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QUALIFICATION WORK

on the topic **«ANALYSIS OF THE QUALITY ASSURANCE SYSTEM FOR PHARMACEUTICAL PRODUCTS»**

Prepared by higher education graduate of group
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ANNOTATION

The qualification work presents the results of the analysis of the main problems of pharmaceutical supply. New approaches to the implementation of quality control of medicines are presented. An analysis of the storage conditions of medicinal products in accordance with the Good Storage Practice was carried out. The work is presented on 54 pages and consists of 3 sections, general conclusions and a list of references, which consists of 37 sources. The results of the research are illustrated by 7 tables and 20 figures.

Key words: quality, international standards, medicine, pharmacist, storage practice, pharmacy.

АНОТАЦІЯ

У кваліфікаційній роботі представлені результати аналізу основних проблем фармацевтичного забезпечення. Представлено нові підходи до здійснення контролю якості лікарських засобів. Проведено аналіз умов зберігання лікарських засобів відповідно до Належної практики зберігання. Робота представлена на 54 сторінках і складається з 3 розділів, загальних висновків і списку літератури, який складається з 37 джерел. Результати дослідження ілюструють 7 таблиць та 20 рисунків.

Ключові слова: якість, міжнародні стандарти, лікарський засіб, фармацевт, практика зберігання, аптека.

CONTENT

ABBREVIATIONS

EMA - European Medicines Agency

EU - European Union

EDQM - European Catalogue of Medicines and Health

FDA - Food and Drug Administration

FIP - International Pharmaceutical Federation

ISO - International Organization for Standardization

NDP - National Drug Policy

GSP - Good storage practices

WHO - World Health Organization

INTRODUCTION

Relevance of a subject. In the pharmaceutical industry, an important problem is the quality of medicines. It is necessary that each structure related to medicines guarantees their effectiveness and safety of use. To ensure the quality of medicines, a set of organizational measures is necessary, which are aimed at maintaining the quality of medicines during the entire shelf life during storage, transportation, wholesale and retail sale.

Interpol estimates that about 10% of pharmaceuticals are counterfeit, costing governments up to $200 billion a year. According to the World Health Organization (WHO), 1 million people die every year from this volume of counterfeit medicines. Counterfeit pharmaceuticals are becoming more common and profitable. Counterfeiters can produce counterfeit versions of all kinds of medicines, and these drugs may not contain the active ingredient, harmful ingredients, wrong medicine, wrong concentration, wrong dose, or expired medicines. All of this puts patients at risk of treatment failure, harmful side effects, and dangerous drug interactions.

Everyone participates in the marketing of counterfeit products, players in the logistics chain in the pharmaceutical market. The issue of control and regulation still remains problematic. Free trade zones have facilitated trade in counterfeit pharmaceuticals. The most interesting at the moment is the consideration of the rules for organizing the storage of pharmaceutical products. The Guide to Good storage practices (GSP) for pharmaceuticals provides professionals with a set of basic requirements for good practice in the storage, transport and distribution of pharmaceutical products.

To achieve the put purpose – analysis of the quality assurance system for pharmaceutical products.

The subject of the study. Analysis of data from specialized literature, which presents the results of the analysis of regulation and quality control of drugs and changes that have occurred in the work and organization of the activities of pharmacists in the healthcare system, including in documents published on the

official websites of the WHO and the International Pharmaceutical Federation (FIP). Studying of policy documents of the national pharmaceutical policy of Morocco, regulatory documents regulating the pharmaceutical industry, scientific papers about pharmaceutical sector in Morocco, expert assessments of local industry experts.

The objects of the study. Quality assurance system for medicines, health care in Morocco, including the organization of the process of storing medicines in a pharmacy.

Methods of researches. In implementing the main research objectives, we used such methods as historical, bibliographic, logical, comparative, and also conducted a sociological survey of pharmaceutical specialists.

The practical value of the work. The analysis of the main problems in the provision of medicines to the population is carried out. As a result of a sociological study conducted in pharmacies in Morocco and the opinion of pharmacists on the storage of medicines, the problems of pharmacies were identified.

Scientific novelty. These results can be used in the development of state programs aimed at state support for the development of pharmacies in Morocco and raising the prestige of the profession of pharmacist.

Structure and volume. The qualification work consists of the introduction, three chapters, conclusions and the list of references. The work is presented on 54 pages and consists of 3 sections, general conclusions and a list of references, which consists of 37 sources. The results of the research are illustrated by 7 tables and 20 figures.

CHAPTER 1. ANALYSIS OF MODERN APPROACHES TO DRUG QUALITY CONTROL

1.1. Analysis of the main problems of pharmaceutical providing

Ensuring the continued availability of safe, effective, affordable and high-quality medicines is an essential benchmark for achieving the right to good health, as well as an integral part of any well-functioning health complex.

Patients' right to health is the highest achievement of the country, and global shortages of medicines violate this right and create obstacles to the achievement of public health goals in the field of prevention and treatment. The ability of governments to scale up services to achieve universal health coverage is threatened.

The main program of the World Health Organization for the past 80 years has been the struggle to improve access to medicines and improve their quality. Universal Health Coverage depends on the availability of affordable health technologies of guaranteed quality and sufficient quantity.

In line with this direction, the International Pharmaceutical Federation has cited its development goals, which state that health is a fundamental human right. These goals aim to strengthen cooperation between health workers, patients, the state and other health actors to improve access and address issues such as affordability, accessibility, quality and safety of medicines, as well as their rational use.

Drug provision is traditionally viewed as a key element of medical care. According to statistics, almost 100 percent of cases of visiting a doctor end with the prescription of medications.

The vast majority of countries experience difficulties related to the providing of medicines. The main problems of supply in developed countries are: excessive consumption and excess of medicines on the market, high expenditures of the population on medicines due to their high cost, regulatory issues, identification of counterfeit products, etc.

For countries where health systems are only at the level of development, these problems are caused by a lack of medicines, their irrational use, and often

unsatisfactory quality, limited availability for many consumers, and difficulties with distribution. The WHO high-level report “Medicines funds in health systems – increasing access, affordability and appropriate use” [23] and other WHO documents in recent years note that the availability and rational use of drugs should form the basis of any efforts to strengthen health systems.

To address these problems, WHO recommends that countries develop and adopt a document at the national level that defines priority goals in the field of drug provision and the main ways to achieve them. This program is called the National Drug Policy (NDP) and it defines strategies for the development of the pharmaceutical sector. Access to health goods and services is a key principle and includes the supply of essential medicines needed to prevent and treat common diseases [24].

We have outlined the main problems of pharmaceutical providing in the figure (fig.1.1).

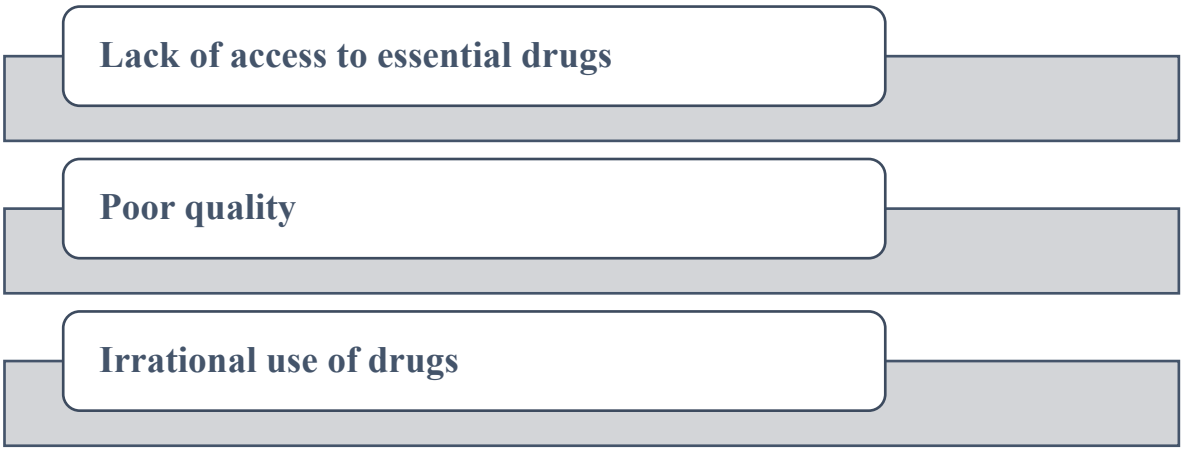
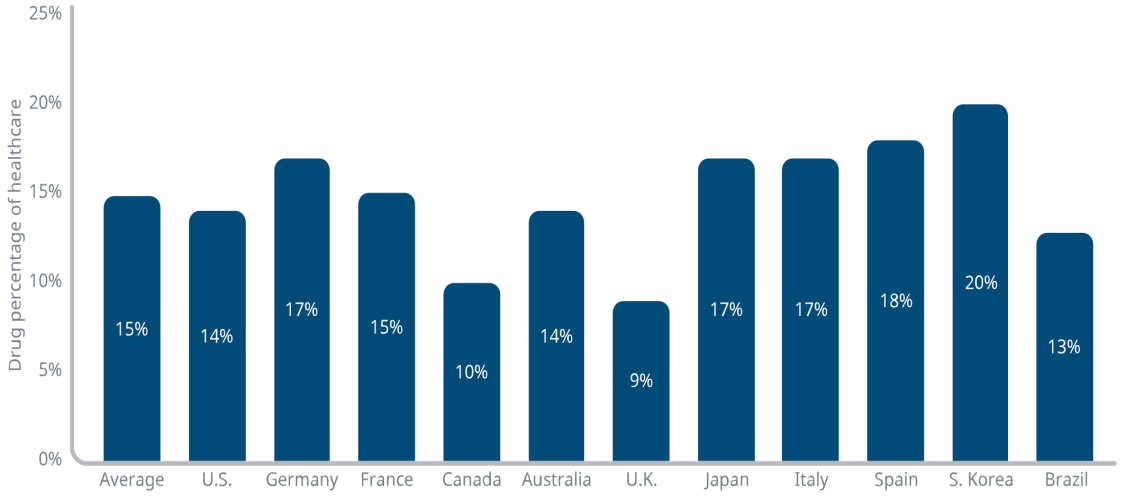


Fig. 1.1. Problems of pharmaceutical providing

Essential medicines are the backbone of every country's public health programme. It aims to reduce morbidity and mortality in every country, and spending on pharmaceuticals accounts for a significant portion of total health spending. Drug spending includes medicines dispensed in both the retail and non-retail sectors and accounts for an average of 15 per cent of total health expenditure, ranging from 9 per cent in the UK to 20 per cent in South Korea (fig.1.2) [16].



Source: IQVIA Institute for Human Data Science, Sep. 2022

Fig. 1.2. Level of spending on general medicines in healthcare

In our work, we pay attention to the main problems associated with the inaccessibility of medicines for all segments of the population, such as:

1) the prevalence of low-quality and counterfeit medicines in the market;

2) the shortage of existing essential drugs due to prohibitive costs;

3) availability of old and new medicines;

4) unqualified assistance of a pharmacist.

Quality health services, including access to medicines, are seen as fundamental to sustainable development, as they contribute to a healthier population, economic productivity, and poverty and inequality.

The pharmaceutical market, unlike the markets of other goods, has such features as: scale, wide range, science intensity, long cycle of drug development. Therefore, the level of drug provision reflects the state of the social sphere and economy in each country.

In recent years, extensive efforts have been made to improve the drug supply system in the world. Most countries have made changes to their regulatory frameworks, increasing the share of spending on medicines in total health spending. Despite all these actions, the situation with the availability of medicines for the population has not improved.

WHO research shows that almost 3.5 billion people (half of the world's population) do not have access to the health services they need, with almost 100 million people spending their out-of-pocket expenses on treatments each year, which lead to extreme poverty [1].

Between 1.5 and 2.5 billion people, or 30% of the total population, do not have access to the essential medicines they need. For example, in India, more than half of the population does not have normal access to medicines, and in all of Africa, where 15% of the world's population is located, another 300 million people also do not have access to them [8].

Another problem in the supply system is when people who have access to medicines do not get the right medicine in the right dosage and at the right time when they need it. Many people buy or doctors prescribe them or pharmacists dispense medicines that do not meet their needs.

Medicines are a simple and cost-effective solution to many health problems, provided they are accessible, inexpensive, of high quality and used correctly. Treatment may not be available if there is no effective and quality medicine, or because it is too expensive [1].

One of WHO's global challenges for patient safety is the implementation of the Medication Without Harm program. It aims to reduce serious, preventable medication-related harms, and is estimated to be 50% implemented over the next five years worldwide. This document provides information on current drug safety initiatives [2].

Access to quality-assured medical products improves health and saves lives. However, one-third of the world's population does not have timely access to quality-assured medicines, while estimates show that at least 10% of medicines in low- and middle-income countries are substandard or falsified, costing around US$ 31 billion per year [22].

In many countries, quality assurance systems for medicines are inadequate because they lack essential components, such as:

1. legislation and regulations on medicines;

2. as well as the current medicines regulatory authority;

3. adequate resources and infrastructure to ensure compliance with laws and regulations.

1.2. Key concepts of the quality of pharmaceutical product

The main aspect related to the circulation of medicines is to ensure their effectiveness. It is the provision of control over the effectiveness of medicines that is the primary task of the state in the pharmaceutical sector. In Ukrainian legislation, "efficacy of a medicinal product" corresponds to the term "quality of a medicinal product". The quality of medicines determines the efficacy and safety of medicines, so quality control is an important part of government regulation.

