MINISTRY OF HEALTH OF UKRAINE
ZAPORIZHZHIA STATE MEDICAL AND PHARMACEUTICAL UNIVERSITY
DEPARTMENT OF MANAGEMENT AND ECONOMICS OF PHARMACY

ORGANIZATION AND ECONOMICS OF PHARMACY

CHAPTER 1 «ORGANIZATIONAL PRINCIPLES OF PHARMACEUTICAL ACTIVITIES»

EDUCATIONAL AND METHODOLOGICAL GUIDE
TO PRACTICAL CLASSES
for IV year students
specialty 226 «Pharmacy, industrial pharmacy»
Professional qualification «Pharmacist»

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Compilers:

N. O. Tkachenko, Head of the Department of Management and Economics of Pharmacy, Doctor of Pharmaceutical Sciences, Professor;

O. V. Lytvynenko, Ph.D. of Pharmaceutical Sciences, Associate Professor;

V. O. Demchenko, Ph.D. of Pharmaceutical Sciences, Associate Professor;

T. V. Mahanova, Ph.D. of Pharmaceutical Sciences.

Reviewers:

Inna Bushuieva, Professor, Dr.SC. in Pharmacy, Head of Department of Management and Economics in Pharmacy, and Pharmaceutical Technology, ZSMPhU;

Vira Odyntsova, Professor, Dr.Sc. in Pharmacy, Department of Pharmacognosy, Pharmacology, and Botany, ZSMPhU.

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The study guide presents educational materials for Section 1 «Organizational principles of pharmaceutical activities» in the discipline «Organization and Economics of Pharmacy» (questions for discussion, self-check questions, overview, practical assignments, guidelines for studying the topics of the discipline, self-check tests and a list of references).

For training of Masters of Pharmacy in the field 22 «Health care», specialty 226 «Pharmacy, industrial pharmacy», professional qualification «Pharmacist»

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Contents

INTRODUCTION

An important component of the curriculum for training specialists of the master's level of higher education in the field of knowledge 22 "Health care" in higher educational institutions of the Ministry of Health of Ukraine with the specialty 226 "Pharmacy, industrial pharmacy" professional qualification "pharmacist" is the study of the independent discipline "Organization and economics of pharmacy", which occupies an important place in the formation of professional competences of masters of pharmacy. When studying this discipline, special attention is paid to the development of independent thinking and practical skills.

The relevance of this publication is the formation of professionally necessary knowledge, abilities and skills in accordance with educational and qualification characteristics; providing a theoretical basis for further study of other pharmaceutical and economic disciplines of the curriculum; creation of a base that determines the professional competence and general erudition of pharmacists with the help of a systematic presentation of the fundamental principles of the specified discipline in three consecutively connected sections - "Organizational principles of pharmaceutical activity", "Organization of retail sale of medicinal products", "Organization of wholesale sale of medicinal products. State quality control".

The first section includes 4 topics covering the organization of work of pharmaceutical institutions. The second section includes 6 topics related to the organization of the work of pharmacies on the sale of pharmaceuticals to the population and other organizations. The third section is devoted to the organization of the wholesale sale of drugs and state control of the quality of drugs during their circulation on the territory of Ukraine and consists of three topics.

For better assimilation of the material on the topic, in addition to control questions, questions for self-control and concise information, a list of recommended literature and an example of 10 test tasks are provided.

CONTENT SECTION 1
ORGANIZATIONAL PRINCIPLES OF PHARMACEUTICAL ACTIVITY

TOPIC 1
INTRODUCTION TO THE DISCIPLINE. MAIN LEGISLATIVE - NORMATIVE ACTS REGULATING PHARMACEUTICAL ACTIVITIES IN UKRAINE

Student should know: terminology and basic principles, the legal framework that regulates pharmaceutical activity.

Basic terms and concepts: pharmaceutical activity, state regulation, legal support, medicine, licensing.

QUESTIONS

1. "Organization and Economics of Pharmacy" is one of the main disciplines in the training of pharmaceutical specialists.
2. The pharmaceutical sector in the healthcare industry
3. Constitutional right to health care: Constitution of Ukraine (Articles 24, 27, 49, 50).
4. State regulation of relations in the field of development, creation, registration, production and sale of medicines: The Law of Ukraine "Basics of the Legislation of Ukraine on Health Care" and the Law of Ukraine "On Medicinal Products ".
5. Licensing as an instrument of state regulation of pharmaceutical activity.

