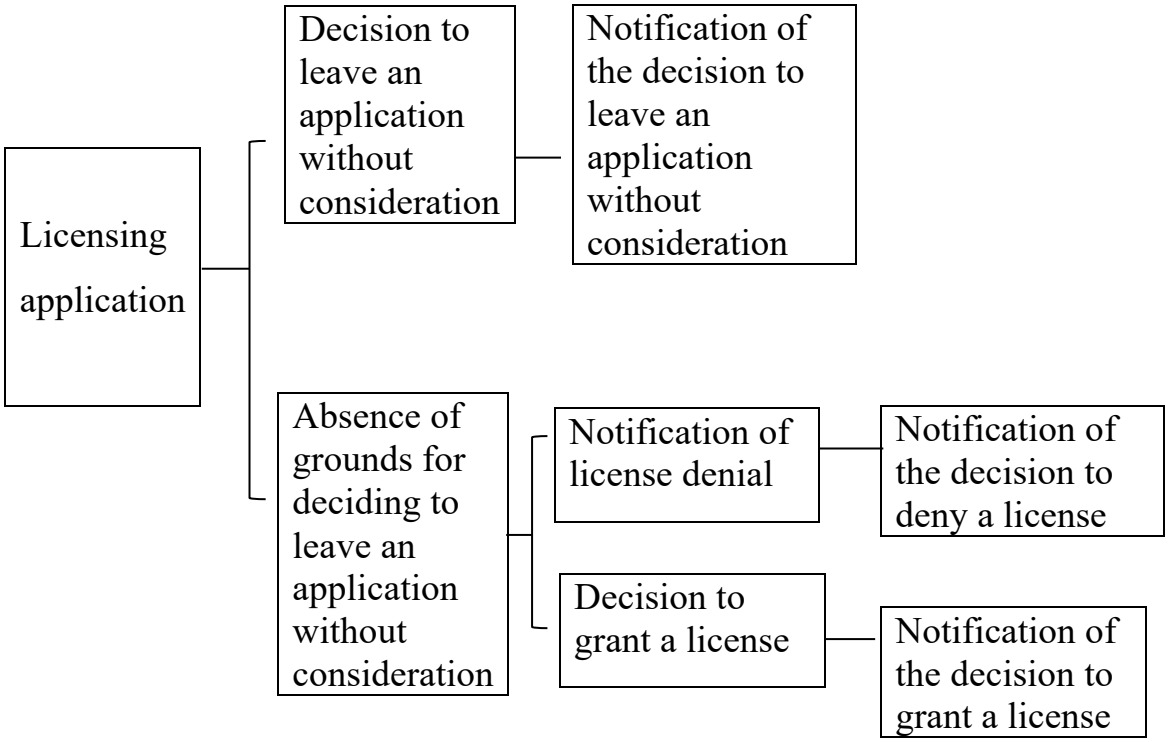

Fig.2.2. Procedure for licensing the production, import and circulation of medicinal products [3,30].

Pharmaceutical licensing practices differentiate licenses according to their intended activity to ensure strict regulation of each segment of the pharmaceutical supply chain.

There are typically several main types of pharmaceutical licenses in countries around the world. Regardless of the methods of implementation, this type of activity is subject to licensing.

- manufacturing;
- wholesale;
- retailsale (sale of goods in pharmacies);
- import/export, specifically designed to regulate various aspects of pharmaceutical activities.

A manufacturing license is required for any company that manufactures pharmaceutical products. It guarantees the manufacturer compliance with the

conditions of Good Manufacturing Practice (GMP), which gives the basis for the compliance of the drug with certain standards of quality, safety and effectiveness [29]. The licensee will receive a license only after intensive inspections of production premises, equipment and processes, as well as qualification training of personnel in accordance with the license conditions.

A wholesale license allows the distribution of pharmaceutical products in bulk to retailers and other suppliers, ensuring that Good Distribution Practices (GDP) and Good Storage Practices (GSP) are followed to maintain the integrity of the supply chain and prevent contamination or adulteration of medicines [22].

A retail license allows the sale of pharmaceutical products directly to consumers from pharmacies and their structural divisions, thus ensuring that these establishments meet the standards of storage, dispensing and patient counseling in accordance with Good Pharmacy Practice (GPP) [23].

Finally, any company engaged in cross-border trade in pharmaceutical products requires an import/export license - the licensing authority ensures compliance with international requirements and standards set to protect public health.

Each licensing type constitutes a long application process, including facility inspections and continual compliance monitoring, thereby making it plausible to say that licensing is a very crucial factor and determinant in the safety, quality, and availability of pharmaceutical products. Together, these licenses represent the cornerstone of pharmaceutical regulation, thus ensuring that every stage of the drug supply chain works within such stringent regulatory oversight that public health will be taken care of.

Although licensing is a necessary and effective regulatory mechanism to ensure the safety, efficacy and quality standards of pharmaceutical products, it has its drawbacks, which take different forms in different countries and regions.

Effective licensing requires enormous regulatory capabilities involving well-trained personnel, funds, and robust infrastructure for inspection, enforcement, and monitoring that not many developing countries can afford. Their limited resources

and expertise can significantly hamper the ability of regulators to conduct thorough inspections or maintain even moderate oversight. Thus, it causes gaps in law enforcement, which can jeopardize public health. Based on the analysis of the literature study, it is possible to determine the main negative and positive aspects of the process (tabl.2.1).

Table 2.1

Disadvantages and advantages of licensing pharmaceutical activities

Advantages	**Disadvantages**
• Quality control To obtain a permit, the licensee undergoes an inspection of the company's infrastructure, equipment, personnel and processes, which prevents low-quality or unsafe drugs from entering the market. • Market stabilization Licensing creates transparent rules of the game for all participants, eliminating the possibility of unfair competition and illegal activity. • Protecting the public interest A license not only protects consumers, but also ensures compliance with sanitary, environmental and legal standards. • Increasing trust For a business, a license becomes a tool that strengthens its reputation.	• The contradiction between the existing procedure for licensing pharmaceutical activities and the real needs of citizens, society and the state in the field of circulation of medicines. • The influence of the state on social relations developing in the pharmaceutical market, which is carried out through the application of strategizing procedures • Economic and political instability negatively affects the activities of enterprises, which is why problems arise in the legal field regulating the licensing procedure. • Great need to attract regulatory capacity (funds, qualified personnel)

There is significant complexity and resource consumption for small

companies associated with the licensing process. These entities are often limited in the scope of spending budgets related to regulatory compliance, including facility modernization, documentation and GMP compliance, thereby limiting competition and innovation in the pharmaceutical market.

Support for SMEs at the management level will help minimize this burden by ensuring an appropriate standard of management.

Even under strict licensing conditions, falsified and illegal medicines remain a serious threat to public health, as they enter the market through unregulated structures through the abuse of illegal channels, endangering patients' lives, as well as violating trust in the system as a whole. Measures that may need to be taken to address this issue include increased enforcement oversight, harsh penalties, and international cooperation. Additionally, supply chain integrity can be improved through technologies such as tracking systems and blockchain. Differences in licensing requirements between countries are also a stumbling block for international trade and cooperation, as pharmaceutical companies operating in different markets must first familiarize themselves with different regulatory frameworks before they can start and operate, often leading to delays, increased costs, and inefficiencies. First of all, this is addressed by strengthening regulatory capacity through training, international cooperation and resource allocation.

Just like all the other licensing procedures for pharmaceutical products, licensing processes for pharmaceuticals in most of the countries are geared towards the regulatory and public health priorities of countries as concerns ensuring safety, efficacy, and quality of pharmaceutical products.

In most cases, entities seeking to obtain a license to market medicines in different countries are subject to the same requirements, including regulatory documents. However, there are differences in the procedure for issuing such licenses in different jurisdictions. The expediency of state regulation of the pharmaceutical market is recognized in all developed countries. At the same time, the question of the principles and methods of this regulation, the degree of state intervention in the economy is acute.

In the system of state authorities of all countries, there are special bodies (usually the Ministry of Health) that implement state policy in the field of issuing licenses for the circulation of medicinal products. We have made a comparison in some countries of the bodies responsible for the licensing process (tabl.2.2) [14,19].

Table 2.2

General concept of pharmaceutical regulation in several countries

Country	**National regulatory authorities**	**Types of activities subject to licensing**
United States	Food and Drug Administration	Pharmacist Licensing Drug manufacturing licensing developing, distribute, or sell another company's pharmaceutical products or technologies under specified conditions and terms
EU	European Agency for the Evaluation of Medicinal Products	Wholesale trade (export-import); retail trade (sale of goods in pharmacies); the provision of various services for the storage of medicines
India	Central Drugs Standard Control Organization	Export of pharmaceutical products Manufacturing, Biotechnology industry, sale of drugs
Brazil	National Health Surveillance Agency	International trade Retale sale Industrial production Prescription manufacturing and homeopathy
Japan	Ministry of Health	Retail trade in medicines, state pharmacist license, Advertising

Each of the regulatory bodies of the countries plays a very important role in ensuring that medicines are manufactured and marketed in accordance with the highest standards of safety, efficacy and quality. The methods in each country may differ significantly from those of other countries, reflecting the unusual regulatory environment and health priorities, highlighting the need for customized licensing practices that exist around the world. These systems not only protect public health, but also promote creative processes, market entry and international trade [16].

2.2. Analysis of norms and requirements for pharmaceutical activity in international practice

Regulation of pharmaceutical activities is one of the important areas in healthcare systems around the world. All forms of state regulation of the production and circulation of medicines are of a national nature, as they are inextricably linked with the peculiarities of legal provisions, state structure, structure of health care and pharmaceutical services, traditions, and available resources of each country. Each country and region have a heterogeneous space of pharmaceutical markets, both economically and regulatory.