Maintaining high quality standards is paramount to ensuring patient safety, regulatory compliance, and market competitiveness.

The quality of medicines includes the complex characteristics of purity, impurities, component content and physical/chemical properties.

The term "quality" has been considered throughout the history of medical product manufacturing and remains a key topic of modern research in science, industry, and government.

There are many definitions of the quality of medicines in the literature. For example, according to the compliance of the product with the specified quality characteristics or regulatory specifications, there is one type of quality. Another type can be distinguished, depending on the compliance of the production of the drug with the latest rules. The availability of a drug to the consumer is another indicator of quality that can be measured. Thus, although there is no single definition of the quality of medicines, a working definition can be found in the legislation of each country that regulates the pharmaceutical sector.

Quality of a medicinal product is the compliance of a medicinal product with the requirements of a pharmacopoeia monograph or, in the absence of such a regulatory legal act [11].

There are several national and international guidelines and regulatory requirements to ensure the efficacy, safety, and quality of medicines [8].

Medicines are safe to use every day to treat illnesses, but over the years there have been cases where taking medicines has been associated with risks. Evidence of harm from drugs inevitably leads to regulatory changes and stricter regulation.

The concept of controlling the development and sale of drugs has been established in most developed countries and is a form of regulation that distinguishes drugs from other consumer products.

The three common pillars of drug regulation are quality, safety and efficacy (fig. 1.3) [22-24].

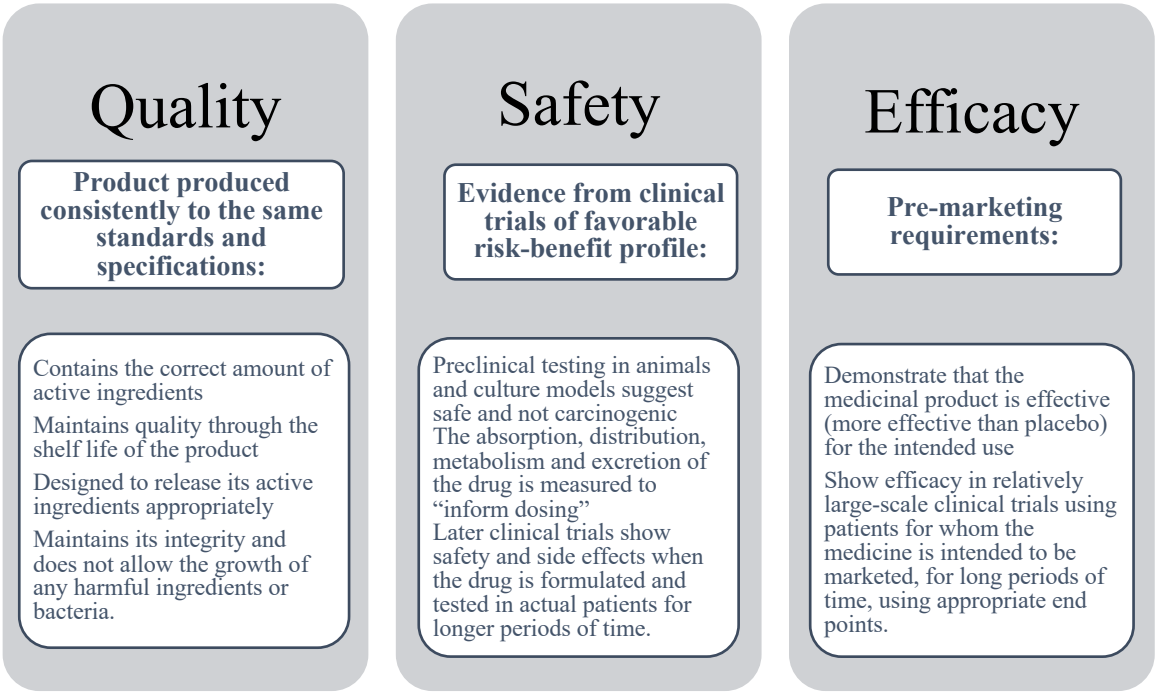


Fig.1.3. Basic principles of drug regulation

The most important international regulatory framework for quality is the collection of guidelines International Council for the Harmonization of Technical Requirements for Medicinal Products for Human Use (ICH Q1-Q14), which are the basis for the development and approval of medicines. In addition, international and national pharmacopoeias and national regulatory authorities, such as the Food and Drug Administration (FDA) and the European Catalogue of Medicines and Health Care (EDQM), must be considered during the life cycle of a drug [27,31].

In Table 1.1, we have highlighted the main definitions of quality in accordance with international standards.

Table 1.1

Definition of quality of medicines product [27]

Regulations	Definition
WHO, 1992	suitability for the intended use and compliance with all requirements of national registration, as well as their ability to cause the intended therapeutic or prophylactic effect after the use of the same dosage forms (tablets, capsules, ampoules, etc.). This effect is possible only when each drug on the market corresponds to a drug that has undergone clinical trials, on the basis of which it was evaluated and registered
ISO 9000 series	a set of characteristics of the object relating to its ability to meet established and anticipated needs
ICH Q6a Specifications: Test Procedures and Acceptance Criteria for New Drugs Substances and New Drugs Products	the degree of conformity of a product, system or process to the established requirements

In Ukraine, the definition of quality is given in the Law of Ukraine "On Medicines". The quality of a medicinal product is interpreted as a set of properties that give the medicinal product the ability to satisfy consumers in accordance with its intended purpose and meet the requirements established by law.

The subjective component of the concept of quality is to satisfy the needs of consumers, and the objective component is to meet the requirements established by law. Medicines must meet the needs of health care in the diagnosis, treatment and prevention of certain diseases.

If you define "Quality" under the measured parameter, the perception of "Quality" will be different for different users (fig.1.4) [34].

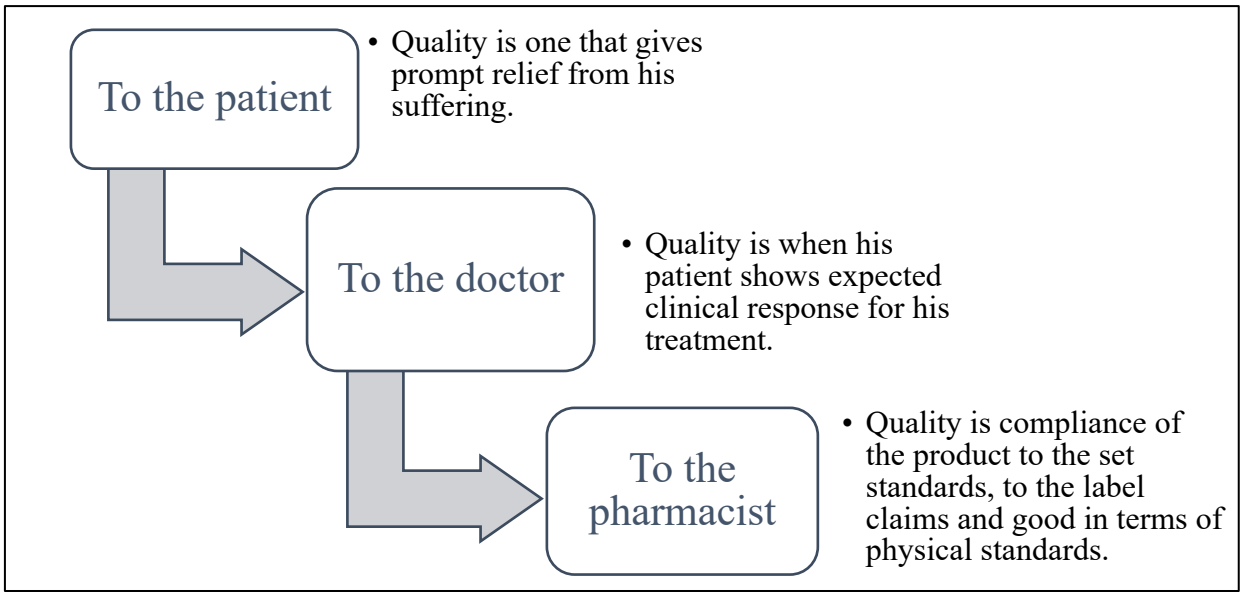


Fig. 1.4. Definition of quality for different consumers

The main properties (characteristics) of the quality of the medicinal product are established by the World Health Organization and include the following mandatory elements [34]:

- effectiveness;
- safety of use;
- significant advantage over known, similar in action drugs (analogues);
- variety of dosage forms and doses;
- frequency of reception;
- rate of occurrence and duration of action;
- ease of use;
- packaging design;
- identification and quantitative content of ingredients;
- absence of impurities (degree of purity);
- activity and stability of chemical composition;
- storage stability;
- reasonable cost (price).

The main indicators of the quality of medicines are [5]:

Identity. The medicinal product must contain the declared quantity and quality of the active substance.

Purity. The medicinal product must be free of impurities that can have an adverse effect on the human body.

Physicochemical properties. The medicinal product must have the necessary physical and chemical properties that ensure its stability and safety during storage and use.

Biological activity. The medicinal product must have the necessary biological activity to ensure its effectiveness.

Security. The medicinal product must be safe for use in accordance with the indications, in the recommended doses and in compliance with the rules of its use.

Potency. The correct amount of active ingredient is present, usually between 95 and 110% of the labeled amount.

Uniformity. Consistency of, shape, and size of the dosage form do not vary.

Bioavailability. Refers to the speed and completeness with which an administered medicine enters the blood stream. It must be consistent to provide a predictable therapeutic result.

Stability. The activity of the medicine is ensured until the expiration date.

Pharmacopeial standard. Medicine is of good quality if its characteristics meet the standards described in a widely accepted pharmacopoeia such as the British Pharmacopoeia, European Pharmacopoeia, International Pharmacopoeia, or United States Pharmacopeia [5].

Based on all definitions, the key principles of quality can be distinguished, which are as follows:

(1) ensuring clinical efficacy as stated on the label,

(2) prevention of additional risks due to unexpected impurities,

(3) providing a reliable manufacturing system that reduces defects and ensures the availability of the drug to the consumer.

In order for the drug to meet quality requirements, it is necessary to ensure quality throughout the life cycle of the drug. Quality assurance refers to the activities

that are planned and carried out to ensure the high quality of products or services. From this definition, it can be concluded that quality assurance consists of planning and executing quality. Quality planning involves translating the plan into procedures that must be applied by each organization.

The drug quality assurance system is a set of all activities aimed at ensuring that pharmaceutical products meet all applicable quality standards. It includes various rules and procedures. The main goal is to achieve a high degree of guarantee of compliance of the quality of the medicinal product with its intended purpose, which corresponds to the main goal of the health care system.

The concept of quality assurance of medicines includes a set of measures that affect the quality of the finished product, guarantee its compliance with the requirements of regulatory documentation and compliance with the quality of medicines. Quality assurance includes quality control, etc.

In order to ensure the proper quality of the medicinal product, which leads to effectiveness, the state exercises control throughout the entire cycle of the drug. This chain begins from the moment of creation, launch on the market and during the period of presence of the medicinal product on the market.

Quality control is the process of ensuring that all materials used to manufacture a pharmaceutical product meet manufacturers or pharmacopoeia specifications for identity, strength, purity, and other characteristics.

Quality control of a medicinal product begins already in the course of its creation, namely in the process of conducting clinical trials. At this stage, control is ensured by licensing institutions that can carry out clinical trials, as well as by approving the protocol of clinical trials, monitoring their progress and approving the results.

One of the most important stages of quality control of a medicinal product is state registration. In the process of state registration, each state, represented by its authorized bodies, officially recognizes a particular medicinal product as meeting the established quality requirements, deciding on the admissibility of its widespread use by citizens on its territory.

Control during the use of the drug is another stage. At this stage, measures are directed in several directions:

- control of the production of medicines;
- quality control of medicines during their import into the country;
- quality control of medicines during their sale to end consumers.

In order to ensure effective quality control of medicines, states create special bodies and services, implement appropriate control procedures and standards.

In most countries, the mechanism of quality control of medicines, both during their registration and in the course of their circulation on the territory of the country, is valid for many years. In this process, both our own experience and the experience of advanced countries were used, which together made it possible to create a fairly effective system.

Conclusions to Chapter 1

Analysis and assessment of the problems of drug supply to the population allowed us to draw conclusions that the pharmaceutical providing should be considered as an element of an integral health care system. Implementation of national drug policy allows countries to achieve a number of important goals in the field of drug supply to the population.

The drug supply to the population consists of the following components: availability of drugs and ensuring their quality (including effectiveness and safety).

Availability to be determined groups of factors: rational use of medicines, sustainable financing, reasonable prices and procedures for pharmaceutical supply, integrated into the healthcare system.

Quality assurance is important not only because it leads to the correction of problems that arose during the execution of the plan, but also because it gives the owners of the organization and customers the assurance that the products and/or services presented are free of defects. Fixing problems can lead to increased efficiency, reduced cost, and improved product quality.

CHAPTER 2. RESEARCH OF CURRENT PROBLEMS AND SOLUTIONS IN INTERNATIONAL DRUG CONTROL PRACTICE

2.1. Modern international practice of regulating the circulation of medicines

An important component of healthcare is compliance with the requirements for the circulation of medicines, including their creation, testing, registration, production, import, sale and use. Recently, the processes of creation, testing, production of medicines, as well as the registration procedure have been undergoing significant positive changes due to the transition of the pharmaceutical sector to another level.

The importance of ensuring the quality of pharmaceutical products cannot be overstated. In the pharmaceutical industry, any compromise on quality can have serious consequences, including damage to patients and the company's reputation.