SELF-CHECK QUESTIONS

1. The purpose and tasks of the discipline "Organization and Economics of Pharmacy"
2. The pharmaceutical sector in the healthcare industry
3. Rights, freedoms and duties of a person and a citizen in accordance with the Constitution of Ukraine.
4. The Law of Ukraine "Basics of the Legislation of Ukraine on Health Care".

5. The Law of Ukraine "On Medicinal Products ".

6. State regulation of relations in the field of development, creation, registration, production and sale of medicines.

7. Licensing as an instrument of state regulation of pharmaceutical activity.

OVERVIEW

The modern development of pharmacy requires from industry specialists a high level of knowledge and creative initiative, knowledge of the norms of pharmaceutical legislation, new methods of managing organizations and effective computer technologies in order to provide the population and healthcare institutions with high-quality medicines.

It is organizational and managerial disciplines that allow this to be achieved. The organization and economics of pharmacy are among such disciplines.

The purpose of studying the discipline is to form students' systemic knowledge about the organizational and economic foundations of pharmaceutical provision of the population and healthcare institutions with medicines and other pharmaceutical products, as well as the organization and provision of pharmaceutical assistance to all those in need.

The main task of studying the discipline is the formation of professionally necessary knowledge, skills and abilities for:

- The ability to organize the activities of a pharmacy to provide the population and healthcare facilities with medicines, other pharmaceutical products, medical devices and medical cosmetic products in accordance with the requirements of the National Drug Policy, Good Pharmacy Practice and other organizational and legal forms of pharmaceutical legislation;
- The ability to organize the operation of the reporting and accounting system (managerial, statistical, accounting and financial) in pharmacies, to carry out commodity analysis, administrative office work, documentation and quality management in accordance with the regulatory legal acts of Ukraine;
- The ability to analyse and predict the main economic indicators of pharmacy

institutions, to calculate the main taxes and fees, to form prices for medicines and pharmaceutical products in accordance with the current legislation of Ukraine.

OEP integrates with other disciplines, such as:

- history of pharmacy
- information technologies in pharmacy
- ethics and deontology in pharmacy
- drug technology
- pharmaceutical chemistry
- pharmaceutical law

OEP lays the foundation for studying other organizational and management disciplines such as:

- pharmaceutical management and marketing
- medical and pharmaceutical commodity science
- pharmacoeconomics
- quality management
- social pharmacy

One of the important problems investigated by the OEF is the question of the rational use of the limited resources of the health care system in order to meet the needs of citizens for the provision of quality pharmaceutical care.

The main goal of pharmaceutical activity at all levels (micro and macroeconomics) is to save life and maintain the health of citizens as the highest value and the main economic resource of the country.

Principles of pharmaceutical activity:

- high professionalism
- social orientation
- economic interest in the results of labor
- information and innovation openness
- harmonization of activities and close cooperation with doctors
- religious and racial indifference
- psychological discretion

Compliance with these principles is impossible without clear and understandable guidance, which pharmacy has in the form of legal acts (such as laws, regulations and orders of the relevant ministry - the Ministry of Health of Ukraine, and in other countries they may have different names).

Such a regulation of pharmaceutical activities by the state gives grounds for asserting the special and responsible role of pharmacists in supporting the national security of the country and ensuring a high quality of life.

In addition, regulatory documents on pharmaceutical activities give us the opportunity to form our own professional language, which is used by pharmacists to communicate and approach the solution of professional problems in the same way.

Therefore, we will constantly refer to the legislation of Ukraine and international standards for pharmaceutical activities.

Pharmaceutical activities are the activities related to the search, creation, development, registration, manufacture, production, quality control, storage, wholesale and retail of medicines and medical products, as well as the training and retraining of specialists.

The pharmaceutical sector in the healthcare industry is now considered to be an independent industry.

The pharmaceutical industry is a set of enterprises, organizations and institutions involved in the creation, production, sale of medicines and medical devices, ensuring their quality control, as well as training and retraining of personnel.

That is, the industry unites enterprises characterized by the relative homogeneity of the products they produce and sell to consumers, as well as the similarity of the technical base and technological processes, the raw materials which are used, common approaches to organizing and managing the process of creation, production, quality control and sale of products and also professional training and has a single management body.

The pharmaceutical industry includes:

- enterprises-manufacturers of substances, medicines, veterinary drugs, medical cosmetics, dietary supplements, etc.;

- enterprises engaged in wholesale and retail sales of these products;
- scientific institutions that carry out research and development work on the creation of new drugs, technological processes, equipment and quality control methods;
- educational institutions providing training and retraining of specialists for the needs of the industry;
- organizations and institutions that form and implement information and analytical support for the pharmaceutical industry.