At the next stage of our research, we considered foreign experience in licensing pharmaceutical activities as an example. In more detail, we will focus on studying the norms and requirements for pharmaceutical activities in countries that already have long-term experience.

Some countries apply licensing, when an entrepreneur is issued a special permit to carry out pharmaceutical activities, while others establish a notification procedure for starting entrepreneurial activities. The licensing mechanism in each country is developed with a high degree of detail and operates on the basis of legal norms.

In France, Germany, Great Britain, Norway, the USA, and Japan, there is a developed pharmaceutical market, with already existing long-standing traditions of state control. The structural organization of licensing control bodies is primarily due

to the delimitation of objects of control and the need to create an architecture of horizontal and vertical power relations based on a clear delineation of control powers. The system of executive bodies includes all organizations of licensing control and distributes control powers that belong to these bodies as part of their general competence [19-22,34].

As a rule, all instruments for regulating the circulation of medicines in these countries can be classified into professional requirements for pharmaceutical activity, certification, registration and regulation of property issues, licensing, direct requirements for pharmacists, pricing. (table 2.3).

Table 2.3

State regulation of the pharmaceutical legislation

Metods of the state regulation of the pharmaceutical acnivity	Switzerlan	Norway	United Kingdom	USA	Italy	Holland	Denmark	Germany	Sweden	Japan	France
Licensing and certification of drugs	+	+	+	+	+	+	+	+	+	+	+
Registration (registers, lists)		+	+	+		+		+	+		+
Monitoring of drugs after registration		+	+				+				+
Licensing of production, wholesale and retail trade	+	+			+	+		+	+		+
Law on pharmacies: restrictions on the number of pharmacies, property	+	+	+	+	+	+	+	+	+	+	+
Medicine prices	+	+	+		+	+	+	+	+		+
Reimbursement	+	+	+		+	+	+	+	+		+

All countries in the European Region require a licence to open and operate a pharmacy. Most often, it is issued by a state authority, but in the federal states, the issuance of a pharmacy license is regulated at the local level. In some countries, the issuance of a license to open a new pharmacy may depend on certain demographic criteria. Among them, the most common is the number of populations in a particular city. Several countries use geographic criteria to decide whether to grant a license or reject an application. This avoids the concentration of pharmacies in one area. Some of these criteria are applied in conjunction with demographic criteria. In many countries, the requirements for pharmacy premises are described in detail. The requirements establish that the premises must meet the purposes of dispensing and storage of medicines, as well as their production, or be suitable for these types of activities in terms of planning and equipment.

In some countries, it is necessary to obtain permission for a new premises in a community pharmacy - this procedure includes conducting an inspection of the premises or reviewing the documentation provided. Several countries have set minimum space standards for pharmacies. They vary from country to country and often depend on the services provided by the pharmacy.

In some countries, such as Lithuania, different types of pharmacy licenses are issued, depending on whether a community pharmacy is allowed to engage in the individual manufacture of medicines.

The license can be revoked if the pharmacy ceases to operate or is not established within the allotted period after the license is issued. Different countries have some rules for withdrawing licenses. For example, in Denmark, Germany and Finland, if a license is not used for one year, it is revoked or canceled. In Belgium, this period is equal to two years. If the license holder or pharmacy employee violates pharmacy practice laws or licensing requirements, the license may be revoked or permanently. Reasons for license revocation may include hiring employees without higher pharmaceutical education, violating the rules for dispensing medicines.

In the table 2.4 we have considered the main requirements for the operation of pharmacies in some countries [3-11,19,22].

Table 2.4

Basic licensing requirements for retail sales

Country	Personnel requirements	Requirements for premises (min. area)	Requirements for pharmacy operating hours	Comments
1	2	3	4	5
Germany	5 years at university: 2 years each of basic and main studies +1 year of practical training	at least 110 square metres	from 09:00 to 18:00 on weekdays	the principle of personal management and ownership of the pharmacy by the pharmacist applies, license is issued for a specific pharmacy
France	higherpharmaceutical education, registered with French Ph. Order	depends on the number of people served by the pharmacy	In general, the work schedule is from 09:00 to 19:00	A pharmacist can own a pharmacy. He must also directly manage the pharmacy
Denmark	5 years of higher education	determined by the authorities, local authorities give permission for the size of the premises	9:30 a.m. – 5:30 p.m. Monday through Thursday, they close a little later on Friday, Saturday hours: 10:00 a.m. – 1:00 p.m.	A pharmacy may have a branch, the opening of which requires a separate license.

Continuation of the table 2.4

1	2	3	4	5
Austria	5 years full-time equivalent	120m2	determined by local authorities	A license is not granted if there is no production premises
Norway	5 years of higher education	determined by the authorities	09:00–18:00 on weekdays	Pharmacies cannot work in the same room where medical practice is conducted
Estonia	The professional qualification is confirmed by the Depart. of Health	80m2, in rural areas, 50 m2	40 hours per week for cities	Pharmacy owners are required to provide training for their pharmacists and druggists for a period of two years
USA	PharmD (Doctor of Pharmacy)	there are no restrictions	depend on the city location	creation of Licensing Centers, issuing licenses for all types of activities
Great Britain	Pharmacy degree equivalent to BPharm or PharmD.	there are no restrictions	Mon-Sat from 09:00 to 18:00.	Any citizen can become the owner of a pharmacy, only a pharmacist can manage a pharmacy. The pharmacy must be registered in the appropriate to the pharmaceutical society

In EU countries, permission is required to open a pharmacy. For this purpose, an application is submitted, which most often indicates (depending on the country): a description of the premises of the pharmacy; the owner of the pharmacy; date of establishment/establishment; other areas of activity; plan in a certain scale and specifications; coordinates of warehouses for which permission must be obtained; address and contact phone number. When deciding on the issuance of a license, as a rule, certain time restrictions are introduced. The license is issued for a period of one to two years (in some countries, for example, in Denmark, up to 20 years).

In almost all countries, the professional activities of a retail pharmacy are under the direct responsibility of the pharmacist. In countries where ownership of retail pharmacies is limited to pharmacists, the owner is responsible for all pharmacy activities, as in France and Germany, where the pharmacist must personally manage the pharmacy.

Working as a pharmacist in Europe is rewarding, but requires a clear understanding of the specific requirements of each country. From the high demand in Germany to the exacting standards in Switzerland, opportunities abound for those willing to meet the qualifications.

Licensing is one of the tools for regulating the pharmaceutical market, it is advisable to use it effectively to improve the quality of life of the population, the provision of the population with affordable medicines. Permitting requirements should be developed considering the possible social effect of pharmaceutical activities, and the goals and objectives of regulation should be clearly defined.

Conclusions to the 2 Chapter

One of the methods of state influence on the economy is the state's permissive policy applied to economic entities, which includes the licensing system.

The institution of licensing allows the state to ensure the safety of potentially dangerous activities without introducing a state monopoly on its implementation and thereby restricting the freedom of enterprise.

In world practice, various mechanisms and methods of regulating pharmaceutical activities are used. In all countries with established forms of management and with a developed market economy, there is an effective system of state control and audit bodies. Regulation of pharmaceutical activities through the licensing mechanism, as the study of foreign experience shows, has been used for a long time and quite widely. At the same time, the mechanism itself is developed with a high degree of detail and operates based on legal norms.

The analysis of the features and trends in the regulation of pharmaceutical activities in foreign countries allowed us to conclude that licensing in most countries of the world is permissive. All the considered models and their components and tools are quite successful, but for their effective implementation it is necessary to have many institutions. Each country has its own licensing model, but there are also common points.

Some countries have adopted specific provisions to ensure that responsible pharmacists have the authority and ability to effectively carry out their duties.

In a few countries, regulations state that a pharmacist can be a responsible pharmacist for only one pharmacy, as in Belgium, Estonia, Portugal and France. This restriction also usually applies in accordance with the ownership provisions (a pharmacy can only be owned by one pharmacist and a pharmacist is only allowed to own one pharmacy). Thus, for example, in France, criteria may be established for a responsible pharmacist in relation to work experience, additional certification, etc.

In countries where the pharmacy must be owned by a pharmacist (and where the pharmacy must be run by its owner), the minimum length of experience clearly applies to the owner.

CHAPTER 3. CURRENT STATE OF THE LICENSING PROCEDURE OF PHARMACEUTICAL ACTIVITIES

3.1. Analysis of the structure of pharmaceutical licensing in different countries

The pharmacy segment of the pharmaceutical industry is part of the critical infrastructure of the state, since not only health, but also the lives of citizens depend on its work. Based on the essence and directions of pharmaceutical activity, pharmaceutical workers are health care workers.

Pharmaceutical activity in Ukraine is regulated by national legislation. Taking into account the provisions of the main regulations in this area, pharmaceutical activity can be defined as a certain type of economic activity carried out by business entities on the basis of a license for the relevant type of activity for the purpose of production, wholesale and retail trade, import of medicines, subject to the fulfillment of personnel, organizational and other special requirements established by law.

According to the "Licensing Conditions for Conducting Economic Activities for the Production of Medicines, Wholesale and Retail Trade in Medicines, Import of Medicines" [30], this activity is carried out through:

• a production site indicating the list of dosage forms, a warehouse area (storage room, warehouse), a quality control zone, an area for issuing a permit for the release of medicines - for the production of medicines (industrial);

• pharmacy - for the production (manufacture) of medicines in a pharmacy;

• pharmacy warehouse (base) - for wholesale trade in medicines;

• pharmacy, pharmacy point - for retail sale of medicines;

• warehouse area (storage room, warehouse), quality control zone, area of issuance of a permit for the release (sale) of a batch of a medicinal product - for the import of medicinal products (except for active pharmaceutical ingredients).

In Ukraine, the validity of the license for pharmaceutical activities is currently unlimited (except for the circulation of narcotic drugs, psychotropic substances).