The resolution of the 28th World Health Assembly listed objectives concerning the regulatory control of medicines. In its twenty-seventh report, the WHO Expert Committee on Specifications for Pharmaceutical Preparations reviewed the various components of a quality assurance system within the pharmaceutical supply chain [2,31].

The quality of medicines is ensured at all stages of their life cycle:

Drug development. At the stage of development of medicines, their efficacy, safety and quality are assessed.

Production of medicines. At the stage of production of medicines, quality control of raw materials, materials and finished products is carried out in accordance with the requirements of Good Manufacturing Practice (GMP) [2].

Registration of medicines. When registering medicines, their quality, efficacy and safety are assessed in accordance with the requirements of the law.

The existence and functioning of a comprehensive legislative system for regulating the production and use of medicines is a prerequisite for the effectiveness

of a universal quality assurance system for medicines. The first duty of the government regulatory agency is to register pharmaceutical products, thus defining the pharmaceutical market in the country. Only when performing this function can a distinction be made between legally sold products and illegal and counterfeit products.

Distribution of medicines. During the distribution of medicines, their quality and storage conditions are monitored.

Use of medicines. When using medicines, it is necessary to follow the rules for their use to ensure their effectiveness and safety.

The fundamental elements of the quality assurance system for internationally recognized medicines are the concept of good practices.

In the United States, in 1938, the Food and Drug Administration first implemented the idea of quality management. Further, similar programs appeared in other countries of the world. Over time, quality standards (ISO) were formed and became widely used, and on the basis of them, industry standards of good practices emerged [5,11].

All standards of good practices, regardless of the developing organization, are similar in content and requirements.

For ease of understanding, the name of the Good Practices standards abbreviated as GxP, the letter X is not constant and can be replaced by any other appropriate letter. GxP requirements cover all stages of the life cycle of a medicinal product from the beginning of development and preclinical trials to the point of sale in the pharmacy. There are also several "practices" that apply to several stages of the life cycle. An example is the Good Storage Practices requirements that apply to manufacturing, wholesale, and retail.

The main goal of implementing GxP standards at each stage of drug circulation is to guarantee that the consumer receives a high-quality and effective drug. Good practice is a set of standards, of which the most important for the pharmaceutical industry are presented in table 2.1 [26,28-30,36].

Table 2.1

Good Practices Overview

Good Practices Standards	Goal	Implementation
Good Laboratory Practice (GLP) Good Clinical Practice (GCP)	proper conduct of preclinical and clinical studies	Prepared by the FDA in 1979. In 1981, the OECD formulated the GLP principles, which were included in the EU regulatory framework.
Good Distribution Practices (GDP)	a set of rules for the processes of managing and organizing wholesale sales	Adopted by the European Community in 1994
Good Storage Practices (GSP)	rules that apply during storage and transportation at all stages of drug circulation	Published by WHO in 2003
Good Manufacturing Practices (GMP)	a standard that establishes requirements for the production and quality control of MP for humans and animals, as well as special requirements	Released in the USA in 1963. The draft international GMP rules were developed by the WHO Secretariat in 1967-1968, taking into account the existing text of the US rules
Good Regulatory Practice (GRP)	to improve the efficiency, effectiveness, coherence of activities of the authorized competent authorities	WHO recommendations, set out in the guidance for National Health Regulatory Authorities (2011)
Good Pharmaceutical Practice (GPP)	requirements for the activities of pharmasist	Developed in 1991 and adopted by FIP in 1993

In the European Union, the task of regulating the quality of medicines is assigned to the European Medicines Agency (EMA). Also, the WHO has its own version of the standards of good practice. The International Conference on Standardization of Requirements in Pharmaceuticals was created with the aim of converging the requirements of good practices in different countries.

All standards of good practices, regardless of the developing organization, are similar in content and requirements.

A characteristic feature of the modern pharmaceutical market is its globalization. The same drug can be supplied to the markets of different countries. A drug produced at several production sites located in different countries may enter the market of a particular country. Each country allows the drug to enter the market only after a detailed examination. The variety of dosage forms, the complexity of technological processes and their specifics require special knowledge. There is a need to harmonize the requirements for production and quality control and the distribution of efforts of regulatory authorities through a procedure for mutual recognition of the results of inspections of production sites. Mutual recognition, in turn, requires standardization of inspection approaches.

It was for these purposes that the Convention on Cooperation of Pharmaceutical Inspections was adopted in the early 1970s (PIC), and in 1995 the PIC scheme was proposed. The well-known acronym PIC/S is now used to describe both the PIC (Pharmaceutical Inspection Convention) and the PIC/S (Pharmaceutical Inspection Co-operation Scheme), which work in parallel [22,31].

PIC/S is headquartered in Geneva, Switzerland.

The Pharmaceutical Inspection Convention and the Pharmaceutical Inspection Cooperation Scheme are two international instruments between countries and pharmaceutical inspection authorities that jointly ensure active and constructive cooperation in the field of GMP. The mission of PIC/S is "to lead the international development, implementation and maintenance of harmonized standards of good manufacturing practice and quality inspection systems in the field of medicines".

The key objective of PIC/S is to harmonize the entire inspection system of the relevant PIC/S member countries, namely [11]:

- simplification of interaction between the national authorities of the participating countries;
- maintaining mutual trust;
- exchange of information and experience;
- joint training of GMP/GDP inspectors;
- harmonization of regulatory requirements.

The PIC/S is based on consensus, mutual trust and considers members as equals, regardless of the wealth of the country from which the regulator is represented. This principle is based on cooperation and ensuring that no participant is left behind. Mutual trust is maintained through voluntary cooperation and the requirement of an equivalence assessment prior to membership, allowing for a smooth and voluntary exchange of information.

The PIC/S Convention has been ratified by 56 countries. In 2023, two more participating bodies were added to the agency: the Bulgarian Medicines Agency and the Saudi Food and Drug Administration [27].

Based on the study of the literature, it can be concluded that the accession of countries to this organization is the basis for actions aimed at simplifying the procedures for quality control of medicines. This integration will lead to positive results in quality issues for both domestic and foreign participants in the pharmaceutical market.

The quality, safety and availability of medicines are a major concern for public health. Regulatory authorities ensure the quality, efficacy and safety of medicines through guidelines and requirements, especially good manufacturing practice guidelines. The first GMP standards were published in 1963 by the WHO and since 1969 all countries began to apply it. Among the GMP requirements, quality control is the key stone of drug quality. It covers all stages of pharmaceutical production, from the control of raw materials (medicinal substances and excipients) to the release of a medicinal product (drugs that will be administered to the patient).

An important guarantor of the quality of medicines, in addition to the pre-marketing phase, is post-marketing quality control, which is carried out by national and international regulatory authorities (for example, WHO) [11].

Appropriate certification is required for the sale of medicines on the national market and for international trade. Certification of medicines is associated with the confirmation of the compliance of their quality, efficacy and safety, as well as the correctness of quality assurance and quality management systems. Therefore, with regard to medicines, certification is a complex procedure, and its rules are established within the framework of certification systems.

The quality assurance and certification system for medicines in the EU includes the following elements [31]:

- licensing of medicines;
- licensing of production and import based on the results of inspections for compliance with GMP rules and registration documentation;
- distribution licensing based on the results of GDP inspections;
- independent quality control, which is associated with the independence of quality control from production, the institution of Authorized Persons, as well as state quality control at the stages of registration and sale;
- pharmacovigilance;
- certification of substances by the European Pharmacopoeia.

Thus, the quality assurance and certification system is comprehensive, and registration, licensing, inspection, pharmacovigilance and other procedures are its elements.

2.2. Analysis of problem of medicine falsification

All medical products have scientific evidence base and are approved for the treatment, prevention or diagnosis of diseases. Unfortunately, this does not mean that all drugs on the market meet approved quality standards. Substandard and falsified products are manufactured, distributed and sold around the world. The

problem is growing as pharmaceutical products themselves and their distribution chains become more complex and pose a new and serious threat to the healthcare system.

This issue was first raised in November 1985 in Nairobi, at the Conference of Experts on the Rational Use of Medicines. In 1988, the Forty-first World Health Assembly adopted a resolution that asked governments and pharmaceutical manufacturers to cooperate to prevent the growing threat of smuggling of pharmaceuticals during their export. The UN Secretary-General called for cooperation in incidents where the terms of international treaties in the field of medicines are grossly violated. In April 1992, a seminar was held in Geneva by WHO and International Federation of Pharmaceutical Manufacturers Associations on the problem of counterfeit medicines [23].

At the seventieth session of the World Health Assembly, definitions of the category of medicines that do not meet quality standards were approved.

Classification of medical products used in the context of the World Health Organization Global Surveillance and Monitoring System (fig.2.1) [31,34].

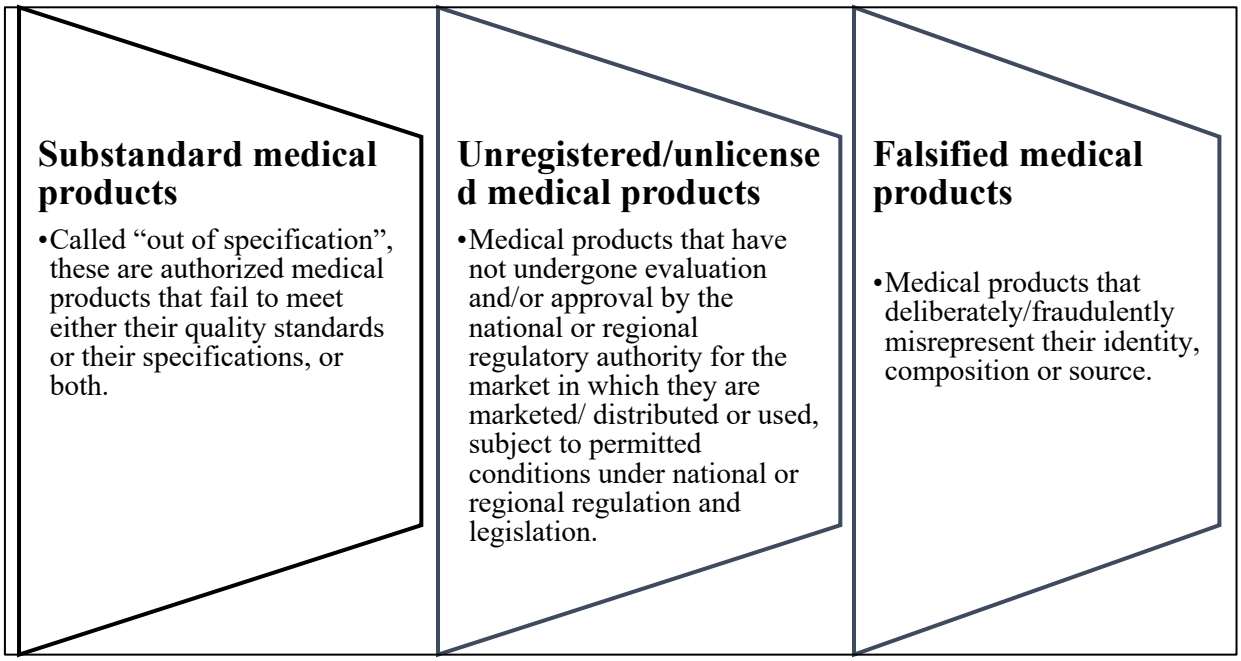


Fig. 2.1. Categories of medicines that do not meet quality standards

Falsification of medicines is a global problem that requires enhanced international coordination and cooperation to ensure greater effectiveness of anti-counterfeiting strategies, in particular with regard to the sale of such products via the Internet [33].

Falsified medicines are divided into several categories:

- containing ingredients of poor quality or in the wrong doses;
- be intentionally and fraudulently mislabeled as to their identity or source;
- have fake packaging, the wrong ingredients, or low levels of active ingredients.

The distribution of falsified medicines in the pharmaceutical market by category, according to the WHO information base, is presented in figure 2.2 [33-35].

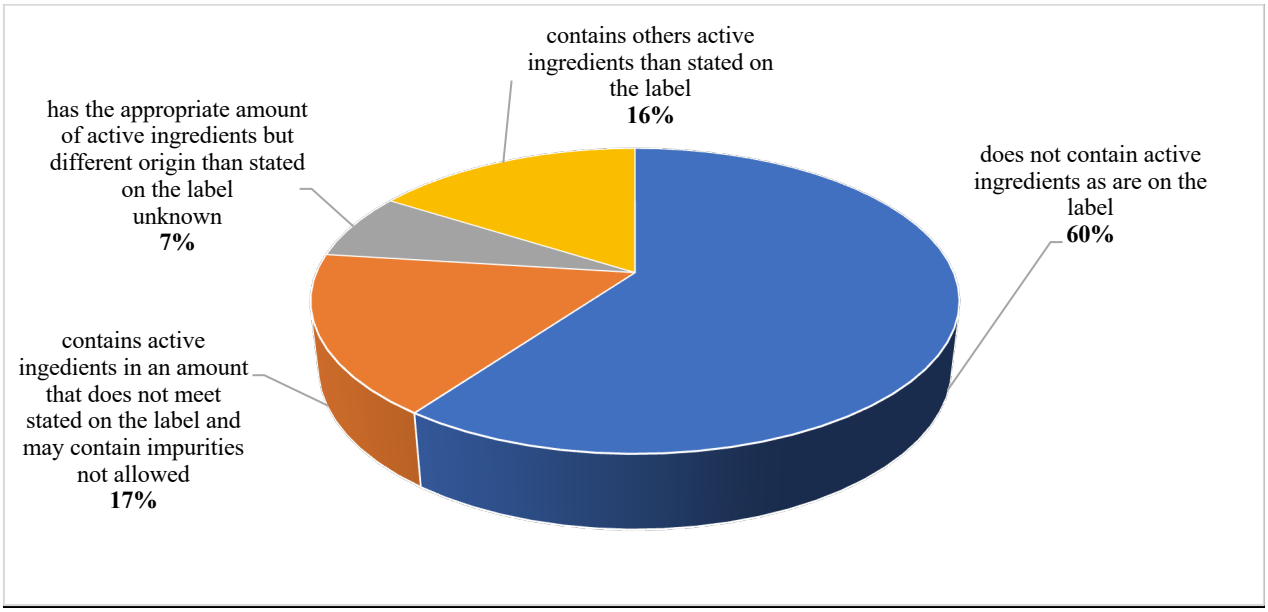


Fig.2.2. Percentage of distribution of counterfeits by category

The globalization of the pharmaceutical industry has created the risk of the rapid spread of substandard drugs around the world before they can be noticed and intervened.