Rights, freedoms and duties of a person and a citizen in accordance with the Constitution of Ukraine

Any type of activity of enterprises, organizations and institutions of the pharmaceutical industry is regulated by the legislation of Ukraine.

The Basic Law of Ukraine is the Constitution.

The Constitution of Ukraine guarantees every citizen the right to healthcare, medical care and medical insurance (Articles 24, 27, 49, 50). This right is ensured by state funding of the relevant socio-economic, healthcare and health-improving and preventive programs. The state must create conditions for effective and affordable medical care for all citizens, and medical care must be provided free of charge in state and municipal health care institutions. In addition, the state should take care of the development of physical culture and sports, ensure sanitary and epidemic well-being.

Article 24. Citizens shall have equal constitutional rights and freedoms and shall be equal before the law.

There shall be no privileges or restrictions based on race, skin colour, political, religious, and other beliefs, sex, ethnic and social origin, property status, place of residence, linguistic or other characteristics.

Equality of the rights of women and men shall be ensured by providing women with opportunities equal to those of men in public, political and cultural activity, in obtaining education and in professional training, in work and remuneration for it; by special measures for the protection of work and health of women; by establishing pension privileges; by creating conditions that allow women to combine work and motherhood; by legal protection, material and moral support of motherhood and

childhood, including the provision of paid leaves and other privileges to pregnant women and mothers.

Article 27. Every person shall have the inalienable right to life.

No one shall be arbitrarily deprived of life. The duty of the State shall be to protect human life.

Everyone shall have the right to protect his/her life and health, and the lives and health of other persons against unlawful encroachments.

Article 49. Everyone shall have the right to health protection, medical care and medical insurance.

Health protection shall be ensured through state funding of the relevant socio-economic, medical and sanitary, health improvement and prevention programmes.

The State shall create conditions for effective medical service accessible to all citizens. State and communal health protection institutions shall render medical care free of charge; the existing network of such institutions shall not be reduced. The State shall promote the development of medical institutions under all forms of ownership.

The State shall provide for the development of physical culture and sports and ensure sanitary-epidemic welfare.

Article 50. Everyone shall have the right to an environment that is safe for life and health and to compensation for damages caused by violation of this right.

Everyone shall be guaranteed the right of free access to information about the environmental situation, the quality of foodstuffs and consumer goods, as well as the right to disseminate such information. No one shall make such information secret.

Other legislation on health care also bases on the Constitution of Ukraine.

Every person shall have an inalienable and indefeasible right to healthcare. Society and the state are responsible to present and future generations for the level of health and preservation of the Ukrainian people's gene pool. They ensure the priority of healthcare in the state activities, improving working conditions, education, living conditions and recreation, solving environmental problems, improving the level of medical care and healthy lifestyle promotion.

Law of Ukraine "Fundamentals of the legislation of Ukraine on healthcare". Fundamentals of the legislation of Ukraine on healthcare prescribe the legal, organizational, economic and social principles of healthcare in Ukraine, regulate public relations in this field to ensure the harmonious development of physical and mental strength, high labour capacity and long active life of citizens, elimination of factors that adversely affect their health, prevent and reduce morbidity, disability and mortality, improve heredity.

Article 54. The procedure for the provision of medications and immunobiological medicines

Citizens shall be provided with medications and immunobiological medicines through healthcare facilities authorized to do so in accordance with the law.

The procedure for providing citizens with medications and immunobiological medicines free of charge or on favorable terms shall be determined by the legislation of Ukraine.

The Cabinet of Ministers of Ukraine shall approve the list of medications, medical devices and auxiliary appliance purchased from the state budget for the implementation of programmes and implementation of centralized healthcare measures.

Healthcare facilities authorized to do so under the law may release only those medications and immunobiological medicines that have been approved for use by the central executive authority shaping state policies in the field of public healthcare and shall be responsible for ensuring the proper regime of their storage and sale, as well as maintaining a mandatory range of medications and immunobiological medicines, including the necessary stock in case of epidemic diseases, natural disasters and catastrophes.

The central executive authority shaping state policies in the field of public healthcare shall regularly inform healthcare workers and the public on the medications and immunobiological medicines approved for use.

Article 55. Production of medications and immunobiological medicines

The production of new medications and immunobiological medicines for medical purposes is allowed with the consent of the central executive authority shaping state

policies in the field of public healthcare after proving their therapeutic or prophylactic efficacy.