Therefore, the general list of positions of employees in the field of health care, contained in the Handbook of Qualification Characteristics of Professions (Vol. 78) [4,30], for pharmaceutical workers. Qualification requirements are partially common for pharmacists of different qualification categories, but there are also certain differences (tabl. 3.1).

Table 3.1

Qualification requirements of pharmacists according to the qualification category

Pharmacist of the highest qualification category	Pharmacist I qualification category	Pharmacist II qualification category	Pharmacist
Higher education of the second (master's) level in the field of knowledge 22 "Healthcare" in the specialty 226 "Pharmacy, industrial pharmacy", specialization 226.01 "Pharmacy", or in the field of knowledge 1202 "Pharmacy", or in the field of training 1102 "Pharmacy"			
Internship in the specialty "Pharmacy", "General Pharmacy". Continuous professional development			
Availability of a certificate in the specialty and a certificate of assignment (confirmation) of the highest qualification category in this specialty	Availability of a certificate in the specialty and a certificate of assignment (confirmation) of the I qualification category in this specialty	Availability of a certificate in the specialty and a certificate of assignment (confirmation) of the II qualification category in this specialty	Availability of a certificate in this specialty
Work experience in the specialty — more than 10 years	Work experience in the specialty — more than 7 years	Work experience in the specialty — more than 5 years	Norequirements for work experience

At that time, the uniform qualification requirements for persons engaged in specific types of pharmaceutical activities are established by the central executive body that forms the state policy in the field of health care.

Responsibility for compliance with these qualification requirements rests with the heads of health care institutions, rehabilitation institutions, departments, divisions, as well as on the bodies that have the authority to issue licenses for the relevant types of economic activity. Licensing requirements for wholesale trade in medicines also include the licensee's obligation to provide proper qualified personnel, the number of which must correspond to the volume and capacity of pharmacy warehouses. This is necessary for the effective performance of all tasks provided for by the license. The licensee must develop an approved staffing table and job descriptions for employees, which define their main functions, powers, professional knowledge, competencies and other requirements.

In relation to the category of pharmaceutical workers engaged in the retail trade of medicines, the licensing conditions determine that such pharmacies and their structural subdivisions must have a staffed staff of employees with appropriate pharmaceutical education. The licensee approves job descriptions of employees whose activities are directly related to the production of medicines in a pharmacy, retail trade in medicines, which indicate the main functions, powers, professional knowledge, competence and other requirements for employees.

Specialists with higher education of the second (master's) level in the specialty "Pharmacy, Industrial Pharmacy" must have a certificate of a pharmacist-specialist, which is issued by a postgraduate educational institution, or a certificate of assignment (confirmation) of the appropriate qualification category [12].

Currently, Ukraine has no legal restrictions on the planning of pharmacy infrastructure. Licensing conditions for the activities of pharmacy establishments are established by only the requirements for the material and technical base of the pharmacy itself. Considering the main directions of pharmaceutical activity, each of its types has its own licensing conditions for its implementation, which include certain qualification requirements for personnel and premises (tabl.3.2) [30].

Table 3.2

Licensing conditions for conducting economic activities

Type of pharm. activity	Qualification requirements for personnel	Requirements for the premises
Production of medicines	Qualified personnel with practical experience in the number that ensures the proper performance of all tasks related to its activities. In this regard, the licensee must approve the organizational chart and job descriptions	Premises to produce medicinal products must be located and arranged according to technological zones: production, warehouse, quality control, auxiliary.
Wholesale trade	Must have a higher education certificate of at least the first (bachelor's) level in the specialty "Pharmacy, industrial pharmacy"	Compliance with the requirements of regulatory documents regarding storage, quality control, and trade in medicinal products; total area of at least 250 sq. meters
Retail trade	Pharmacists and pharmacist assistants who have the appropriate education in the specialty "Pharmacy, industrial pharmacy", considering the requirements of the legislation	Be in a separate building removed from the housing stock or a built-in isolated room on the first floor with a separate independent exit to the outside from the trading floor
Production of medicines in a pharmacy	Higher education not lower than the initial level (short cycle) in the specialty "Pharmacy, industrial pharmacy"	Min. area:in cities, - 50 sq. m. (hall - 18 sq. m.); in villages, - not less than 30 sq. m. (hall - not less than 11 sq. meters);

In Ukraine, the term for deciding on issuing a license is quite short - 10 working days from the date of receipt of the license application by the licensing authority. The cost of official payments for obtaining a permit in Ukraine is one minimum wage. In EU countries this term is 90 days, and the cost is much higher.

Licensing pharmacy activities in the Middle East is a complex process that requires special attention to the qualifications of pharmacists, the requirements for pharmacy establishments, and the local regulatory framework. Both individual pharmacists and pharmacies themselves with different requirements and restrictions in different countries are subject to licensing in this area. The main elements of this process include orientation in a variety of regulatory environments, understanding of the local legal framework and compliance with specific licensing procedures established by national regulatory authorities. Licensing can affect the regulation of the number of pharmacies in one direction or another. In countries where the healthcare sector is developing rapidly, pharmacies can benefit because they require less labor than in typical healthcare facilities. The aging of the population in the MENA region, and the consequent growth of health services, inevitably leads to an increase in the consumption of pharmaceuticals. This, in turn, increases the demand for pharmacies, where the consumer can receive both prescription and over-the-counter medications and treatments.

The economic structure of the country is also important for the development of the pharmacy sector. If the country is in a favorable state, then trade will grow when pharmacies open. Support from the state government, in the transport sector, or with the help of money or liberalization of the regulatory process, can also be of great importance. In most cases, territories where the issuance of pharmacy licenses is built on simple, clear and fair systems can boast of an increase in the number of pharmacy establishments over time. Then it is beneficial for the population in this region to receive more funds through the health care facilities that currently exist. In the qualification work, we consider the main requirements and restrictions established by the relevant local legislation for pharmacies operating in some MENA countries (tabl.3.3) [17,24]

Table 3.3

Basic licensing requirements in MENA countries

Country	Licensing of an individual pharmacist	Licensing of a pharmacy establishment	Regulatory authority
United Arab Emirates	Bachelor's degree, 2 years of experience and passing the Ministry of Health exam with a minimum score of 60%.	One person may be licensed to operate up to two pharmacies only	MoH; Dubai, Abu Dhabi Healthcare Authority
Saudi Arabia	Eligibility requires a 5-year bachelor's degree in pharmacy and completion of a one-year internship.	The owner of the pharmacy must be a pharmacist with KSA. Limits on the number of licenses held by one owner: cannot hold a license for more than 30 pharmacies.	MoH and Saudi Food and Drugs Authority
Egypt	Pharmacist must be an Egyptian national and have graduated from an accredited pharmacy school. Pharmacy license is also granted to the individual	The pharmacy license is issued in the name of the applicant, who must be an Egyptian citizen. A pharmacy must also be registered with the Pharmacist Syndicate.	MoH and Population, Central Administration for Pharmaceutical Affairs
Oman	Oman Prometric Exam, including holding a pharmacy degree, being registered in their home country, and having a minimum of three years of work experience in a pharmacy	Executive regulations for pharmacy practice and pharmaceutical establishments, including registration and licensing of medicines and pharmaceutical business	MoH

In general, the increase in the number of pharmacies in each location must take place according to conditions, costs and regulations that may be established by public authorities. With lower licensing costs, new pharmacies can be allowed. There are additional elements that play a crucial role in the growth of pharmacies in all conditions. For example, as the population grows, even more consumers will need medicines and, therefore, even more pharmacies will be opened.

In most MENA countries, the pharmacist himself is subject to licensing. The main qualification requirements are a Bachelor of Pharmacy degree from an accredited institution along with relevant work experience and passing an exam administered by the relevant Ministry of Health or a similar regulatory body. In addition to individual licensing of a pharmacist, pharmacies must obtain a separate license for the operation of the institution [24].

There are numerous independent regulatory bodies in the regions of these countries, each with its own processes and requirements for the registration of pharmacies and pharmacists and other formalities.

In **Morocco, the** Ministry of Health plays a central role in the regulation of pharmacy activities. The General Directorate of Pharmaceuticals in the Ministry of Health and Population is responsible for issuing licenses. Regulatory procedures in Morocco are under the control of the Directorate of Medicine and Pharmacy at the Ministry of Health, which is divided into three sub-areas [33]:

- the pharmacy department, which is responsible, among other things, for the clinical evaluation of medicines, registration and pricing;
- the Pharmaceutical Sector Monitoring Department, which is responsible for activities such as scheduling the inspection to establish the GMP certificate;
- LNCM, which is responsible for checking pharmaceutical documentation as well as the quality of laboratory tests.

The legal framework for pharmaceutical activities in Morocco is mainly regulated by Law No. 13 on Medicines and Pharmacy of 2013.

In the chemical industry of Morocco, the pharmaceutical sector ranks second with a turnover of about 17 billion dirhams. At this stage, the pharmaceutical industry includes almost 40 laboratories, 33 production sites, 50 distributors and more than 12,000 pharmacies [31].

The pharmaceutical industry sector is characterized by numerous local pharmaceutical players as well as national companies. Such types of pharmaceutical activities as the production of medicines, distribution, retail trade are necessarily subject to licensing.

Pharmacies in Morocco must be owned and operated by a licensed pharmacist. To practice pharmaceuticals in Morocco, an individual pharmacist must obtain a valid pharmacist's diploma and a license from the Ministry of Health. This licensing process involves rigorous testing and assessment of professional competence.

To run a pharmacy, individuals need a recognized pharmacy diploma and passing licensing exams to demonstrate their professional skills. Pharmaceutical licenses in Morocco are usually valid for at least five years and an application for obtaining costs between 500 and 2000 euros. The process of compliance checks with material and technical requirements consists of several series and requires from two to six months. It takes a lot of time to renew a pharmaceutical license in Morocco and requires a lengthy procedure. Any Moroccan who wishes to practice pharmaceuticals privately must submit a request for approval from the National Council of the Order of Pharmacists against receipt. Requirements for premises of all types of activities are described in the "Technical Standards for Installation, Sanitation and Area of Premises for Pharmacy Placement and Relevant Technical Standards for Pharmacy Establishments" of 2008 [33].