The main factors contributing to the spread of counterfeit products are:

- high cost of medicines and treatment;

- disruptions in the legal supply chain;
- gaps in legislation;
- easy access to technology;
- poverty of the population;
- lack of strict compliance with the law.

The large supply chain of medical supplies is another major challenge. Medicines are sold through numerous intermediaries and free trade zones, sometimes repackaged and labelled to hide their true source or identity, which can lead to the spread of counterfeit medicines.

Substandard and falsified medicines cause unnecessary suffering to people and their loved ones, and have far-reaching consequences for society. Based on the studied literature, it is possible to identify the main directions of influence of low-quality drugs (tabl.2.2).

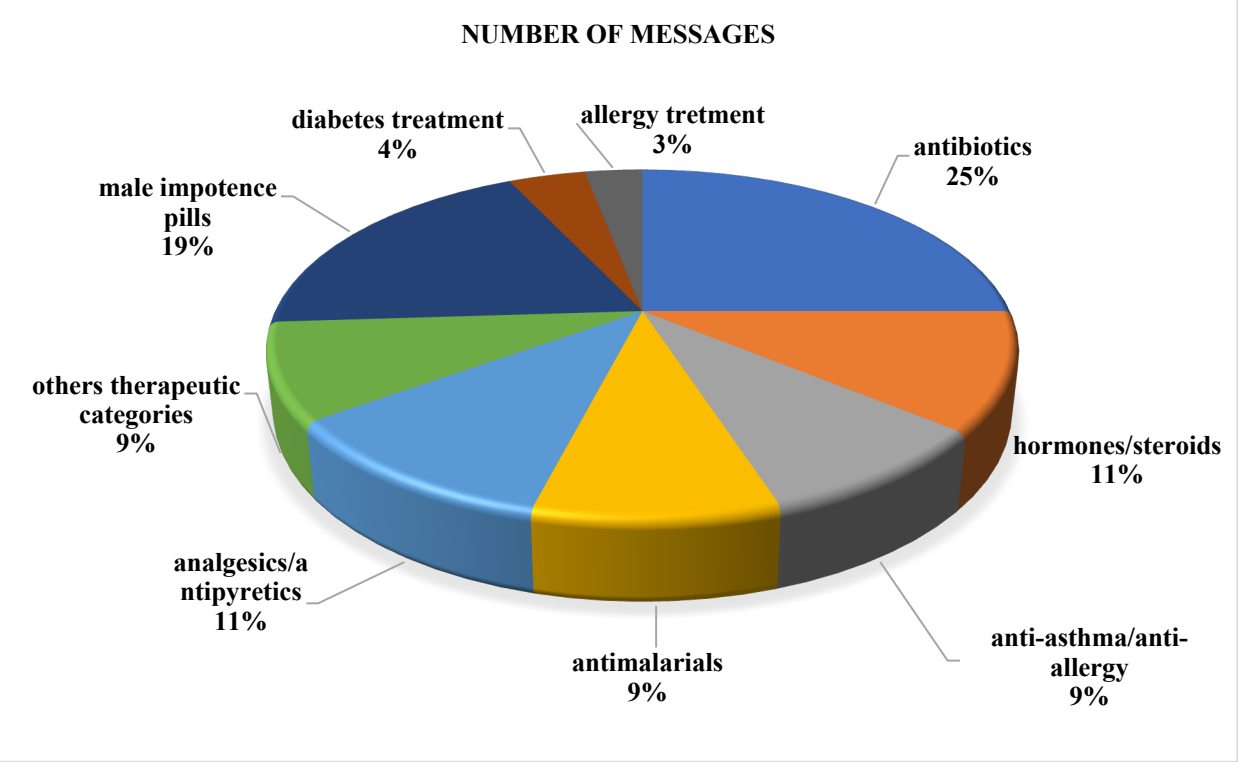
Table 2.2

Consequences of exposure to counterfeit drugs

Types of impact	**Content**
Health Effects	Adulterated and low-quality products do not work properly and can cause serious side effects. They also contribute to drug resistance, leading to more infections that cannot be cured by existing drugs (such as antibiotics). As a result, people lose trust in health systems and do not go to the doctor for the treatment they need. All this increases mortality and morbidity.
Economic impact	Patients, their families, healthcare systems, manufacturers, and others in the supply chain waste time and money. The burden on health professionals, national medicines regulators, law enforcement agencies and criminal justice systems is increasing, further straining already scarce resources, staff and infrastructure.
Socio-economic impact	More deaths and long-term illnesses lead to lost household income, increased poverty, and lost productivity in societies

Calculating the true results of the problem is quite difficult, but various studies have the opportunity to highlight this scale. To address these challenges, the World Health Organization launched a global surveillance and monitoring system in 2013. Encouraging Member States to report incidents involving medical products in a systematic format leads to a more accurate and informed assessment of the scale and area of harm caused by the problem. In the period from 2014 to 2018, the system received 1650 reports of cases of low-quality or falsified products.

Of these, painkillers (11%) and antibiotics (25%) were the most commonly reported (fig.2.3) [16,33].



Source: WHO Database on Counterfeit Medicines

Fig.2.3. Reports of counterfeit drugs by therapeutic class received by WHO

Another problem that provokes the appearance of counterfeit products on the market is patent law. Some drugs patented in developed countries are "copied" in developing countries, where patent rights for pharmaceutical products are not protected. Such production competes with innovative laboratories.

For example, Bayer Laboratories, the owner of the patent for “praziquantel”, was outbid on price by the Korean laboratory Shin Poong, which developed a less

expensive manufacturing process [21]. In addition to these copies, which arise from a different notion of intellectual property rights, there are cases of pure and simple piracy (appropriation of the name and appearance of a medicinal product), which are common in countries where informal markets play a significant role [22]. The term "counterfeit" is commonly associated with the protection of intellectual property rights, an area that is explicitly excluded from the mandate of the WHO Member States' Substandard and Falsified Medical Products Mechanism.

According to the WHO, counterfeit medicines kill more than 700 thousand people every year. The WHO regularly conducts large-scale inspections, publishes their results on its website, after which the participating countries issue internal orders to ban certain drugs.

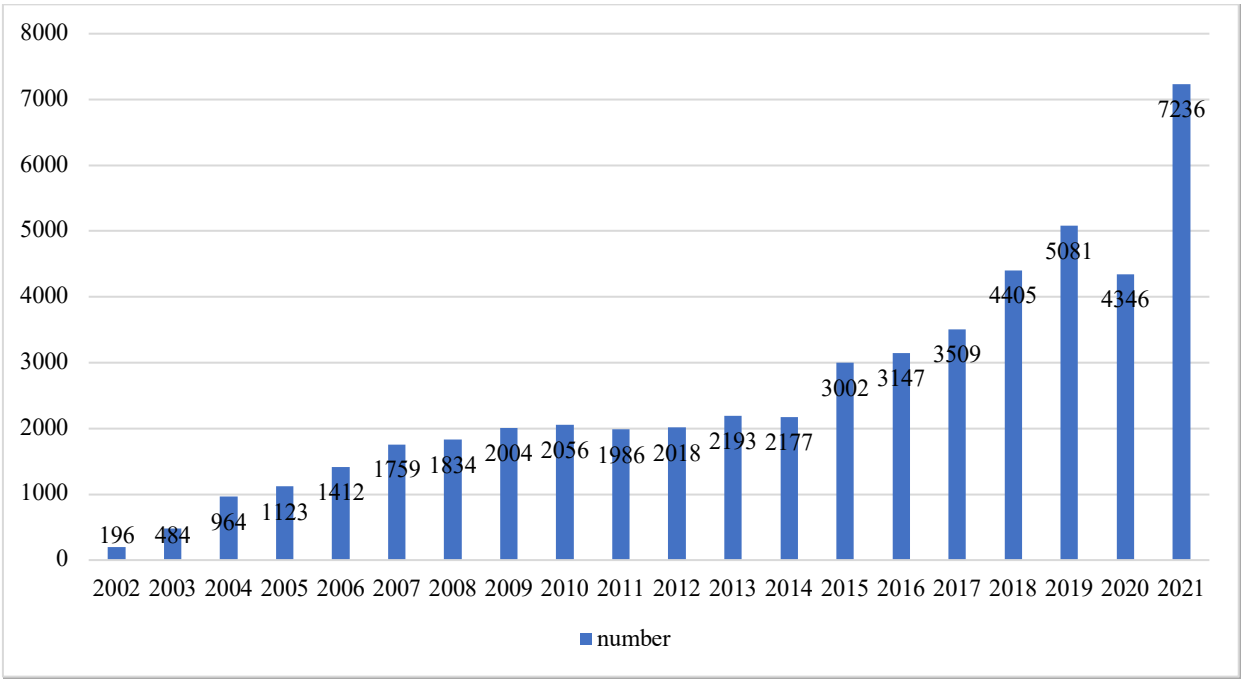
Distribution channels for low-quality drugs can be internet-pharmacies that operate without a license and online sales. И это неудивительно, потому что преступники используют современные технологии, социальные сети, где предлагают более дешевые лекарства. If we summarize the channels for the distribution of counterfeit products, these are websites, Facebook pages, Instagram accounts (i.e. everything happens online, except for the receipt of medicines).

Most of all (more than 50% of medicines) of counterfeit products are sold on the Internet: in online pharmacies, on forums or from individuals. According to the WHO, medicines purchased through illegal online pharmacies that hide their physical address are counterfeit in half of the cases.

In 2018, Interpol, together with the UN and the WHO, conducted a special operation, after which about 5,000 online pharmacies were closed in more than 100 countries, 13 million packages of counterfeit medicines and 300,000 medical products were seized B [17].

Unfortunately, not all countries have yet developed a systematic approach to solving this problem, but individual trade groups, such as the Pharmaceutical Security Institute, track counterfeit pharmaceutical products [3]. Understanding the seriousness of the issue, Interpol conducted the international operation "Pangea" to curb the online sale of fake and illegal medical products. Since the launch of the

program in 2008, the operation has withdrawn more than 105 million items (pills, ampoules, sachets, vials, etc.) and made more than 3000 arrests [4]. The latest WHO report shows that cases of falsified pharmaceutical products increased by almost 50% from 2014 to 2021, becoming even more widespread during the COVID-19 pandemic (fig.2.4).



Source: https://www.psi-inc.org/incident-trends

Fig.2.4. Total number of counterfeit incidents concerning pharmaceuticals worldwide from 2002 to 2021

Conclusions to Chapter 2

The modern world pharmaceutical market is developing dynamically, which leads to increased competition and the emergence of new requirements for the organization of enterprise management.

The results of the analysis of pharmaceutical enterprises in the leading countries of the world economy show that the achievement of the strategic goal in management is ensured through the use of European methods of quality management and certification of management systems in accordance with ISO 9001, ISO 13485, GMP, GLP, GCP, GDP, etc.

The goal of good practices is to organize each stage of the life cycle in such a way as to minimize the risks to patients associated with errors and deviations in the execution of processes that can negatively affect the quality of finished products.

Quality control is proof of the efficiency of the product quality system: firms, enterprises and organizations, regardless of departmental subordination and forms of ownership, must produce and sell medicines that meet all regulatory requirements.

The presence of counterfeit or substandard medicines on the market poses risks to patient safety and public health.

Drug resistance caused by counterfeit drugs poses a very serious global health threat and exacerbates the problem of combating infectious diseases such as malaria and tuberculosis. In most cases (60%), fake preparations contain fewer or no active ingredients.

No single country or organization can tackle this international challenge alone, and cooperation and coordination are critical to success.

Counterfeiting, adulteration and diversion of pharmaceuticals are on the rise for many reasons, including an imbalance between supply and demand for a genuine product or its ingredients, poor practices in the supply chain, inadequate quality control at the production site, lax regulatory measures, non-adoption and proper use of anti-counterfeiting technologies, enforcement measures and, above all, awareness.

As a result of systematization of data from specialized literature, we have established that the number of counterfeit and non-standard drugs on the pharmaceutical market has increased recently. Over the past 10 years, this figure has been about 50%, not least due to the influence of diseases associated with Covid-19.

CHAPTER 3. ANALYSIS OF QUALITY CONTROL OF MEDICINAL PRODUCTS DURING SALE TO END CONSUMERS

3.1. Analysis of the implementation of medicines storage systems in pharmacies

Pharmacists play an important role in distributing quality pharmaceuticals and providing quality services to patients. The International Pharmaceutical Federation, together with WHO, has developed recommendations for effective pharmaceutical practice. The main objective of these recommendations is to encourage national pharmaceutical organizations to focus the attention of pharmacists on the development of their service structures in accordance with the main task of the pharmacy organization.