The quality of medications and immunobiological medicines shall meet the requirements of the State Pharmacopoeia of Ukraine, as well as the specifications approved in the prescribed manner.

Quality control of medications and immunobiological medicines manufactured by Ukrainian enterprises shall be carried out by the central executive authority implementing state policy in the field of quality and safety control of medications.

Article 56. Provision of prosthetic care

Citizens shall be provided with prostheses, orthopaedic, corrective devices, glasses, hearing aids, physical therapy equipment and special means of transportation if necessary.

Categories of persons who are subject to free or favourable provision of the specified devices and products, as well as the conditions and procedure for their provision shall be established by the legislation of Ukraine.

Article 74. Carrying out of medical, pharmaceutical activities, delivery of rehabilitation care

Persons who have the appropriate special education and meet the uniform qualification requirements may carry out medical and pharmaceutical activities and deliver rehabilitation care.

Uniform qualification requirements for the persons performing certain types of medical and pharmaceutical activities, delivering rehabilitation care, shall be set by the central executive authority shaping state policies in the field of public healthcare. Heads of healthcare facilities, rehabilitation facilities, departments, units, as well as bodies authorized to issue a license to carry out the relevant types of economic activity shall be responsible for compliance with these qualification requirements.

Persons who have passed medical, pharmaceutical or rehabilitation training in educational institutions of foreign countries shall be admitted to professional activity after verification of their qualifications in the manner prescribed by the central executive

authority shaping state policies in the field of public healthcare unless otherwise provided for by law or international treaties, which Ukraine is a party to.

Article 75. Training, retraining and professional development of medical, pharmaceutical and rehabilitation specialists

Training, retraining and professional development of medical, pharmaceutical workers and rehabilitation specialists shall be carried out by relevant facilities of professional higher education and higher education, as well as through internship trainings, medical residencies, clinical residencies, postgraduate and doctoral studies in accordance with the education legislation.

Curricula and programmes of training, retraining and professional development of medical, pharmaceutical workers and rehabilitation specialists shall be duly agreed with the central executive authority shaping state policies in the field of public healthcare.

Article 77. Professional rights and benefits of medical and pharmaceutical workers

Medical and pharmaceutical workers have the right to:

a) performing medical and pharmaceutical activities in accordance with their speciality and qualification;

b) appropriate conditions of professional activity;

c) professional development, retraining at least once in five years in the relevant facilities and institutions;

d) free choice of tested forms, methods and means of activity, a due introduction of modern achievements of medical and pharmaceutical science and practice;

e) free use of social, environmental and special medical information necessary for the performance of professional duties;

f) compulsory insurance at the expense of the owner of the healthcare facility in case of harm to their life and health in connection with the performance of professional duties in cases provided by law;

g) social assistance from the state in case of disease, injury or other cases of disability that occurred in connection with the performance of professional duties;

h) establishment of official salaries (tariff rates) in state healthcare facilities on the basis of the Unified Tariff Grid in accordance with the procedure established by the Cabinet of Ministers of Ukraine;

i) reduced working day and additional paid leave in cases established by law;

j) favourable conditions of the pension provision;

k) favourable conditions for housing and telephone provision;

l) free use of housing with lighting and heating within the norms established by law for those who live and work in rural areas and urban settlements, as well as pensioners who previously worked as medical and pharmaceutical workers and live in these settlements, the provision of benefits on payment of land tax, lending, furnishing and construction of private housing, purchase of motor vehicles.

Benefits for the free use of housing with heating and lighting, provided for in the first paragraph of this clause, shall be provided if the average monthly total family income per person for the previous six months does not exceed the amount of income that entitles to social tax benefits in the procedure determined by the Cabinet of Ministers of Ukraine;

m) priority medical care and provision of medications and prosthetic devices;

n) creation of scientific medical societies, trade unions and other public organisations;

o) judicial protection of professional honour and dignity;

p) gratuitous acquisition of land plot within the land share of a member of an agricultural enterprise, agricultural institution and organization located on the territory of the relevant council, from the lands of the agricultural enterprise, agricultural institution and organization being privatized, or land reserves or a reserve fund, but not more than the norms of gratuitous transfer of land plots to citizens, established by law for personal farming.