Any space intended to house a pharmacy must have a surface area greater than or equal to 24 m2 on the ground and be equipped and adapted to its activities to allow the execution of pharmaceutical actions in accordance with good pharmacy practice. The front entrance to the pharmacy must provide direct access to the public highway, except for the location of the pharmacy within the shopping center.

The area of the premises for wholesale trade must be at least 500 m2 on the

ground. In addition, the administration must be separate from the premises intended specifically for distribution activities. This activity must be carried out in accordance with the requirements of the GDP. A valid pharmacy diploma is the foundation for pharmacy practice in Morocco. The Ministry of Health issues licenses to pharmacists to ensure that they meet the required standards. We have described the main activities and licensing requirements in figure 3.1 [33].

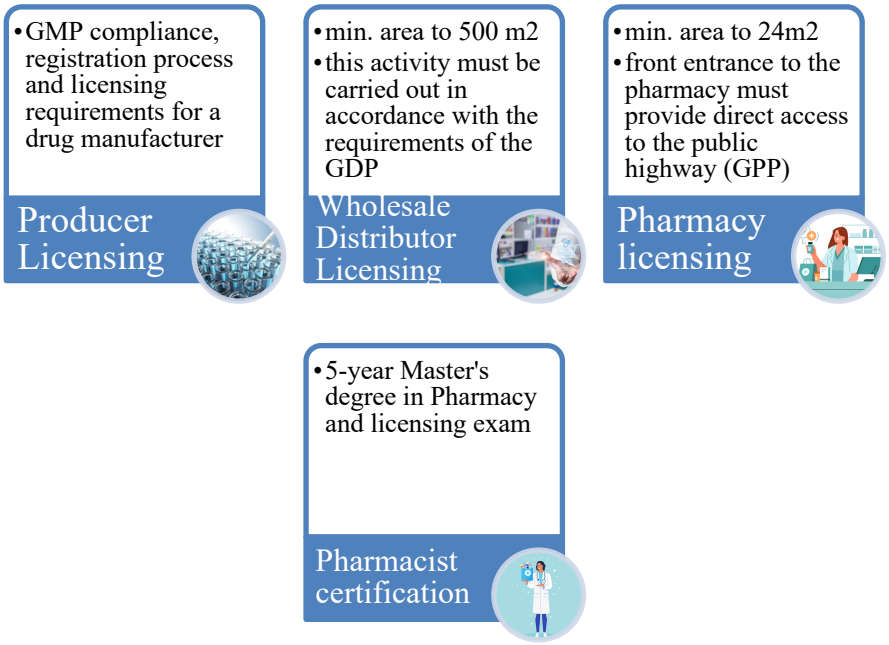

Fig.3.1. Pharmaceutical market: licensing components

The quality of services provided by the pharmacy is ensured by the criteria and conditions of licensing for its activities, which contributes to increasing attention to health care issues. Individual requirements for the staff (performance of their professional activities) and for the pharmacy (establishment of the minimum number of personnel, duties and powers of the pharmacist or the holder of a pharmacy license) and the formation of prescriptions for the premises contribute to the provision of high-quality pharmaceutical services.

3.2. Organizational issues of conducting survey research on the licensing process

The demand for pharmacists in Morocco is increasing due to the expansion of

the healthcare sector and the increasing population. There are opportunities to work in a variety of locations, including community pharmacies, hospitals, pharmaceutical companies, and scientific institutions. Pharmacists in Morocco can try their hand at a variety of fields, including clinical pharmacy, research, and regulatory issues. The pharmaceutical industry is also expanding, with many multinational companies establishing their presence in the country. This growth provides an opportunity for pharmacists to work on drug development, quality control, and marketing.

Many of pharmacist's graduates from pharmaceutical institutions, and various factors influence their career choices. Few studies have been conducted in one higher education institution that would evaluate the choice of profession of pharmacy students with an assessment of influencing factors.

We conducted a study in which 5th-year pharmacy students of Kharkiv Pharmaceutical University were interviewed using an online questionnaire. The survey was sent during the last month of rotation in the internship year (September–November 2024). The profession of a pharmacist offers a variety of career paths. Still, pharmacy students may not be familiar with them, and they may find it difficult to choose the one that best suits their interests, goals, and values. The purpose of the first block of our questionnaire was aimed at determining the correctness of the choice of career and in the second block was to assess the degree of awareness of pharmacists in licensing issues.

As a result of the survey, we received 47 questionnaires, of which 45 questionnaires were used for further processing. The content and structure of the questionnaire was developed by us independently. In the questionnaires, we used open (the respondent himself answers questions from the proposed options) and closed (which requires confirmation in the "yes" or "no" format).

As a result of the analysis of the address part, we found that most respondents were Moroccan students – 99.0%, 0.5% – Tunisia, 0.5% – Lebanon (fig. 3.2).

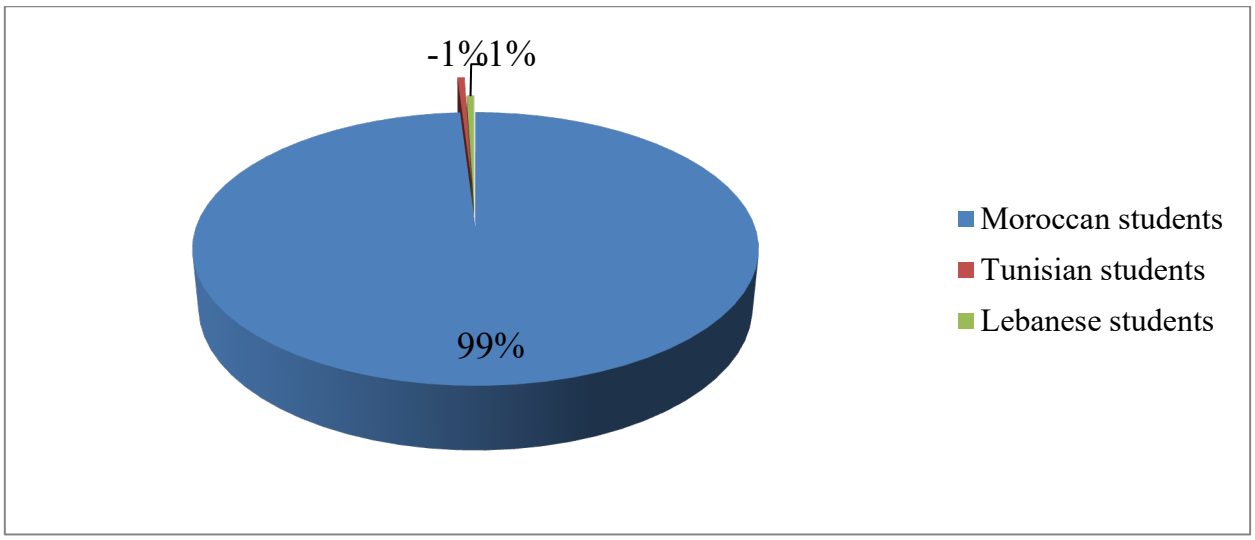

Fig.3.2. Rating of respondents by place of residence

Next, we identified factors influencing the future professional interests of pharmacy students and offered several options to choose from. Students were asked to select one or more factors that determined their choice of profession (fig.3.3).

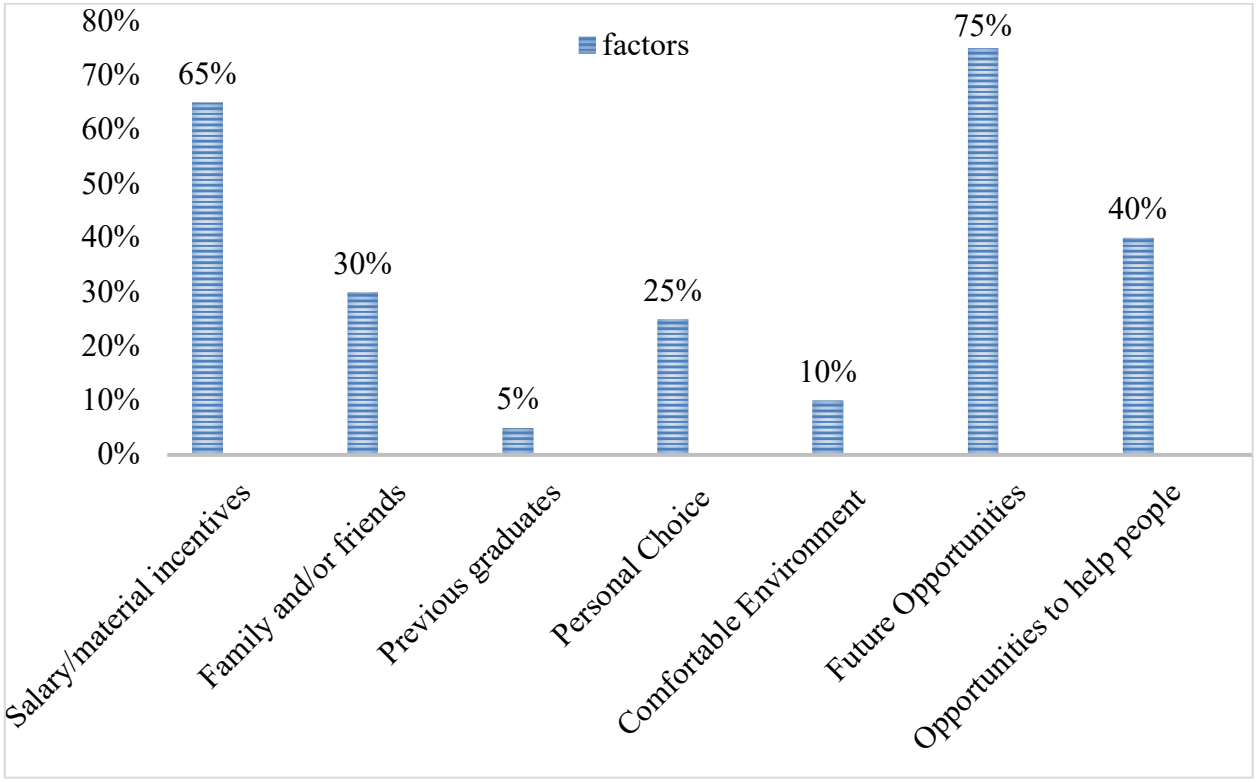

Fig.3.3. The predominance of various factors influencing the choice of profession

The responses show that the choice of the majority of students was influenced

by future opportunities in the profession (34 respondents – 75%); material reward (29 respondents – 65%); the profession of a pharmacist will give the opportunity to help people (18 respondents – 40%); advice from friends and relatives influenced (14 respondents – 30%).