The instructions present the basic requirements for quality control of medicines in pharmacies. These include:

- availability of appropriate means for control;
- qualified personnel who are entrusted with the function of quality control.

Ensuring the quality of medicines during reception and storage in a pharmacy is one of the three components of the pharmacy institution's activities, the norms of which are established by regulatory enactments.

Quality depends on proper production and storage: high-quality products are available using rational procurement procedures and reliable suppliers. It is also important to ensure optimal transportation and storage conditions.

"Good Storage Practice" (GSP) means that part of quality assurance that ensures that the quality of a pharmaceutical product is maintained through adequate controls throughout storage. GSP standards in pharmacy are a synthesis of principles and measures for the preservation of medicines at all stages of raw material preparation, production, transportation to distribution to consumers [29]. This

International Standard aims to ensure the quality and safety of medicines when they reach consumers and are a guide for pharmacists.

Retail pharmacies sell finished medicines and their work plan is based on the control of drugs after they go on sale.

The main procedures for the implementation of this goal are described in regulatory legal acts [36]:

1. Planning the procurement of pharmaceutical products from qualified and licensed suppliers. Purchasing products from an unknown or unqualified supplier may result in the sale of ineffective or toxic products.

2. Planning the storage of the product in the most suitable conditions as specified by the manufacturer or established by the pharmacopoeia. The storage conditions of pharmaceutical products are important to maintain their effectiveness.

3. Planning the recruitment of professional pharmacists and providing them with ongoing training makes them aware of modern pharmaceutical practices.

4. Planning to educate clients on certain precautions for handling certain medications and storing them at home.

Each drug is characterized by certain norms prescribed in pharmacopoeias or files submitted by manufacturers and recognized competent authorities in each country. These standards cover many aspects such as physicochemical properties, analysis procedures, shelf life and storage conditions.

Certificates of analysis ensure that single-batch products meet the official quality standards in the country of manufacture. These certifications are provided for each product by the manufacturers. Each unit of goods must be clearly marked, each label must clearly indicate [4,5]:

- International Nonproprietary Name (INN),
- form and dosage,
- number of units (tablets, ampoules, etc.) or volume (syrup, etc.),
- name and address of the manufacturer,
- batch number,
- shelf life.

In European countries, a general concept of quality assurance in a pharmacy has been formulated:

- during storage, the drug must be protected from light,
- temperature and humidity fluctuations, that is, factors affecting the quality of medicines during storage, etc.

The stability of medicinal products depends on both environmental and drug-related factors, such as: active ingredient, dosage form (tablet, solution, etc.) and manufacturing process. Therefore, it is necessary to comply with the storage conditions given in the instructions or on notifications from manufacturers and labels, unless the recommendations are identical. The need for the number and size of premises depends on the number of medicines that need to be stored. Security and fire protection systems should be installed in the selected storage of medicines. The optimal result of storage of medicines is achieved only if the conditions and storage regime are observed.

Storage of goods is a process that involves placing goods in a storage room, maintaining and caring for them, and the main purpose is to ensure the quality and quantity of medicines.

Storage conditions are a set of external environmental influences associated with the storage regime and placement of goods in a warehouse.

Based on this, it is possible to identify the main conditions for organizing the storage of medicines in a pharmacy [4]:

- availability of appropriate premises;
- creation of the necessary regime;
- organization of placement of goods.

The availability of a wide range of medicines in the modern pharmaceutical market, as well as a large number of regulatory documents governing the organization of storage of medicines, require careful systematization and comprehensive assessment.

Thus, it can be concluded that an effective model for organizing the process of storing medicinal products consists in compliance with the requirements for

storage rooms, personnel responsible for the storage of medicinal products, as well as requirements for special storage conditions (tabl.3.1) [4,10,12,29].

Table 3.1

Model of organization of the process of storage of medicines

Availability of appropriate premises	**Creating the necessary regime**	**Organization of premises in accordance with the functions performed**
• the number and size of the premises depends on the number of medicines that need to be stored and on the type of pharmacy activity	*Drug protection:* • from dust and foreign odors; • temperature; • optimal air humidity	• receiving area; • main storage area; • storage area for medicines that require special conditions; • storage area for identified falsified, substandard, counterfeit medicines is a quarantine storage area, for example, when it is found that there are no accompanying documents, as well as documents confirming the quality of the goods received by the organization.
Necessary possession		
fire protection systems	thermometers hygrometers	control inventory
Personnel		
qualified pharmacists; responsible person		

Indoors, it is necessary to ensure the protection of medicines from factors that can affect their quality. For this purpose, it is necessary to equip the premises with thermometers and hygrometers, thermometers must also be installed in refrigerating chambers. In addition, it is necessary to regularly carry out metrological verification of equipment and monitor its serviceability.

The average storage temperature in warehouses should not exceed 25 °C and is determined by the European Pharmacopoeia (tabl.3.2) [5].

Table 3.2

Drug storage requirements in pharmacies

Storage conditions	**Recommendations**	**Example**
freezer	– 15 to 0 °C	vaccines, organ preparations
refrigerator	+ 2 to + 8 °C	insulin
cool	+ 8 to + 15 °C	vaginal and anal preparations
ambient temperature	+ 15 to + 25 °C	most medicines
room temperature	the temperature prevailing in a working area	
controlled	+ 20 to + 25 °C	narcotics & psychotropic substances
warm	+ 30 to + 40 °C	
excessive heat	any temperature above + 40 °C	plasma replacement and detoxification solutions
“Store in a place protected from light”	medicine should be stored in a place that prevents light from entering	solid and gaseous (aerosols)
“Store in a dark place”	this is storing the medicine in its original secondary packaging	tablets and capsules
“Store in a dry place”	this is storage at a relative humidity of no more than 60%	medicinal plant raw materials

It is important to know the usual characteristics of each drug (color, odor, solubility, consistency) in order to detect changes that may indicate a deterioration

in its properties. It is important to know that deterioration does not always lead to detectable external changes.

The main consequence of deterioration is a decrease in therapeutic activity, which leads to more or less serious consequences for the individual and/or community. For example, the use of expired antibacterial drugs does not cure the infection, and also contributes to the emergence of resistant strains.

In accordance with the current legal regulation, the process of storage of medicinal products is carried out in accordance with certain rules. One of the features of storage of medicinal products is their separate placement in the premises in accordance with the classification of groups of medicinal products and depending on the physical and chemical properties for the organization of special storage conditions (tabl.3.3) [5,37].

Table 3.3

Features of storage of medicines

Intention	**Examples**
toxicological groups	poisonous and narcotic substances; potent substances and tonic drugs
Current Instructions	pharmacological groups
Method of administration	internal, external
state of aggregation	liquid separately from free-flowing, gaseous, etc.
physical and chemical properties; environmental factors	volatility photosensitivity
taking into account the established shelf life	Less stable - 1-2 Stable - 3-5

In other countries, such as Ukraine, the principles of quality control are based on the requirements for the distance between the places where the drugs are located. There is a fundamental difference in approaches. Modern pharmacists require

special knowledge and skills of pharmacists to navigate in various situations and achieve the final result.

Medicines deteriorate gradually and according to various processes, even if they are stored in proper conditions. In most countries, regulations oblige manufacturers to study the stability of their products under standardized conditions and guarantee a minimum shelf life. The expiration date specified by the manufacturers indicates the date until which the therapeutic effect remains unchanged (at least 90% of the active ingredient must be present and without a significant increase in toxicity).

The shelf life indicated on the label is based on the stability of the drug in its original and unopened packaging. Shelf life is currently usually guaranteed for 3 and 5 years. Less stable substances are only guaranteed for 1 or 2 years. The expiration date should be indicated on the storage instruction label [5,12,29].

Shelf life must be respected due to legal obligations and therapeutic liability considerations.

The expiration dates of drugs that require a very precise dosage should be strictly observed due to the risk of insufficiency for treatment. This applies to cardiac and antiepileptic drugs, as well as drugs that can become toxic, such as cyclins.

The principles and requirements for the storage of different groups of medicines and medical devices are determined by the Order of the Ministry of Health of Ukraine "On the Organization of Storage of Various Groups of Medicines and Medical Products in Pharmacies".

Each pharmacy has an authorized person who is responsible for the acceptance of goods and incoming control of medicines. There are also requirements for the length of service and qualifications of the authorized person. This employee has a university degree in pharmacy and at least two years of work experience.

In the event that a business entity has more than one pharmacy, the plan of urgent measures determines the procedure for obtaining information by authorized persons of pharmacies about medicines whose circulation is prohibited in Ukraine, medicines not registered in Ukraine, as well as the distribution of responsibilities

and coordination of actions of authorized persons of pharmacies in terms of providing information to the territorial body of the central body the executive power implementing the state policy in the areas of quality control, safety of medicines, countering their illicit trafficking, in case of detection of low-quality medicines, medicines the circulation of which is prohibited in Ukraine, medicines suspected of falsification, unregistered medicines.

When taking medicines, the authorized person checks them according to the following parameters:

1. Visual control of the integrity of the package and its contents.
2. Determination of conformity of marking and content of data specified in quality certificates.
3. Checking expiration dates.
4. Checking the availability of manufacturer's quality certificates for each batch of medicines received.

Every day, specialists of partner pharmacies on the official website of the State Service of Ukraine on Medicines and Drug Control track medicines prohibited for sale. The information is promptly transmitted to the pharmacies of partners and authorized persons who are engaged in the acceptance of goods and take this data into account during the incoming control. Such double control by the distributor-pharmacy completely excludes the presence of goods prohibited for sale for sale.

3.2. Organization of quality control in the pharmacy sector in Morocco

The proliferation of substandard medicines and weak regulatory enforcements are some of the significant challenges facing the pharmaceutical sector in Africa in recent years. Addressing these issues through the provision of high-quality medicines is vital to improving health outcomes across the continent. The trend towards quality by design in the quality assurance system becomes very useful in conditions of extreme pressure on the healthcare system.

To counter this threat, the Moroccan government has implemented a series of measures, these attempts aimed at controlling and reducing the circulation of counterfeit medicines. We have identified the main measures and their focus in table 3.4 [6,14].

Table 3.4

Measures aimed at distributing low-quality products

Propositions	**Performance**
Strengthening legislation	Morocco has adopted stricter laws to combat counterfeit medicines, which include severe criminal penalties for violators. Law 17-04, which regulates the pharmaceutical sector, is the legislative framework aimed at ensuring the safety of the entire medicine supply chain. Article 30 of Law 17-04 on the Code of Medicines and Pharmacy Activities establishes the obligation to sell medicines in pharmacies.
Enhanced control	Authorities have stepped up border and distribution controls to detect and seize counterfeit medicines. These operations are often carried out in collaboration with international organizations such as the WHO and foreign regulatory authorities.
Information campaigns	The government is conducting information campaigns to educate the public about the dangers of counterfeit medicines. These campaigns aim to encourage patients to purchase medicines only from approved pharmacies and to report any suspicious activity.
Participation in Operation PANGAEA	Coordinated by Interpol, Morocco is involved in Operation PANGEA, aimed at dismantling criminal networks involved in counterfeiting medicines worldwide. Thanks to the joint efforts, several clandestine laboratories have been dismantled and thousands of boxes of counterfeit medicines have been seized.

According to statistics from the World Health Organization, about 50 percent of counterfeit medicines in the world are distributed in Africa [7,8]. These drugs are prohibited, often ineffective and dangerous, their use threatens the health of patients, and does not cure.

Access to medicine is a defining element of any health policy. This is guaranteed by the pharmaceutical policy of each country, which aims to ensure geographical, physical and financial accessibility, as well as guaranteeing its effectiveness and quality accessibility. The quality of medicines in general, both manufactured and imported, has always been considered a priority area of pharmaceutical policy. The latter continue to introduce effective tools to ensure the quality required according to international standards and the safety of medicines entering the Moroccan market.

Pharmacists are the first to contact patients, so they must carefully check the authenticity of the drugs they sell and provide relevant information.

The International Guidelines on Good Pharmaceutical Practice in Pharmacies recommend the identification of national standards for the promotion of human health by improving the practice of the pharmacist profession.

Moroccan pharmacists play an important role in the fight against falsified medicines. They are responsible for verifying the origin of the drugs they buy and sell. Pharmacies must source products exclusively from approved distributors and constantly monitor the authenticity of the products they receive.

Health care workers should also be trained to detect subtle signs of counterfeiting and report any suspicious medications to the appropriate authorities. Continuing education programs are necessary to inform them about the new methods used by counterfeit manufacturers.

Dahir No 1-06-151 of 30 Chahual 1427 (22 November 2006) on the promulgation of Law No 17-04 on Pharmaceuticals and the Pharmacy Code provides for the rules of Good Pharmacy Practice, which covers the actions of a pharmacist in the exercise of his profession [15].

The Law describes the requirements for the premises of a pharmacy. The dispensing and preparation area should be organized in such a way as to prevent access to medicines by unauthorized persons and should be supervised by pharmacists. The pharmacy owner must provide and maintain such personnel, facilities, equipment and procedures for the storage, preparation, dispensing, sale and supply of medicinal products, including veterinary medicinal products, which the pharmacy stores, prepares, dispenses, mixes, sells and supplies in its retail business, which are necessary to prevent deterioration in the quality of products and must not use premises for such purposes, except for those that constitute the retail pharmacy business and who were identified in the application for registration under section 17 of the Act. Regulation 6(3) of the current Law sets out the requirements for the storage of medicines previously dispensed or delivered, which have been returned to the pharmacy [18-21].