Clause “p” shall not apply to citizens who have previously acquired the right to land allotment (share) and land for personal subsidiary farming or personal farming, except in cases of inheritance of the right to land allotment (share), land plots for personal subsidiary farming or personal farming under the law;

q) physicians of district hospitals, chief physicians and physicians of outpatient clinics located in rural areas, district primary care physicians, pediatricians, district nurses of territorial sections of polyclinics (polyclinic units) and district nurses of outpatient clinics, general practitioners (family physicians) and hospital nurses of general practice and family medicine, heads of therapeutic and pediatric departments of polyclinics, heads of outpatient clinics and family medicine departments, medical workers of emergency (ambulance) brigades of emergency medical care and disaster medicine centres, medical workers of emergency (ambulance) medical care of the stations of emergency (ambulance) medical care, medical workers of operative-dispatching services of the centres of emergency medical care and disaster medicine, medical workers of departments of emergency (urgent) medical care – for continuous work on the positions of the specified establishments (on territorial districts) shall be entitled to additional paid annual leave of three calendar days for more than three years. At the same time, the rights of other categories of medical workers to additional paid leave within the existing norms shall be preserved;

r) free parking of vehicles in specially designated places in the case of:

equipment of a vehicle driven by a medical worker with a special identification mark of the standard established by the legislation;

placement of a special sticker on the car indicating the contact phone number of the medical worker who drives this vehicle.

Owners of specially designated parking lots shall provide and allocate free parking spaces for vehicles driven by medical workers.

The form, procedure and conditions for issuing a special sticker shall be established by the authorized central executive authority in the field of health care.

Legislation may provide other rights and benefits for medical and pharmaceutical workers. They may also be covered by the benefits provided to the employees of enterprises, institutions and organizations, to whom they provide medical care.

Article 78. Professional obligations of medical, pharmaceutical and rehabilitation professionals

Medical, pharmaceutical and rehabilitation specialists shall be obliged to:

a) foster the protection and promotion of human health, prevention and treatment of disease, provide timely and qualified medical, healthcare and rehabilitation care;

b) provide free emergency medical care to citizens in case of an accident and other extreme situations;

c) disseminate scientific and medical knowledge, knowledge on the functioning and vital activity limitations among the population, to promote, including by own example, a healthy lifestyle;

d) comply with the requirements of professional ethics and deontology, maintain medical privacy;

e) constantly increase the level of professional knowledge and skills;

f) provide counselling to their colleagues and other healthcare workers, rehabilitation specialists;

g) carry out activities in accordance with the principles of evidence-based medicine/evidence-based rehabilitation.

Medical, pharmaceutical and rehabilitation professionals shall also perform other duties provided by law.

Article 78^{-1}. Restrictions imposed on medical, pharmaceutical and rehabilitation specialists in the course of their professional activities

Medical, pharmaceutical and rehabilitation specialists during their professional activity shall not have the right:

1) to receive illegal benefit from economic entities producing and/or selling medications, medical devices (healthcare products), technical and other means of rehabilitation, and their representatives;

2) to receive from economic entities engaged in the production and/or sale of medications, medical devices (healthcare products), technical and other means of rehabilitation, or their representatives the samples of medications, medical devices (healthcare products), technical and other means of rehabilitation for use in professional activities (except for cases related to the conduct of clinical trials of medications or clinical trials of medical devices (healthcare products), technical and other means of rehabilitation);

3) to advertise medications, medical devices (healthcare products), technical and other means of rehabilitation, including prescribing medicines on the forms containing information of an advertising nature, and indicate the manufacturers of medications (trademarks);

4) at the request of the consumer during the sale (release) of the medication neither to provide information nor provide inaccurate information about the availability in this pharmacy of medications with the same active substance (under the international non-proprietary name), a form of release and dosage, including concealment of information on the availability of such medications at a lower price.

The provisions of this paragraph shall apply exclusively to pharmaceutical workers.

Law of Ukraine "On Medicinal Products". This Law shall regulate legal relations connected with the development, registration, manufacturing, quality control and sale of medicinal products, including medicinal products made from human blood and blood plasma (blood-derived products), processing, transportation, storage and distribution of blood components used for manufacturing of medicinal products, shall determine the rights and obligations of enterprises, institutions, organisations and citizens, as well as the competence of the executive authorities and officials in this field.

The state policy in the field of development, manufacturing, quality control and sale of medicinal products shall be focused on the support of scientific research, the development and implementation of new technologies, as well as the development of manufacturing highly efficient and safe medicinal products, meeting the demands of the population for medicinal products of proper quality and in the required range by maintaining the State Register of Medicinal Products of Ukraine with public access to it, implementation of relevant national programmes, priority financing, concessional loans, tax abatements, etc.