The data presented in fig. 3.4 show in which sector of pharmacy students plan to work after graduating from university.

In general, the further professional path of the graduates coincided with the initial choice of profession of the students. The respondents initially chose the professions of pharmacist (56%), clinical pharmacy (30%), pharmaceutical industry (4%), control and analytical laboratory (10%). The best career paths of the following pharmacists were working in a city pharmacy.

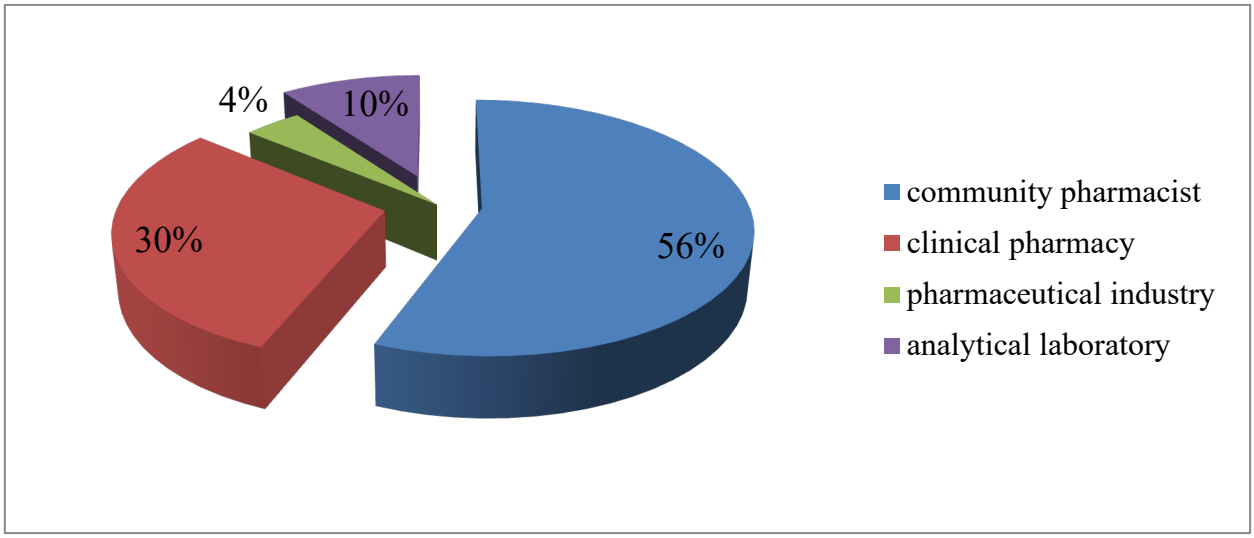

Fig.3.4. Results of distribution of students' choice of types of pharmaceutical activities.

Working as a pharmacist in Morocco provides an opportunity to realize yourself as a specialist and entrepreneur and to significantly influence the healthcare system as a whole through your work. After graduation, students can work as mercenaries in a pharmacy or open their own business. The next question was devoted to determining students' plans for their own business (fig.3.5).

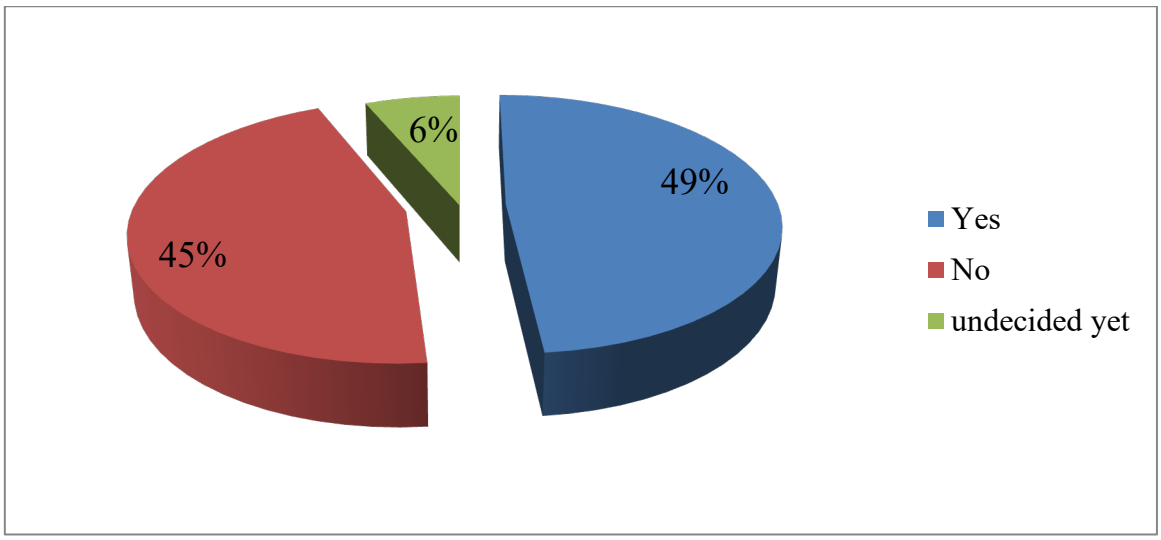

Fig.3.5. Results of the distribution of respondents' answers to the question: "Do you plan to open your own pharmacy?"

The answers were distributed approximately equally, with only 6 percent undecided on this question.

State regulation of pharmaceutical activities is a set of means, instruments and forms by which the state, represented by state authorities, determines the requirements for participants in legal relations of pharmaceutical activities.

Next, we conducted a survey of respondents about the effectiveness of specific methods of state regulation used to ensure high-quality pharmacy work in the country. The data given in fig. 3.6 indicate that the majority of respondents (45% and 43% of respondents in private) recognize the most effective method of licensing and inspection.

And this is not surprising, because licensing is the most stringent form of regulation of economic activity. In the case of licensing, the state establishes certain requirements for economic entities, the non-implementation of which may entail damage to the health of citizens and damage to the protection of the rights of employees.

Almost the same preferences were given by the respondents to the registration (37%) and certification (24%) of pharmaceutical activities.

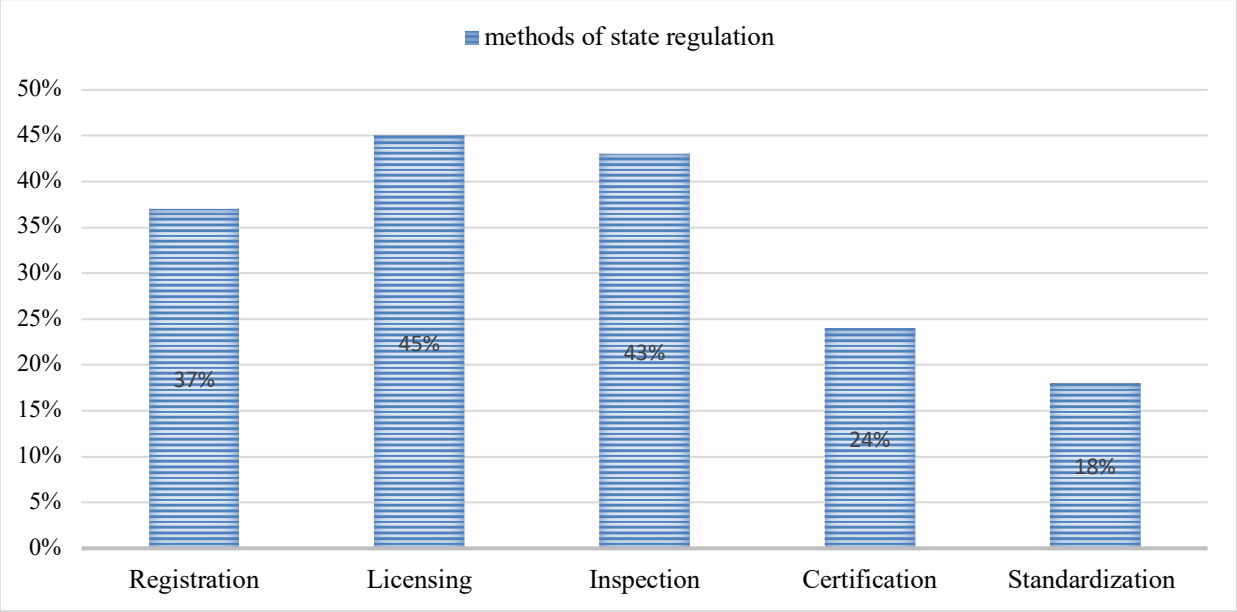

Fig.3.6. What methods of state regulation contribute to the efficient and high-quality work of a pharmacy?

Licensing is a means of regulatory influence of the state on the activities of business entities and control over the licensee's compliance with the requirements of the legislation for various types of pharmaceutical activities. "Do you consider licensing a necessary measure in the regulation of pharmaceutical activities?" was our next question. The number of students gave qiu a measure of necessity (88%) (fig.3.7).