Rules and procedures regarding cleanliness, hygiene, disinfection and ventilation are established and precautions are taken to avoid any product alteration and any contamination.

Temperature, humidity and light conditions meet the requirements of conservation practices. These conditions are periodically checked and logged.

As part of information on the correct use of medicines and other medical products. which he dispenses, the pharmacist draws the patient's attention to the danger of using drugs whose expiration date has passed.

Expired medicines cannot be counterfeited, sold or dispensed. They become unfit for consumption and must be returned for destruction to the manufacturer's pharmaceutical establishment, either directly or through the wholesale distributor of pharmaceutical products that provided the distribution.

If it turns out that the drugs are no longer of the required quality and pose a danger to public health, preventive and protective measures provided for by current regulations are applied. A permanent control system makes it possible to guarantee the quality and safety of use of all medicines authorized for sale, as well as to strengthen and consolidate the quality system of medicines in Morocco.

Inspections of pharmacies can be carried out by the Ministry of Health or the Tax Service. Inspectors are interested in compliance with the storage conditions of medicines, prescription drug dispensing logs.

3.3. Analysis of pharmacists' opinions on issues of storing medicines in a pharmacy

The World Health Organization defines good storage practices as "a part of quality assurance that ensures that the quality of medical products is maintained through adequate controls throughout their storage." This includes, but is not limited to, the quality control of pharmaceuticals in retail trade and pharmacists are subjects of this process.

The organization of the effective work of a pharmacy depends on the action of a number of factors, one of which is the responsible storage of drugs. Therefore, the purpose of our further research was to conduct an express survey of pharmacists who are in the age range from 30 to 50 years.

In our survey, we sought to focus on appropriate storage practices in pharmacies, as they can prevent changes in the quality of drug supplies and harm public health. We were interested in answers to questions about compliance with storage rules in pharmacies.

57 pharmacists took part in the sociological survey, among which 37 were women (65.0%) and 20 men (35.0%), respectively, the experience of practical work in the pharmacy was more than 15 years. Pharmacies in which the surveyed pharmacists worked are engaged in serving the population and dispensing drugs, both with a prescription and without a doctor's prescription. In addition to the sale of drugs, other pharmacy products are quite widely represented in pharmacies.

The questionnaire contained 12 questions, among which eight were closed-ended questions. Let's dwell in more detail on the analysis of the questionnaire and present for discussion the results that we received for the period from June to October 2024.

In order to ensure the high quality and preservation of medicines and medical devices during storage in pharmacies, safe working conditions must be created when working with them. The organizational structure of a pharmacy depends on the type of activity, the services that are given to the population and on the amount of turnover. The premises of the pharmacy should be sequentially interconnected depending on the work performed. In a pharmacy, the premises for storing products can be located separately, and if the pharmacy is small, medicines can be located in the premises where they are directly sold to the public. Therefore, our first question was about the presence of a separate or joint storage department in the pharmacy (fig.3.1).

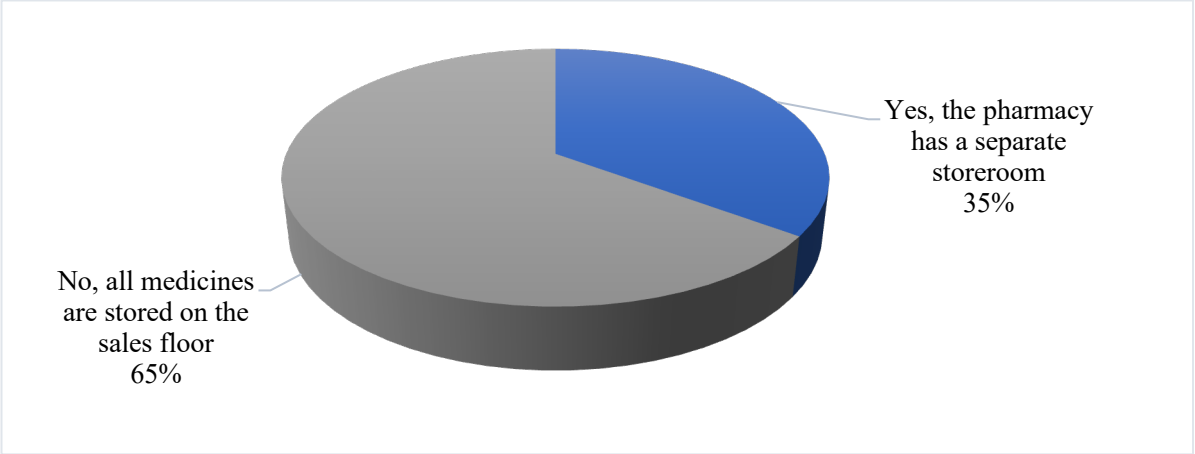


Fig. 3.1. Analysis of the results of pharmacists' responses to the question about the presence of a separate room for storing medicines in the pharmacy

Analyzing the answers, we found out that not all pharmacies have a separate room for storing medicines (35%). It is quite difficult to find a suitable premises in Morocco and the property is quite expensive, and pharmacies have a small area and all medicines are located at the points of sale. Deliveries of medicines to pharmacies in Morocco are carried out daily, even if a small amount of medicines is needed, so there is no storage in pharmacies in significant quantities.

Medication storage is a process that reflects the proper handling of medications to ensure their integrity, safety. It involves following certain guidelines and procedures to maintain the quality and efficacy of medications. To answer the

next question, we wanted to find out if all medicines are kept under control, and most pharmacists (81%) answered in the affirmative (fig.3.2).

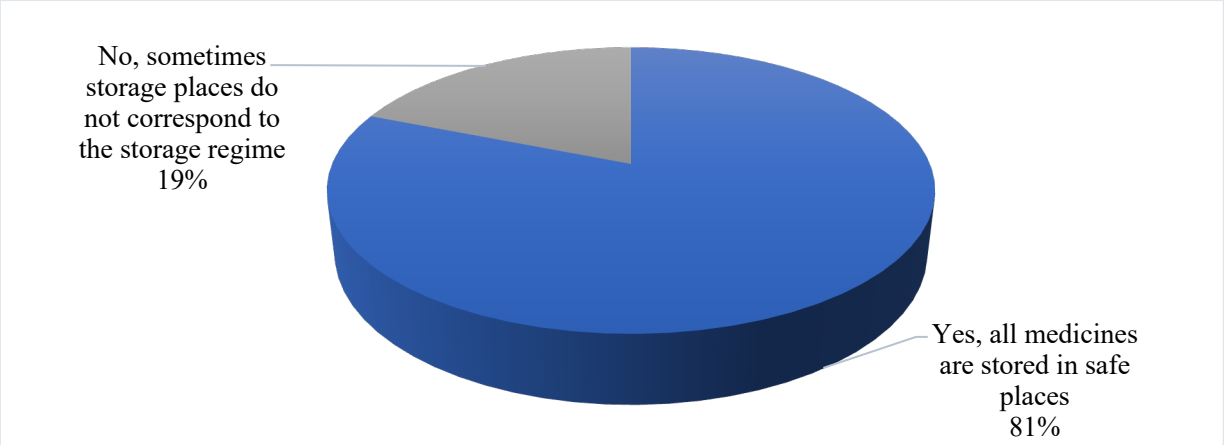


Fig. 3.2. Analysis of the results of pharmacists' responses to the question 2

Storage and transportation of pharmaceutical products takes place at all stages of circulation. It is impossible to speak with certainty about the quality, safety and efficacy of medicines without developing a national or intrapharmacy standard for the storage of medicines that complies with GSP standards, and without complying with it in practice. Therefore, the storage of medicines in a pharmacy should be organized in accordance with specific norms or standards. To the next question, we received information that about 33% of pharmacists use state regulations when storing drugs. 28% use GSP, and 21% - manufacturers' instructions (fig.3.3).

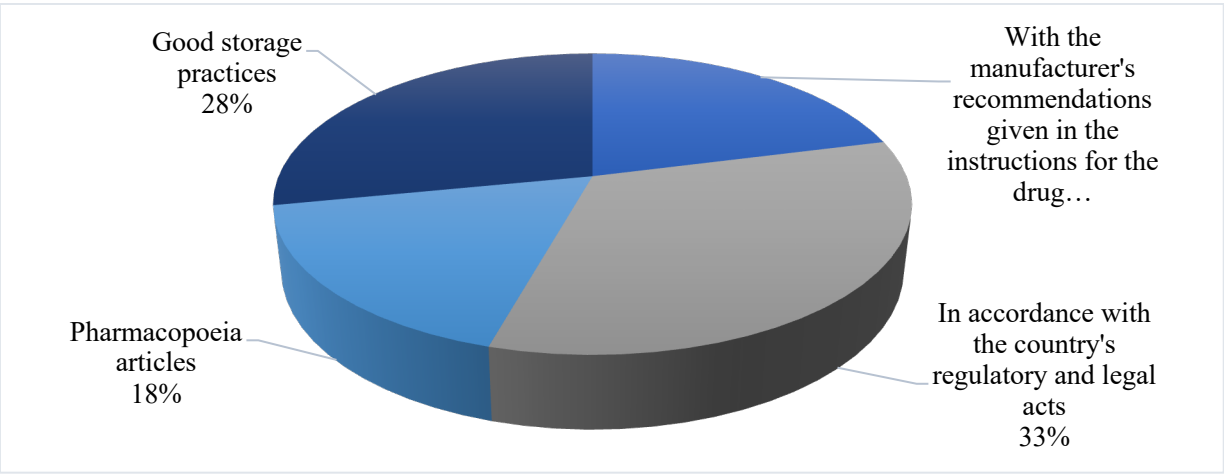


Fig.3.3. Analysis of the results of pharmacists' responses regarding the organization of storage of medicines in the pharmacy

To the question "Who is responsible for quality control of medicines in the pharmacy?" – The majority of respondents identified an inspector from the control laboratory and only 16% answered correctly – authorized employee appointed by the head (fig.3.4).

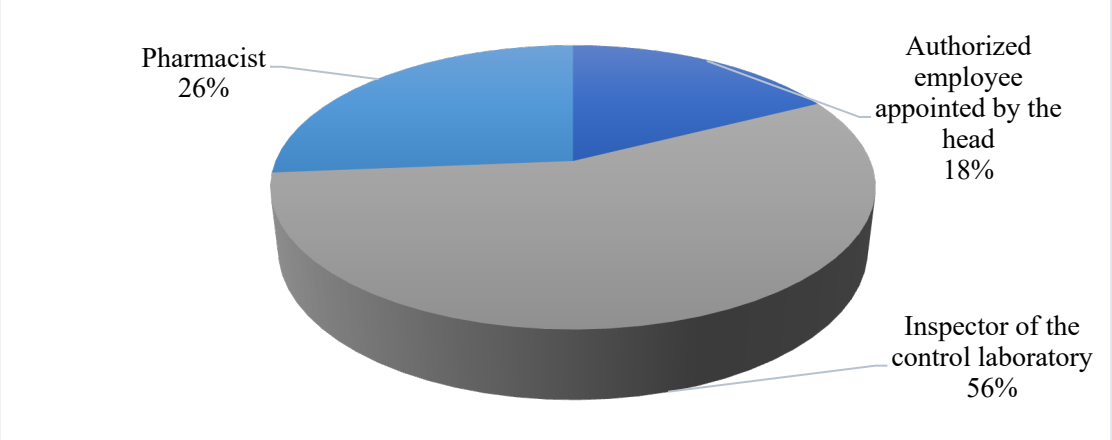


Fig. 3.4. Analysis of the results of pharmacists' answers to the fourth question

The fifth question of the questionnaire was supposed to ask pharmacists about the obligations of the responsible person. This was one of the open-ended questions in our questionnaire. Visual control of the received medicines and preparation of relevant documents were chosen by 45 and 47 pharmacists out of 57 respondents.

The results of the processing of the questionnaire data are shown in figure 3.5.

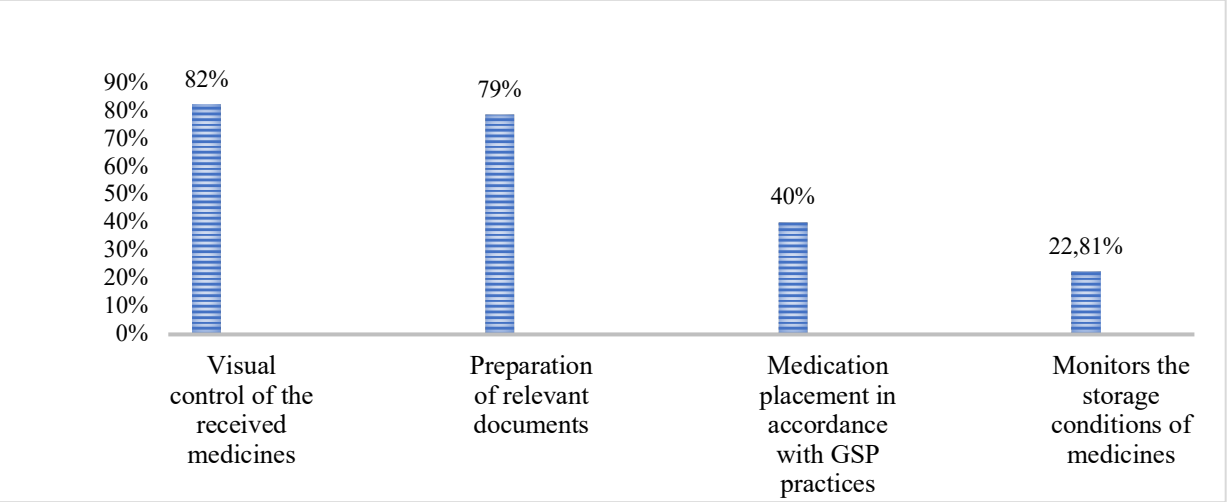


Fig. 3.5 What are the responsibilities of the responsible person when accepting the goods?