To implement the right to health protection of the citizens of Ukraine, the State shall ensure the availability of the most demanded medicinal products, protection of citizens in the event of harm as a result of the on-label use of medicinal products, and also shall establish benefits and guarantees for certain groups of the population and

categories of citizens to provide them with medicinal products in the case of illness.

The Verkhovna Rada of Ukraine shall determine the state policy and carry out legislative regulation of relations in development, manufacturing, quality control and sale of medicinal products.

The Cabinet of Ministers of Ukraine, through the system of executive authorities, shall implement the state policy in the field of development, manufacturing, quality control and sale of medicinal products, shall organize the development and implementation of relevant national and other programmes within the framework of its competencies, and shall control enforcement of the law on medicinal products.

The central executive authority in charge of shaping the state policy in the field of healthcare, the central executive authority implementing the state policy in the field of control over the quality and safety of medicinal products shall be responsible for the management in the field of development, manufacturing, quality control and sale of medicinal products within their competence.

Law of Ukraine "On Licensing of Economic Activities Types". This Law shall regulate public relations in the area of licensing of types of economic activities, defines an exclusive list of types of economic activities subject to licensing, establishes a unified procedure for their licensing, supervision and control in the field of licensing, liability for violation of the legislation in the field of licensing of types of economic activities.

Licensing - a mean of state regulation of the carrying out of types of economic activities aimed at ensuring the safety and protection of economic and social interests of the state, society, rights and legitimate interests, human life and health, environmental safety and environmental protection.

PRACTICAL ASSIGNMENTS

Task 1. Analyse "Fundamentals of the Legislation of Ukraine on Health Care" to identify pharmacy and pharmaceutical industry-related articles, and take notes.

Task 2. Compare and analyse main definition from low «On Medicinal Products», Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 «On the Community code relating to medicinal products for human use» (https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32001L0083), FDA and EMA glossary (https://www.fda.gov/patients/clinical-trials-what-patients-need-know/glossary-terms, https://www.ema.europa.eu/en/about-us/about-website/glossary)

Definition	On Medicinal Products	On the Community code relating to medicinal products for human use	FDA glossary	EMA glossary
1	2	3	4	
Medicinal product				
Active pharmaceutical ingredient (Active substance)				
Bioequivalence				

Generic medicine (drug)				
Biological medicine (drug)				
Herbal medicinal product (drug)				
Labelling				
Pharmaceutical form				

Pharmacovigilance system (Pharmacovigilance)				
Risk management system				

After completing the practical task, the student should acquire practical skills and abilities:

• navigate the main legal framework that regulates pharmaceutical activities (on the example of the Law of Ukraine "On Medicines" and the Law of Ukraine "Fundamentals of Ukrainian Legislation on Health Care")

TOPIC 2
ORGANIZATION OF PHARMACEUTICAL ACTIVITIES. STATE REGULATION OF MEDICINES TURNOVER

Student should know: basic principles, tasks of providing pharmaceutical assistance and providing the population with medicines in Ukraine and abroad.

Basic terms and concepts: pharmaceutical assistance, pharmaceutical service, pharmaceutical provision, National drug policy, National list of essential drugs, licensing of pharmaceutical activity, complex of good pharmaceutical practices.

QUESTIONS

1. Socio-economic significance of pharmaceutical activity and its terminological apparatus
2. National drug (pharmaceutical) policy (NDP): main goals and priorities, principles, tasks
3. Subjects and principles of state regulation of pharmaceutical activities in Ukraine.
4. Licensing as an instrument of state regulation of pharmaceutical activity
5. The concept of a set of good practices as international standards governing pharmaceutical activities

SELF-CHECK QUESTIONS

1. Socio-economic significance of pharmaceutical activity
2. Pharmaceutical activity and its terminological apparatus: pharmaceutical assistance, pharmaceutical service, pharmaceutical provision, licensing of pharmaceutical activity, Medicinal Products etc.
3. National drug (pharmaceutical) policy (NDP): main goals and priorities.
4. National drug (pharmaceutical) policy (NDP: principles and tasks.
5. Subjects and principles of state regulation of pharmaceutical activities in Ukraine.

6. Licensing as an instrument of state regulation of pharmaceutical activity

7. Good clinical practice

8. Good manufacturing practice

9. Good distribution practice

10. Good storage practices

11. Good regulatory practice

12. Good pharmacy practice

OVERVIEW

The main goal of the pharmaceutical sector in healthcare is the high-quality, timely, economically justified provision of pharmaceutical assistance and the organization of the provision of medicines to the population and medical institutions.