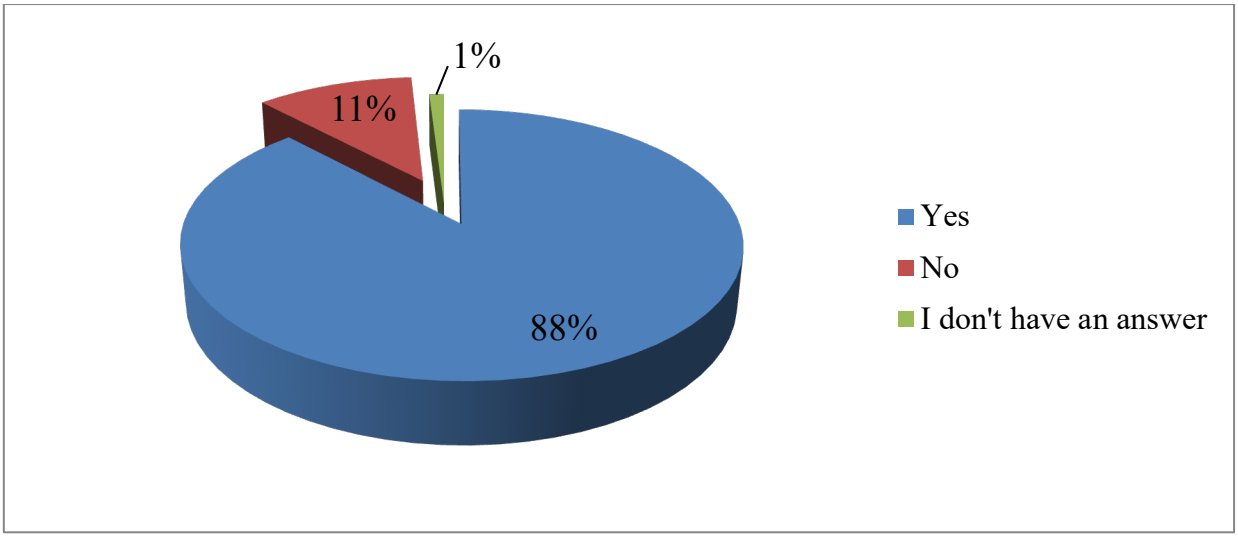

Fig.3.7. Results of distribution of respondents' answers regarding the need for licensing

Licensing certain areas of business activity is necessary for better control and guaranteeing a high level of service provision for the population. We wanted to find out what types of economic activities students think are mandatory for the pharmaceutical industry (fig.3.8).

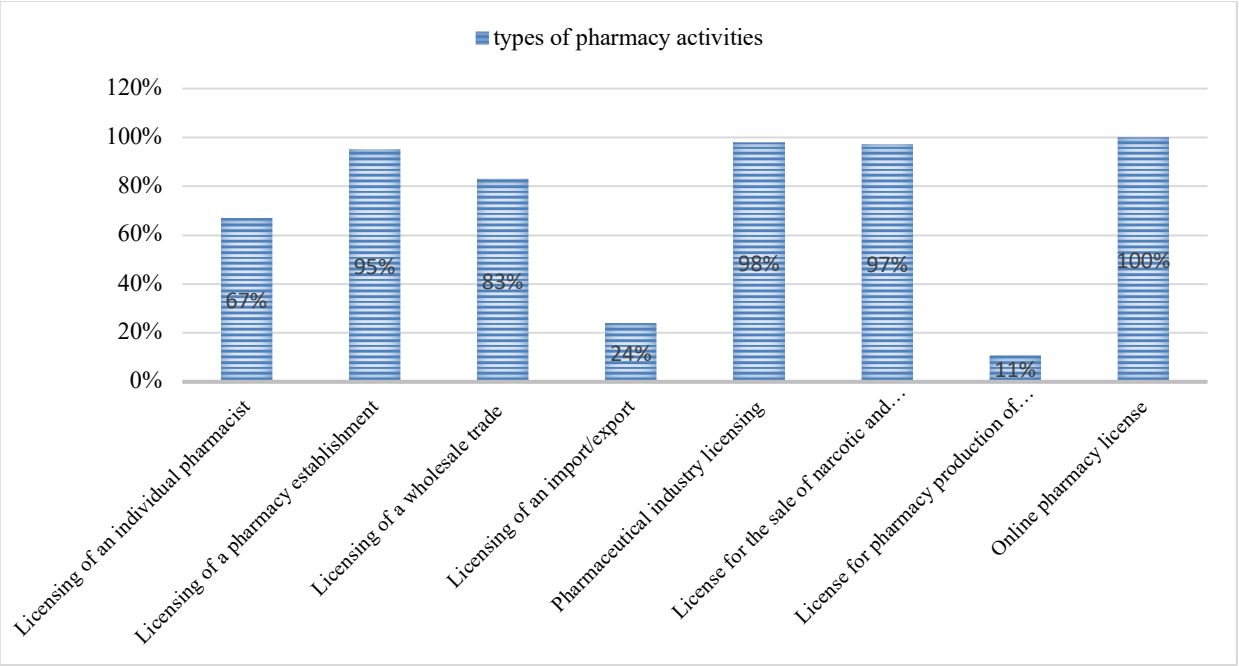

Fig.3.8. What types of activities do you think need to be licensed?

Each country, in accordance with its legislation, determines an exclusive list of types of economic activity subject to licensing and establishes a unified procedure for their licensing. Among the main types of activities that require licensing, respondents identified: individual pharmaceutical activities (67%), distribution (83%), and the overall proportion of respondents indicated that industrial production (98%), sale of controlled substances (97%), and retail trade (95%) are subject to mandatory licensing.

Every person who wishes to practice pharmacy within country must obtain a pharmacist's license.Typically, they will need to apply for a pharmacist's license to do so. Some countries may require the applicant to pass a pharmaceutical aptitude test or assessment of professional competence, depending on national regulations. Some countries may require a period of supervised practice or work experience before granting full registration as a pharmacist. If the pharmacist will be managing

a pharmacy, the requirements for a pharmacist's license may vary depending on the country in which the pharmacy is located. Each country determines the rules for licensing a pharmacist according to its own legislation. In general, the applicant must complete an approved practical training program under the supervision of a licensed pharmacist.

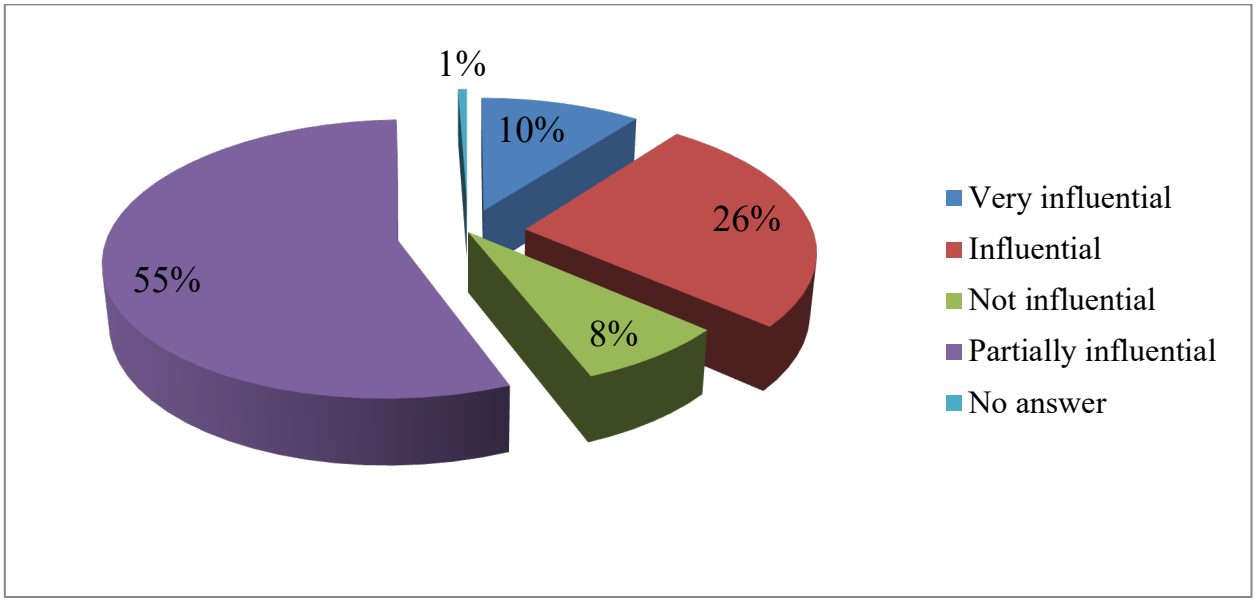

Fig.3.9. The impact of individual pharmacist licensing on the quality of services and drug safety.

To the question: "In your opinion, to what extent does individual licensing of a pharmacist contribute to improving the quality of services and the safety of medicines?" we received the following answers (fig.3.9). Student responses indicate that they believe it is necessary to introduce licensing of pharmacists, as it affects the quality of services provided and increases consumer safety (55%).

Obtaining a license electronically can simplify the work of entrepreneurs, reduce corruption risks, and ultimately have a positive impact on economic development.

It is possible to submit documents to a business entity for obtaining a license of a pharmacy institution both in paper and electronic form. In Ukraine, this procedure was proposed by the government back in 2022. It was interesting to know if this service exists in other countries. Most of the respondents were not familiar

with this question and could not answer, 15% answered positively (fig.3.10).