No medicines, raw materials or other products with an expired shelf life may be stored in the pharmacy. Expired medicinal products are destroyed in accordance with the current legislation and rules. Expired and unused raw materials are also disposed of in accordance with the law and applicable regulations.

Compliance with storage rules minimizes losses due to expiration of products. According to international storage standards, which Moroccan pharmacies adhere to, drugs whose expiration date is approaching must be sold first. The remaining shelf life must be sufficient to allow the product to be used before the expiration date. To facilitate surveillance, place products approaching expiration dates first before pharmaceutical products with later expiration dates. Expiry dates should be recorded on stock cards so that stock can be returned to facilities at least 6 months before expiration. Unfortunately, only 39% of pharmacists regularly document the expiration date, the rest are noted in the process of taking medications from the supplier (fig.3.6).

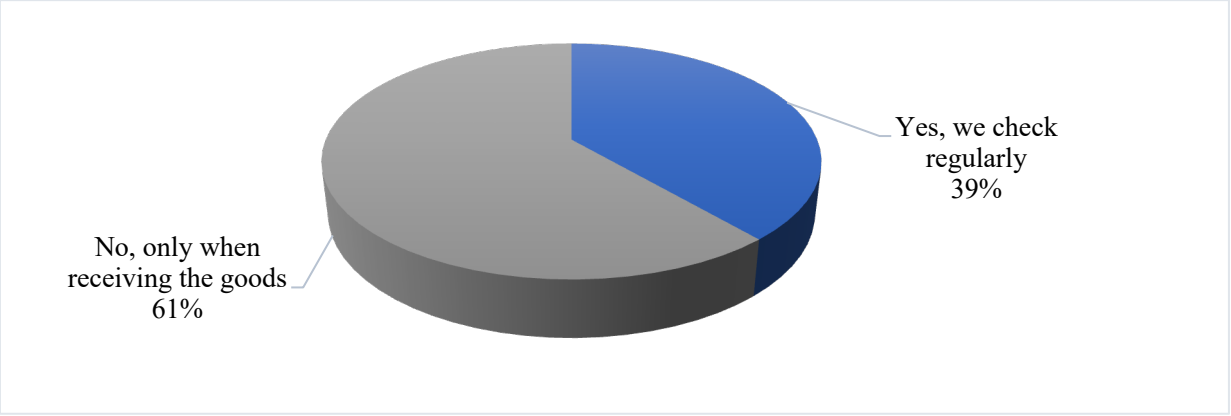


Fig. 3.6. Analysis of responses regarding the presence of a documented expiration date verification procedure

Storage of medicines is one of the most important duties of a pharmacist. Therefore, it is necessary to develop and implement adequate methods to ensure the fulfillment of these obligations. One of the duties of the person responsible for quality control of medicines is to provide the relevant authority with information about detected low-quality medicines, medicines in respect of which there is a

suspicion of falsification and unregistered medicines, other defects or inconsistencies.

If samples of such medicinal products are detected, take measures to withdraw them from circulation by placing them in a specially designated, clearly defined, marked quarantine zone (premises), separately from other products, with the designation "Quarantine" indicating the reasons for withdrawal from circulation and the date of movement. About 38% of pharmacists perform these duties, and 44% immediately prescribe such medicines to the supplier (fig.3.7).

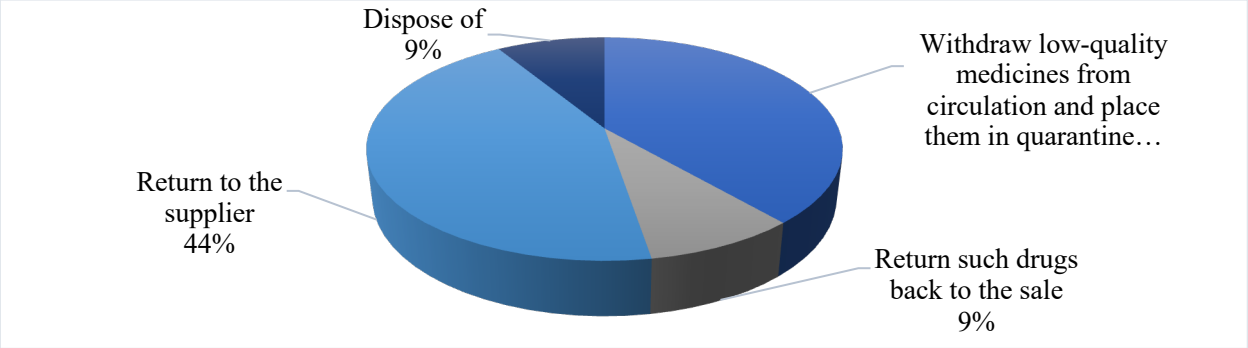


Fig. 3.7. Processing of pharmacist survey results data (questions:" What to do if you find medications with a changed appearance and/or doubt their quality?")

The main task of the pharmacist is to provide the patient with information about medicines, including instructions on the proper storage of their medicines. It can be argued that a significant majority of the surveyed pharmacists (74%) meet their qualifications and work within the framework of pharmaceutical practice (fig.3.8).

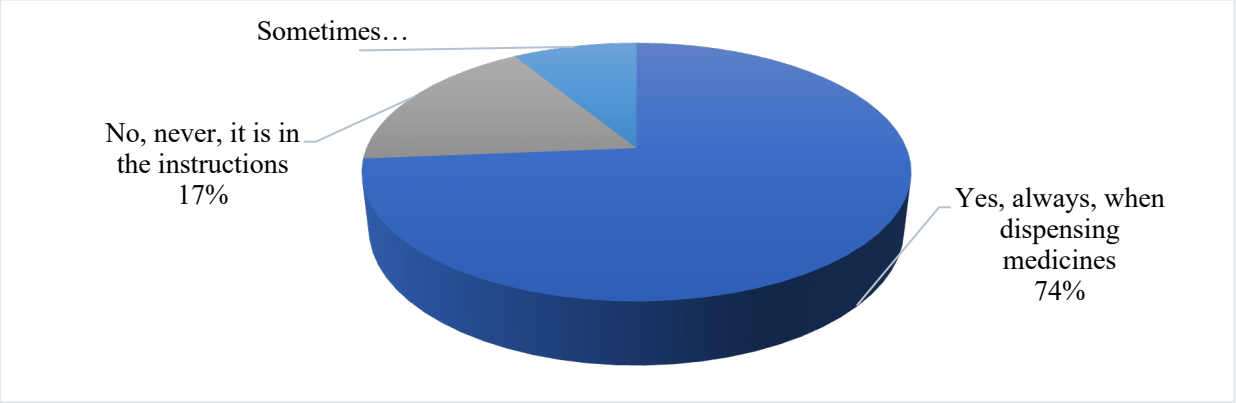


Fig. 3.8. Have patients been provided with the necessary information and guidance on how to properly store their medications?

The optimal result of storing goods is achieved only if the conditions and storage regime are observed.

Storage conditions are a set of external environmental influences associated with the storage regime and placement of goods in storage. The main conditions for organizing the storage of goods are: the availability of appropriate storage premises; creation of the necessary storage regime; organization of placement of goods during storage.

Under special storage conditions (e.g. temperature, relative humidity), it is necessary to maintain, monitor and record the indicators. Monitoring implies the presence of measuring instruments, the most important of which are a thermometer for measuring temperature and a hygrometer for measuring humidity.

After extracting the data, the answers were ranked and showed the presence of thermometers for measuring air temperature in the pharmacy – 100% (57 people); The presence of hygrometers was noted by 53 respondents, and a thermometer for controlling the temperature in the refrigerator by 43 respondents (fig.3.9).

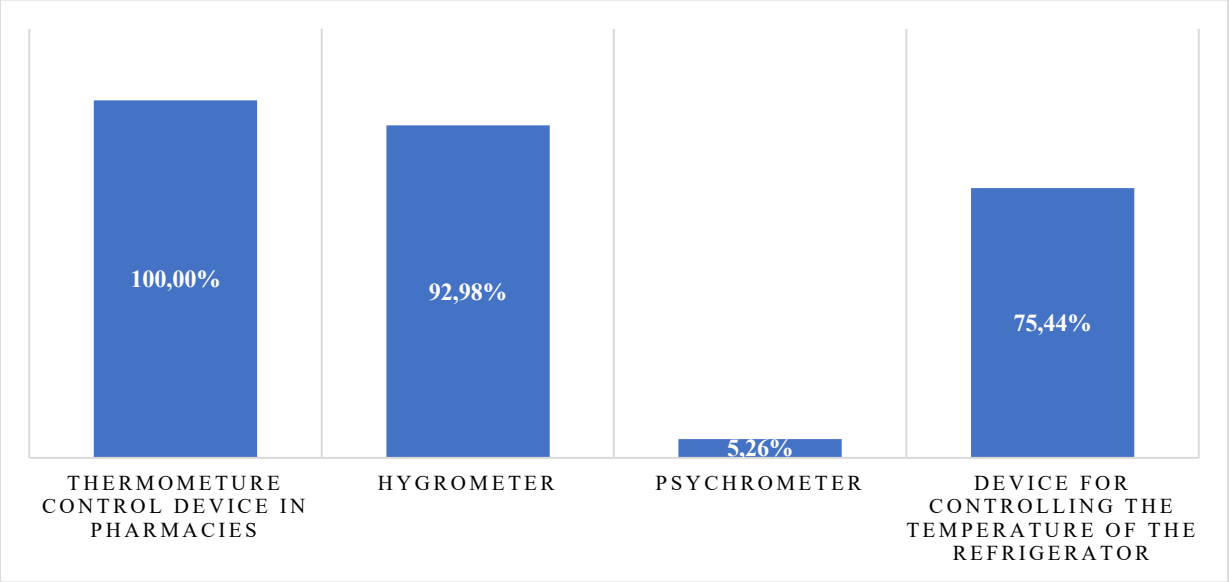


Fig. 3.9. What measuring devices for recording storage conditions exist in a pharmacy?

Storage regime is a set of climatic and sanitary-hygienic requirements that ensure the safety of goods.

The climatic mode of storage includes requirements for temperature, relative humidity, gas composition of air, air exchange and illumination.

The fundamental principles of storage of pharmacy products include:

- continuity of compliance with storage conditions;

- protection from adverse climatic and other conditions during transportation and storage;

- information support;

- systematic control is the mandatory periodic control at all stages of the movement of goods, both for short-term and long-term storage.

Temperature control data should be recorded in special logs and be available for viewing. The readings of the equipment used for monitoring should be checked at certain predetermined intervals and the results should be recorded and stored. When answering the question "Are the readings of measuring instruments recorded daily in the relevant logs", we found a discrepancy. Although compliance with the presence of a refrigerator was quite high, there was a low record compliance (35%) and no monitoring at all (18%) (fig. 3.10).

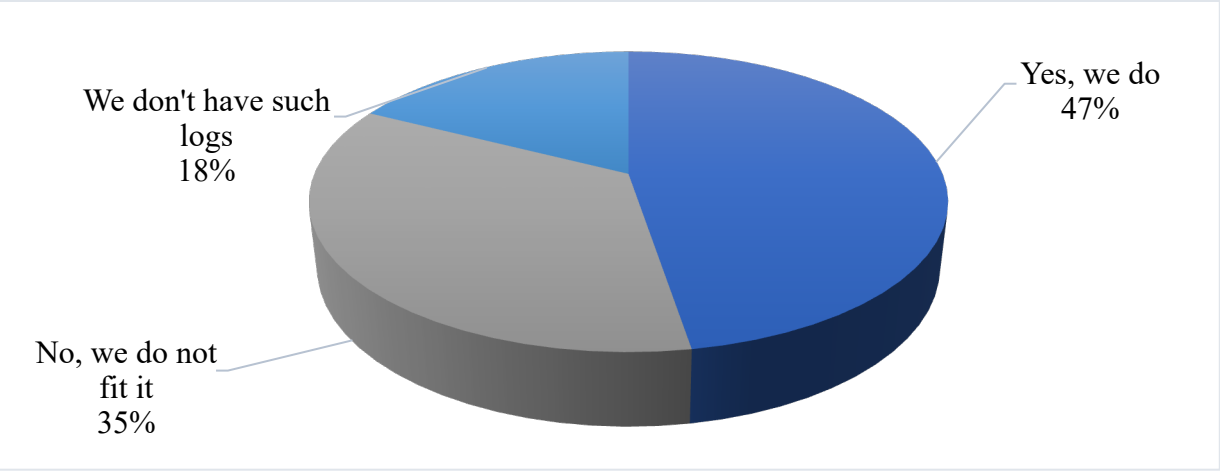


Fig. 3.10. “Are the readings of measuring devices recorded daily in the appropriate logs?”

Compliance with the cold chain and storage of medicines are unique functions of a pharmacist.