The social significance of pharmacy can be explained in several theses:

- a medicine is a social good, because it is directly related to the health and life of a person (it provides a certain level of quality of life);
- the pharmaceutical assistance is provided to all those in need (including at the expense of the state for low-income persons)
- medicines have a preferential tax burden and regulated pricing by the state;
- the pharmaceutical industry means jobs, filling the state budget by paying taxes, socially responsible business, etc.;
- the pharmaceutical science is innovation, development and progress in the industry.

Will consider the essence and terminological load of pharmaceutical activity in accordance with the regulatory legal acts of Ukraine.

Pharmaceutical activity combines the processes of providing medicines and pharmaceutical products to all those who need them, as well as providing pharmaceutical assistance and other pharmaceutical services.

According to the thesaurus "Provision" means the satisfaction of someone, something in some needs, the creation of reliable conditions for the implementation of something; guaranteeing something: providing industry with energy carriers, providing

medicines for the treatment process.

Therefore, **pharmaceutical provision** is a set (complex) of organizational, legal, medical, pharmaceutical and socio-economic measures aimed at ensuring the treatment process, individually or collectively affecting the quality of disease prevention and treatment of the population, and their implementation is entrusted to medical and pharmaceutical healthcare institutions.

Pharmaceutical assistance is a set of organizational, legal, special medical, pharmaceutical and socio-economic measures aimed at ensuring effective pharmacotherapy, rational use of drugs, including solving problems with their individual prescription, including the participation of a pharmaceutical worker together with a doctor in the treatment process in parts of substantiating the choice of necessary medicines, advising the patient on their use, monitoring and evaluating the results of pharmacotherapy, achieving optimal clinical results at minimal economic costs, optimizing the system for selecting necessary medicines, as well as summarizing information about them for the population in order to optimize pharmacotherapy.

Pharmaceutical service is a service for the provision of pharmaceutical assistance by a pharmaceutical worker of a pharmacy, in particular when dispensing a medicinal product, including the sale, information about the use, education and promotion of a healthy lifestyle for a person and the provision of information about medicines, including as part of ensuring responsible self-medication in accordance with from the protocols of a pharmaceutical worker.

Pharmaceutical care is a component of pharmaceutical help, which consists of creating and implementing a set of effective interactions between a pharmacist and a patient throughout the entire period of medical therapy. The main goal of the pharmacist's activity in the course of pharmaceutical care is to provide objective, reliable, accessible to consumers information about medicines and their use.

In order to realize the right of citizens to health care, any state (and Ukraine is no exception) ensures the availability of necessary medicines, the protection of citizens in case of harm to their health due to the use of medicines for medical purposes, and also establishes benefits and guarantees for certain groups and categories of citizens by

providing them with medicines in case of illness.

Therefore, will also consider the concept of "medicine".

Medicinal product is any substance or combination of substances that has properties and is intended for the treatment or prevention of diseases in humans, or any substance or combination of substances that can be intended to prevent pregnancy, restore, correct or change physiological functions in humans through the implementation of pharmacological, immunological or metabolic action or to establish a medical diagnosis.

The medicines include active pharmaceutical ingredients, "in bulk" products; finished drugs; homeopathic remedies; means that are used to detect pathogens, as well as to combat pathogens or parasites; medicinal cosmetics and medicinal food additives.

Finished medicinal products (drugs, medicines, medicaments) are dosed medicinal products in the form and condition which they are used in that have passed all stages of production (manufacturing), including final packaging.

Active pharmaceutical ingredient (medicinal substance, active substance, substance) is any substance or mixture of substances intended for use in the manufacture of a medicinal product and during this use becomes its active ingredient. Such substances have a pharmacological or other direct effect on the human body, they are used as part of finished forms of medicines for the treatment, diagnosis or prevention of a disease, for changing the state, structures or physiological functions of the body, for the care, treatment and relief of symptoms.

National drug (pharmaceutical) policy (NDP)

The national drug policy is a document where the state defines the goals of the pharmaceutical industry to provide the population with medicines, as well as the state strategy for achieving them in the search, production and distribution in accordance with the real needs of the public healthcare. NDP has no force of law.

The NDP formulates general rules and coordinates the activities of structures involved in the pharmaceutical sector.

Such a document is formed in accordance with WHO recommendations and contributes to the achievement of the highest possible level of public health.