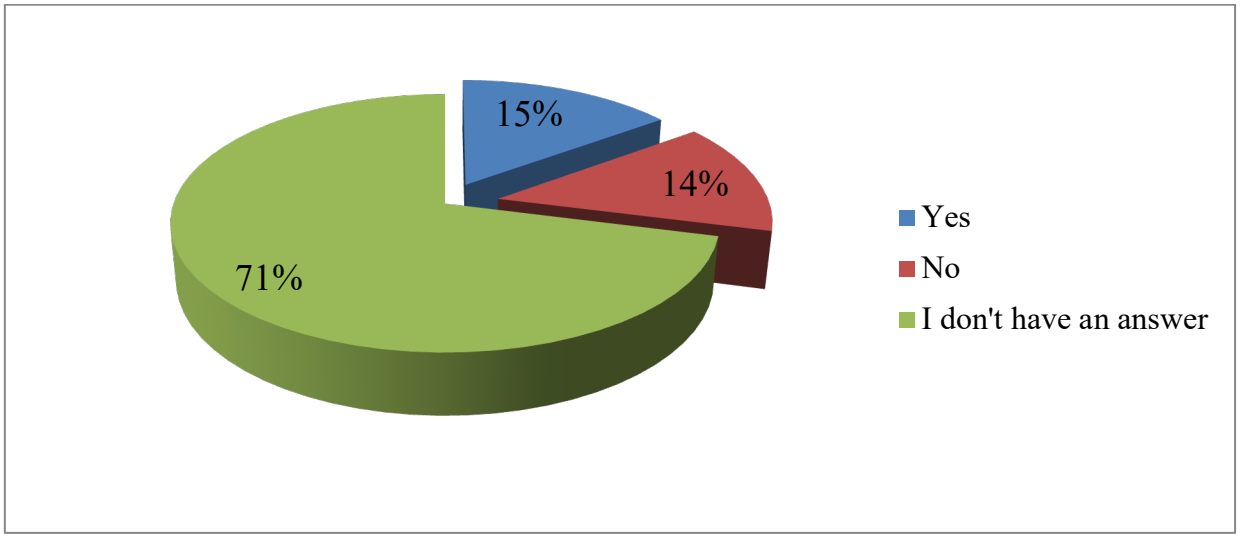

Fig.3.10. Is it possible to obtain licenses in electronic form in your country?

And the last question of our questionnaire was related to the complexity of the procedure for obtaining a license. The difficulty in obtaining a license lies in the fact that the business entity must confirm the availability of the necessary material and technical base and qualified personnel during an inspection conducted by an inspector on the territory of the pharmacy. In this process, we also included the time it takes to obtain this permit, as well as the cost of the procedure itself (fig.3.11).

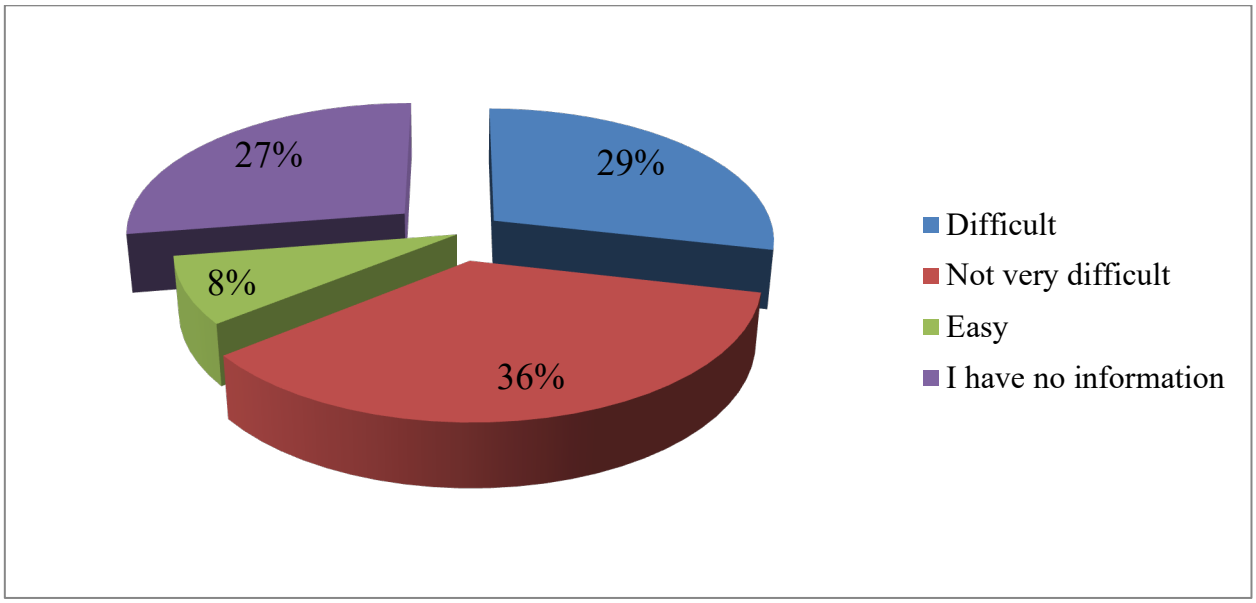

Fig.3.11. How do you assess the complexity of the procedure for obtaining a license in your country?

36% consider this process not very complicated, but 29% hold a different opinion and define the process as complicated. A fairly significant part of the respondents could not answer because they do not have information on this issue.

Our questionnaire was aimed at determining students' attitudes towards choosing a profession and obtaining their opinions on licensing. We also wanted to identify problematic aspects of the licensing process. A survey on licensing can provide valuable information for improving the licensing system and increasing its efficiency.

Conclusions to the 3 Chapter

Summing up the results of the research, it can be noted that in Ukraine uniform qualification requirements are applied to persons engaged in specific types of pharmaceutical activities, they are established by the central executive body that forms the state policy in the field of health care. The qualification requirements of pharmacists in accordance with pharmaceutical activity are characterized.

It is determined that Ukraine does not have statutory restrictions in the planning of pharmacy infrastructure. Despite this, the license conditions contain an exhaustive list of mandatory requirements for the licensee and an exhaustive list of documents attached to the application for obtaining a license for the implementation of economic activities to produce medicines, wholesale, retail trade in medicines, import of medicines (except for active pharmaceutical ingredients). These License Conditions apply to all business entities registered in accordance with the procedure established by the legislation of Ukraine.

In MENA countries, pharmacist registration is a prerequisite for working as a pharmacist. To work in a pharmacy, pharmacists must have a Bachelor of Pharmacy degree (5-year pharmacy program) or a PharmD degree (6-year pharmacy program).

A sociological study was prepared and conducted to determine effective and promising methods of regulating the effectiveness of the introduction of pharmaceutical activities. A total of 45 participants who had studied at the National

University of Pharmacy within the last five years participated in the survey. More than half of the participants lived in Morocco (99%), and 1% each in Tunisia and Lebanon.

The most important factors influencing their choice were considered by most respondents to be future career opportunities (75%) and financial support (65%). Helping people was also an important influencing factor for 40 percent of students.

As a result of the analysis of the data processing of respondents' answers to the question about the most effective methods of state regulation that affect the efficiency and quality of work of pharmacy establishments, we established the following. Most respondents consider the most effective method of regulation to be licensing (45%) and inspection (43%).

The dominant share of students recognized licensing as a necessary process in the regulation of pharmaceutical activities (88%).

This is reported in a study of important licensed activities, where online pharmacy licensing ranks first (1000% of 45 respondents). Interestingly, the study also found that essential activities that require licensing are pharmaceutical manufacturing (98%), retail trade (95%), and the sale of controlled substances (97%).

Our study assessed graduates' career choices and correlated these choices with various influencing factors. From this survey, we learned about the attitudes of future pharmacists towards methods of regulating pharmaceutical activities, in particular licensing.

GENERAL CONCLUSIONS

1. An analysis of data from special literature was conducted, which presents the results of research on various aspects of the application of the method of state regulation of pharmaceutical activities in the world, as well as in individual countries.

2. A description of the main methods of state regulation, in particular licensing, of pharmaceutical activities in various countries of the world, including Morocco and Ukraine, has been provided.

3. It is determined that a license to conduct pharmaceutical activities is a document certifying the ability and right of its owner to carry out this type of activity, provided that the quality and effectiveness of the medicines and services provided are ensured.

4. The features of the functioning of various methods and conditions for licensing pharmaceutical activities in Morocco and other MENA countries are analyzed.

5. Currently, Ukraine has no legislative restrictions on the planning of pharmacy infrastructure. The licensing conditions for pharmacy establishments only set requirements for the material and technical base of the pharmacy itself and the level of qualification of pharmacists.

6. Analysis of the features and trends of pharmaceutical regulation in foreign countries led to the conclusion that the licensing of this sector in most parts of the world is permissive. All the considered models, their components, and mechanisms are productive, but their implementation requires the presence of many institutions. Each country has its own model of pharmaceutical activity licensing, but there are also common points.

7. It has been determined that pharmacist in the EU is one of the regulated professions, access to which depends on the possession of a certain professional qualification. According to Directive 2005/36/EC, a certificate of qualification of a pharmacist certifies training lasting at least 5 years, including at least 4 years of full-

time theoretical and practical training at a university, as well as 6 months of internship in a pharmacy or hospital.

8. Two approaches to licensing are common in countries. In the first case, the license is “tied” to the facility and allows the pharmacy to operate in a specific area. It can be transferred when the pharmacy is sold to another owner. In the second, the license is granted to a specific pharmacist and is not transferable.

9. The approaches of the MENA countries in the region also differ in terms of the level of regulatory regulation of restrictive criteria for planning the infrastructure network of pharmacy establishments.

10. A sociological survey was organized and conducted to determine the opinions of future pharmacists regarding the choice of profession and the licensing process as one of the instruments of state regulation of pharmaceutical activities.

11. As a result of the systematization of the research results, the main directions of state regulation aimed at improving the efficiency and quality of pharmacy operations were identified.