Optimal storage conditions require appropriate equipment. In addition to a refrigerator designed exclusively for storing medicines and equipped with a thermometer, it is advisable to equip the pharmacy with a suitable air conditioning system and appropriate cabinets. In the next question, we asked pharmacists to note the availability of equipment for storing medicines (fig.3.11).

The presence of a refrigerator was high (100%), the refrigerator was intended only for medicines. The availability of air conditioning was also high (96,49%).

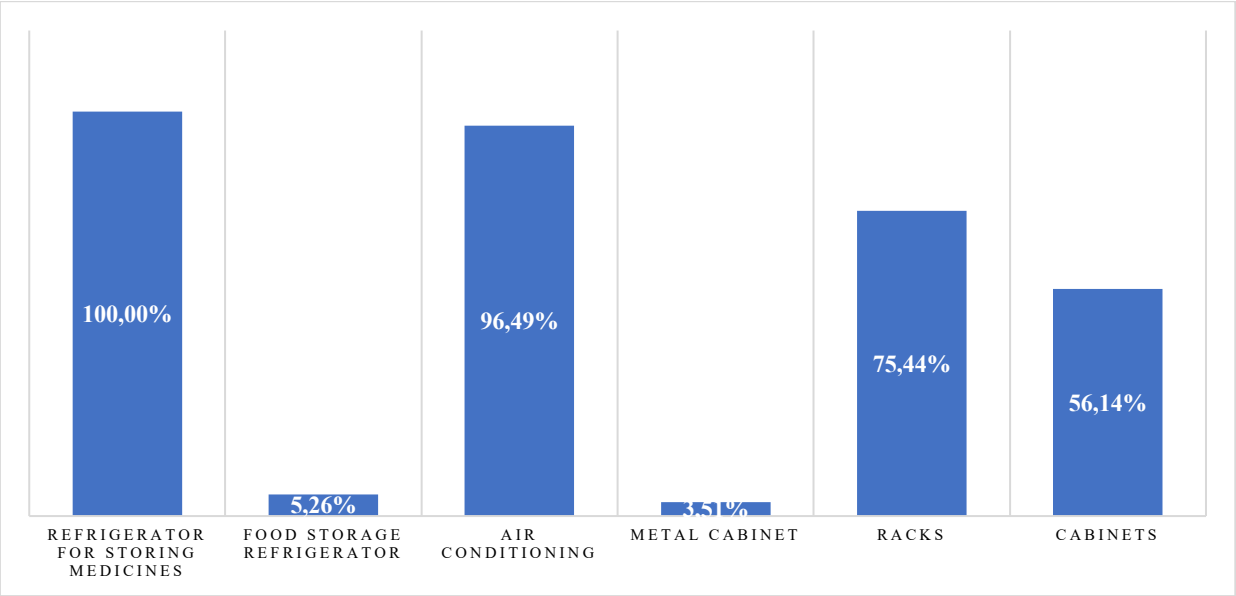


Fig.3.11 What equipment is available in the pharmacy for optimal storage of medicines?

In the climate of Morocco, it is difficult to talk about the ambient temperature (+15 to +25°C). In summer, the temperature is well above 30°C, so the storage temperature should be below + 30°C.

Various agents can change the drug, including heat, frost, light, humidity, air, radiation, etc. Failure to comply with storage conditions for a long period casts doubt on the effectiveness of the drug. Morocco, in a country where ambient temperatures are high for most of the year, the correct storage of medicines and, therefore, respect for the cold chain are essential elements for the success of a pharmacy. Therefore, we were interested in how the pharmacy conducts the protection of medicines in such conditions (fig.3.12).

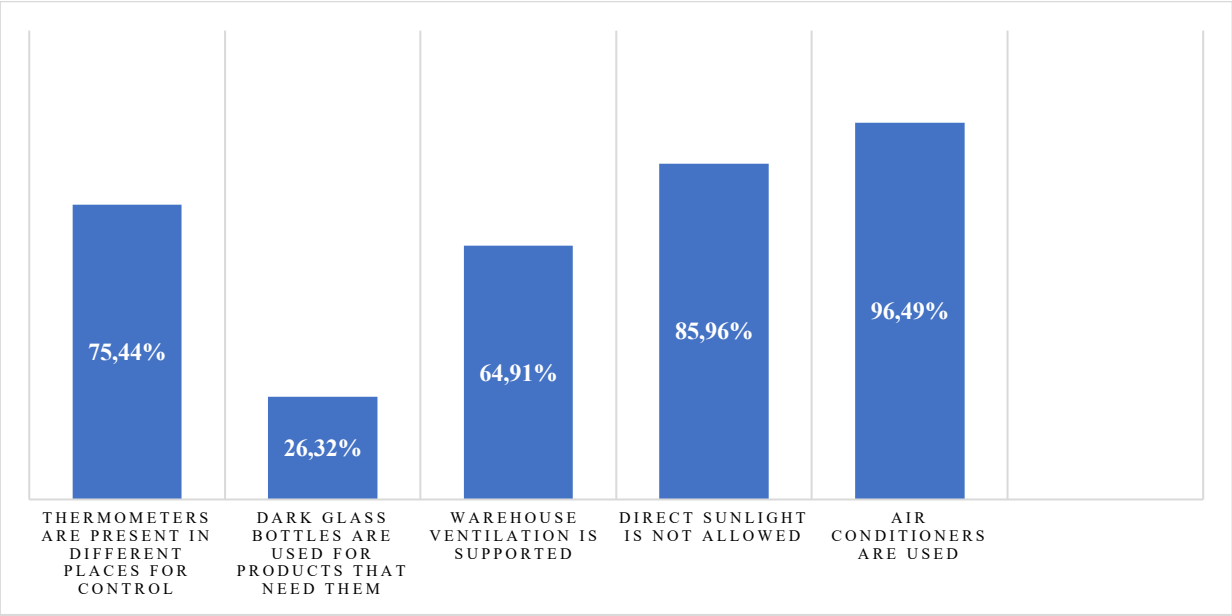


Fig.3.12 What operation does a pharmacy perform to protect medications from high temperatures?

For cooling, almost all pharmacies have an air conditioner for cooling (96.49%) and a thermometer for temperature control (75.44%). The word "protected from moisture", which is often mentioned on the packaging, means that the product in question should be stored in a dry place (outside the refrigerator), so 64.91% use ventilation. Where pharmacies protect the shelter from direct rays (64.91%).

Conclusions to Chapter 3

As a result of the analysis of legislative and legal documents, it can be concluded that all processes for ensuring the quality of medicines in a pharmacy are aimed at organizing the proper quality of the main processes of the "life cycle" of medicines.

Supervision over the procurement of medicines, incoming quality control of medicines, verification of the presence and isolation of low-quality and falsified medicines, their transfer to quarantine until the final decision, ensuring quality control of medicines in the process of sale, ensuring and checking the storage

conditions of medicines is provided by a responsible person appointed by the head in accordance with the law.

It is indicated that one of the key indicators guaranteeing the population to receive high-quality, effective and safe medicines is the mandatory implementation of the approved conditions for their storage.

It is determined that in Morocco, the fight against falsified and low-quality medicines begins with the requirements for the regulation of the supply and quality control of medicines. Transparent access of patients to medicines and permission to purchase them through official means. Recognizing this is vital to ensuring patient safety and achieving optimal health outcomes.

Under the influence of various environmental factors, medicines can not only lose their therapeutic efficacy, but also become unsafe for the end consumer.

Thus, it can be concluded that an effective model for organizing the process of storing medicinal products consists in compliance with the requirements for storage rooms, personnel responsible for the storage of medicinal products, as well as requirements for special storage conditions.

GENERAL CONCLUSIONS

1. The analysis and systematization of the data of special literature, which present the results of the analysis of problems arising in the provision of the population with medicines on a global scale, are carried out.

2. The quality of medicines is assessed and the main problems causing its change are identified.

3. The analysis of the main regulatory legal acts that regulate the quality system of pharmaceuticals is carried out.

4. It is noted that the quality of medicines can be guaranteed at all stages of their life cycle, in particular during preclinical and clinical trials, production, wholesale and retail sale of pharmaceutical products. The most optimal sets of international requirements play an important role in this process — GLP, GCP, GMP, GDP, GPP.

5. It is determined that the requirements of GSP (Good Practice for the Storage of Medicines) are of particular importance in the activities of employees of the pharmaceutical industry.

6. The definition of falsified drugs is given and the threat posed by falsified and low-quality drugs to the safety and health of patients is determined.

7. It has been established that an important role in ensuring the quality of medicines is played by ensuring the proper qualification of employees involved in all stages of production (manufacture), storage, sale and use of medicines.

8. Uncover the main obstacles that remain and affect the ability to control the huge volumes of medicines coming to countries, as well as the difficulties in monitoring rural areas and informal markets. Online trade makes it even more difficult to fight counterfeiting, since medicines and especially parapharmaceutical products can be easily purchased online, avoiding traditional controls.

9. It is determined that in order to strengthen the fight against substandard products, it is extremely important to intensify international cooperation, improve

drug traceability technologies and strengthen the capacity of local authorities to detect and intercept counterfeit products.

10. Constantly monitor the storage conditions of medicinal products in accordance with the requirements of the instructions for medical use of the medicinal product.

11. It is determined that the market for counterfeit medicines in Morocco is a complex and dangerous problem that requires constant and coordinated efforts on the part of the state, health workers and civil society.

12. A sociological study (57 pharmacists) was organized and conducted in order to determine the opinion of specialists on the problems and prospects for the development of pharmacies in Morocco.

13. The main problems in the work of modern pharmacies in Morocco with the storage of medicines are identified and possible ways to solve them are indicated.

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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

Mohamed ELAAMIRI

1. Topic of qualification work: «Analysis of the quality assurance system for pharmaceutical products», 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 main problems of pharmaceutical providing; studying of the problem of medicine falsification; analysis of quality control in the pharmacy sector in Morocco; research of pharmacists' opinions on issues of storing medicines in a phamacy.
5. List of graphic material (with exact indication of the required drawings):
tables – 7, schemes – 20.

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 key concepts of the quality of pharmaceutical product	*October/November 2024*	**done**
2	Study of international practice of regulating the circulation of medicines. Analysis of the problem of counterfeiting of medicines	*December/January 2024-2025*	**done**
3	Research of the organization of quality control in the pharmacy sector in Morocco	*February/March 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 _____ Mohamed ELAAMIRI

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				
Елаамірі Мохамед	Аналіз системи забезпечення якості фармацевтичної продукції	Analysis of the quality assurance system for pharmaceutical products	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

«05» травня 2025 р. № 331121102

Проаналізувавши кваліфікаційну роботу здобувача вищої освіти Елаамірі Мохамед, групи Фм20(4,10)англ-05, спеціальності 226 Фармація, промислова фармація, освітньої програми «Фармація» навчання на тему: «Аналіз системи забезпечення якості фармацевтичної продукції / Analysis of the quality assurance system for pharmaceutical products», 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 quality assurance system for pharmaceutical products»**

Relevance of the topic. The importance of quality assurance in pharmaceutical activities cannot be overstated. In the pharmaceutical industry, any compromise in quality can have serious consequences, including harm to patients and the company's reputation. A drug quality control system ensures that every stage of the circulation process meets strict standards and ensures quality.

Practical value of conclusions, recommendations and their validity. One of the aspects related to the circulation of medicines is ensuring and controlling their quality. In order to ensure the proper quality of a medicine, the state exercises control throughout the entire cycle of a medicine, from the moment of its creation, its introduction on the market, and throughout the period of its presence on the market. Thus, the research direction of Mohamed ELAAMIRI qualifying work is relevant and has practical significance.

Assessment of work. During his qualification work, Mohamed ELAAMIRI 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

«08» 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

Mohamed ELAAMIRI

on the topic: **«Analysis of the quality assurance system for pharmaceutical products»**

Relevance of the topic. The availability of quality medicines is a key element of any health policy. This is guaranteed by the pharmaceutical policy of each country and is considered a priority. Each country implements effective instruments to ensure the quality required by international standards and the safety of medicines entering the market.

Theoretical level of work. The qualification work is a theoretical generalization and solution to the problem, which is designed to substantiate the effectiveness of implementing a quality system at all stages of the circulation of medicines in modern conditions.

Author's suggestions on the research topic. As a result of the study, the following conclusions were drawn ensuring the quality of medicines is achieved by improving the system of state registration, certification and quality control of medicines throughout their entire journey from the manufacturer to the consumer. It has been established that an important role in ensuring the quality of medicines is played by ensuring the proper qualification of employees involved in all stages of production, storage, sale and use of medicines.

Practical value of conclusions, recommendations and their validity. These studies have shown that the counterfeit medicine market in Morocco is a complex and dangerous problem that requires continuous and coordinated efforts from the state, health professionals, and civil society.

Disadvantages of work. Mohamed ELAAMIRI's qualification work, submitted for review, made a good impression, primarily due to its content and compliance with current standards for research results.

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

«09» 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 Елаамірі Мохамед на тему: «Аналіз системи забезпечення якості фармацевтичної продукції».
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 Елаамірі Мохамед на тему: «Аналіз системи забезпечення якості фармацевтичної продукції».

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 Елаамірі Мохамед 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 quality assurance system for pharmaceutical products»

Кваліфікаційна робота і рецензія додаються.

Декан факультету _____ / Микола ГОЛІК /

Висновок керівника кваліфікаційної роботи

Здобувач вищої освіти Елаамірі Мохамед 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

«08» травня 2025 р.

Висновок кафедри про кваліфікаційну роботу

Кваліфікаційну роботу розглянуто. Здобувач вищої освіти Елаамірі Мохамед 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 /