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Ф А 2.2.1–32-366

National University of Pharmacy

Faculty pharmaceutical
Department of social pharmacy
Level of higher education master's
Specialty 226 Pharmacy, industrial pharmacy
Educational and professional program Pharmacy

APPROVED
The Head of Department
of Social Pharmacy

_____
Alina VOLKOVA
"11" of September 2024

ASSIGNMENT
FOR QUALIFICATION WORK
OF AN APPLICANT FOR HIGHER EDUCATION

Badre Eddine MARZAK

1. Topic of qualification work: «Analysis of the licensing as a form of state regulation of pharmaceutical activities», supervisor of qualification work: Lyubov TERESHCHENKO, PhD, associated professor, approved by order of NUPh from "27" of September 2024 № 237

2. Deadline for submission of qualification work by the applicant for higher education: May 2025.

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

4. Contents of the settlement and explanatory note (list of questions that need to be developed):
analysis of the peculiarities of state regulation of pharmaceutical activity; studying of norms and requirements for pharmaceutical activity in international practice; analysis of the structure of pharmaceutical licensing in different countries; research of student's opinions on issues of licensing process.
5. List of graphic material (with exact indication of the required drawings):
tables – 9, schemes – 16.

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	11.09.24	11.09.24
2	Lyubov TERESHCHENKO, associate professor of higher education institution of department of social pharmacy	21.11.24	21.11.24
3	Lyubov TERESHCHENKO, associate professor of higher education institution of department social of pharmacy	24.12.24	24.12.24

7. Date of issue of the assignment: «11 » of September 2024.

CALENDAR PLAN

№ з/п	Name of stages of qualification work	Deadline for the stages of qualification work	Notes
1	Analysis of the peculiarities of state regulation of pharmaceutical activity	*October/November 2024*	**done**
2	Study of norms and requirements for pharmaceutical activity in international practice	*November/December 2024*	**done**
3	Analysis of the structure of pharmaceutical licensing in different countries	*January/February 2025*	**done**
4	Registration of a qualification work according to the general requirements	*March/April 2025*	**done**
5	Preparation of the report and multimedia presentation in official protection of a qualifying work	*May 2025*	**done**

An applicant of higher education _____ Badre Eddine MARZAK

Supervisor of qualification work _____ Lyubov TERESHCHENKO

ВИТЯГ З НАКАЗУ № 237

По Національному фармацевтичному університету

від 27 вересня 2024 року

Затвердити теми кваліфікаційних робіт здобувачам вищої освіти 5-го курсу Фм20(4,10д) 2024-2025 навчального року, освітньо-професійної програми – Фармація, другого (магістерського) рівня вищої освіти, спеціальності 226 – Фармація, промислова фармація, галузь знань 22 Охорона здоров'я, денна форма здобуття освіти (термін навчання 4 роки 10 місяців), які навчаються за контрактом (мова навчання англійська та українська) згідно з додатком № 1.

Прізвище, ім'я здобувача вищої освіти	Тема кваліфікаційної роботи		Посада, прізвище та ініціали керівника	Рецензент кваліфікаційної роботи
по кафедрі соціальної фармації				
Марзак Бадр Еддін	Аналіз ліцензування як форми державного регулювання фармацевтичної діяльності	Analysis of licensing as a form of state regulation of pharmaceutical activities	Доцент Терещенко Л.В.	Доцент Бондарєва І.В.

Ректор

Вірно Секретар

ФА2.8-03-317

ВИСНОВОК

експертної комісії про проведену експертизу
щодо академічного плагіату у кваліфікаційній роботі

здобувача вищої освіти

«14» травня 2025 р. № 331206293

Проаналізувавши кваліфікаційну роботу здобувача вищої освіти Марзак Бадр Еддін, групи Фм20 (4,10д) англ-04, спеціальності 226 Фармація, промислова фармація, освітньої програми «Фармація» навчання на тему: «Аналіз ліцензування як форми державного регулювання фармацевтичної діяльності / Analysis of licensing as a form of state regulation of pharmaceutical activities», експертна комісія дійшла висновку, що робота, представлена до Екзаменаційної комісії для захисту, виконана самостійно і не містить елементів академічного плагіату (компіляції).

Голова комісії,
проректор ЗВО з НПР,
професор **Інна ВЛАДИМИРОВА**

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

on the topic: **«Analysis of the licensing as a form of state regulation of pharmaceutical activities»**

Relevance of the topic. Various mechanisms and methods of regulation are used in international practice pharmaceutical activity. The mechanism of licensing has been used for a long time and is quite widespread, at the same time the mechanism itself is developed with a high degree of detail and operates based on legal provisions norms. Increasing the effectiveness of such regulation is of relevance in countries that are actively participating in the reform of national healthcare systems to increase the physical and socio-economic accessibility of medicines to the population.

Practical value of conclusions, recommendations and their validity. The licensing institute is one of the leading institutions in the system of regulating economic activity. The results of applied research presented in the paper can be used to formulate practical recommendations for developing effective strategies to increase the awareness of future pharmacists on the issue of methods of regulating pharmaceutical activities, in particular licensing. Thus, the research direction of Badre Eddine MARZAK qualifying work is relevant and has practical significance.

Assessment of work. During his qualification work, Badre Eddine MARZAK 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

«15» of May 2025

Ф А 2.2.1-25-356

REVIEW

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

Badre Eddine MARZAK

on the topic: **«Analysis of the licensing as a form of state regulation of pharmaceutical activities»**

Relevance of the topic. Appropriate legal regulation of the licensing process in the pharmaceutical sector is a prerequisite for the population to receive quality medicines. Retail trade is an important sector of circulation, because this is how medicines reach citizens. Compliance by pharmacies with the requirements of the licensing conditions for conducting such activities is extremely important for ensuring the health of the population.

Theoretical level of work. The qualification work was carried out at a high theoretical level, as evidenced by the diversity of the analysis conducted and the sufficient volume of modern sources of information processed.

Author's suggestions on the research topic. Based on the results of the study, the following conclusions were made regarding the licensing of each type of pharmaceutical activity, ensuring the quality of medicines by improving the system of state regulation throughout their entire journey from the manufacturer to the consumer. It has been established that ensuring the proper qualification of employees working in the field of sales and use of medicines plays an important role in ensuring the quality of medicines.

Practical value of conclusions, recommendations and their validity. Understanding the licensing process in developing countries and comparing it with other countries is crucial for the development of the pharmaceutical industry and pharmaceutical companies.

Disadvantages of work. There are some spelling errors in the text of the work, but this does not affect the quality of the research performed.

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 _____ Irina BONDAREVA

«16» of May 2025

Ф А2.5-32-231

ВИТЯГ
з протоколу засідання кафедри соціальної фармації
№ 21 від «16» травня 2025 року

ПРИСУТНІ: зав. каф. доц. Аліна ВОЛКОВА, проф. Ганна ПАНФІЛОВА, проф. Вікторія НАЗАРКІНА, доц. Галина БОЛДАРЬ, доц. Наталія ГАВРИШ, доц. Тетяна ДЯДЮН, доц. Юлія КОРЖ, асист. Альміра НОЗДРІНА, доц. Вікторія МІЩЕНКО, доц. Ірина ПОПОВА, доц. Олександр СЕВРЮКОВ, доц. Ірина СУРІКОВА, доц. Любов ТЕРЕЩЕНКО, доц. Наталія ТЕТЕРИЧ.

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

СЛУХАЛИ: завідувачку кафедри доц. Аліну ВОЛКОВУ з рекомендацією представити до захисту в Екзаменаційній комісії кваліфікаційну роботу здобувача вищої освіти спеціальності 226 Фармація, промислова фармація Марзак Бадр Еддін на тему: «Аналіз ліцензування як форми державного регулювання фармацевтичної діяльності».
Науковий керівник к. фарм. н., доцент кафедри СФ Любов ТЕРЕЩЕНКО.
Рецензент к. фарм. н., доцент кафедри ММЗЯФ Ірина БОНДАРЄВА.

УХВАЛИЛИ: Рекомендувати до захисту в Екзаменаційній комісії кваліфікаційну роботу здобувача вищої освіти Марзак Бадр Еддін на тему: «Аналіз ліцензування як форми державного регулювання фармацевтичної діяльності».

Завідувачка каф. СФ, доцент Аліна ВОЛКОВА

Секретар, доцент Наталія ТЕТЕРИЧ

Ф А2.2.1-32-042

НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

ПОДАННЯ
ГОЛОВІ ЕКЗАМЕНАЦІЙНОЇ КОМІСІЇ
ЩОДО ЗАХИСТУ КВАЛІФІКАЦІЙНОЇ РОБОТИ

Направляється здобувач вищої освіти Марзак Бадр Еддін до захисту кваліфікаційної роботи
за галуззю знань 22 Охорона здоров'я
спеціальністю 226 Фармація, промислова фармація
освітньої-професійної програми Фармація
на тему: «Analysis of the licensing as a form of state regulation of pharmaceutical activities»

Кваліфікаційна робота і рецензія додаються.

Декан факультету _____ / Микола ГОЛІК /

Висновок керівника кваліфікаційної роботи

Здобувач вищої освіти Марзак Бадр Еддін 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.

Таким чином, кваліфікаційна робота може бути рекомендована до офіційного захисту в Екзаменаційній комісії Національного фармацевтичного університету.

Керівник кваліфікаційної роботи _____ Любов ТЕРЕЩЕНКО

«15» травня 2025 р.

Висновок кафедри про кваліфікаційну роботу

Кваліфікаційну роботу розглянуто. Здобувач вищої освіти Марзак Бадр Еддін допускається до захисту даної кваліфікаційної роботи в Екзаменаційній комісії.

Завідувачка кафедри
соціальної фармації _____ Аліна ВОЛКОВА

«16» травня 2025 р.

Qualification work was defended

of Examination commission on

« » June 2025

With the grade _____

Head of the State Examination commission,

DPharmSc, Professor

_____ / Volodymyr YAKOVENKO /