The main goals of NDP include:

- *drug availability (*equal access of the population to quality medicines, both in physical and economic aspects);
- *drug quality (*development according to the established standards, proof of their effectiveness, safety and stability in the production, sale and use by the methods of evidence-based medicine);
- *rational use of medicine (*creation of conditions when the prescription and consumption of medicines would be carried out exclusively according to the rules of clinical expediency and economic rationality);
- *formation of management in the pharmaceutical industry,* which will ensure the development of a transparent system of its functioning and information support;
- *reforming the system of scientific support and education a*dequate to the problems of the industry and the current state of the society reformation;
- *creation of the system for providing information on medicines* to medical, pharmaceutical workers and the patient, that is an important factor in pharmaceutical care, in particular, the implementation of elementary knowledge about drugs among the population and the opposition to aggressive advertising.

NDP tools are:

- regulation of drug pricing;
- their purchase by the hospital sector, financed from the budgets of all levels;
- standardization and certification at all stages of drug circulation;
- tax and customs policy;
- investment and innovation policy;
- policy in the field of training of professional personnel
- policy in the field of education and promotion of adequate use of drugs, as well as in the field of their advertising.

The elements of NDP, according to WHO recommendations, include:

- selection of basic preparations,
- availability of drug prices,
- funding of medical care,

- pharmaceutical supply system (wholesale and retail),
- development of national pharmaceutical production of preparations,
- regulating and ensuring their quality,
- their rational use,
- organization of research and development of medicines,
- personnel support of pharmaceutical organizations,
- control and evaluation of the work performed.

Currently, the NDP in Ukraine is presented in the form of a resolution of the Cabinet of Ministers of Ukraine dated December 05, 2018 No. 1022 "On approval of the state strategy for the implementation of the state policy of providing the population with medicines for the period until 2025".

This state strategy has been developed on the basis of WHO recommendations.

According to the recommendations, the state strategy for providing the population with drugs is defined as a political commitment and guidance for actions to ensure the availability and rational use of effective and safe drugs of appropriate quality in the state.

The state strategy defines the framework for the interaction of all participants in such a process, in particular, the public and private sectors, public organizations, and other stakeholders, and determines their role in this process.

Providing the population with medicines and increasing the level of their availability is an integral part of the state health policy aimed at creating a patient-oriented system.

The state strategy is a system of actions, measures, regulations, priorities defined in the healthcare system, aimed at solving a set of interrelated problems in the field of providing the population with high-quality, effective and safe drugs.

Subjects and principles of state regulation of pharmaceutical activities in Ukraine

State regulation is the organizational and regulatory activity of the state, which is aimed at industries and areas of public life that require its intervention.

Any type of activity of enterprises, organizations and institutions of the pharmaceutical industry is regulated by the legislation of Ukraine.

The state administration of pharmacy is based on the formation of state policy,

coordination, control and supervision of compliance by all pharmaceutical organizations (both business entities, regulatory authorities and local authorities) with legal acts.

Functions of state regulation:

- *target (*determination of goals, priorities and main directions of the development of the pharmaceutical industry);
- *stimulating (*impact on the economic activity of the subjects of the pharmaceutical market for its direction in the desired direction for the society);
- *normative (regulating) (*establishment by the state of certain rules for pharmaceutical activities through legislative acts and regulations);
- *corrective (*adjusting the distribution of resources in order to ensure the normal socio-economic conditions of the society);
- *social (*regulation of socio-economic relations, provision of social guarantees, preservation of the environment etc.);
- *direct management of the non-market sector of the economy (*it is the regulation of the public sector of the economy, the creation of public products and benefits);
- *controlling (*state supervision and control of compliance with legal acts, economic, environmental and social standards, etc).

The only legislative body in Ukraine that determines the foundations of state policy in the field of healthcare is the Verkhovna Rada of Ukraine.

The main law regulating legal relations as for the creation, registration, production, sale and quality control of drugs is ***the Law of Ukraine "On Medicinal Products".***

The state policy in the field of drug circulation is carried out by the ***President of Ukraine*** *and* ***the Cabinet of Ministers of Ukraine*** through the system of ***central and local executive authorities together with local governments.***

The state policy is carried out through priority state financing of relevant socio-economic, medical and sanitary and health-improving and preventive programs, programs for the development of the medical industry, the provision of soft loans, the establishment of tax incentives, etc. and consists of:

- support for scientific research;

- creation and implementation of new technologies production;
- development of production of highly effective and safe drugs of proper quality and in the required assortment;
- provision of healthcare drugs and standards for the provision of medical care to the population and drug treatment of certain types of diseases.

Management in the field of creation, production, quality control and sale of medicinal products, within the limits of its competence is carried out by:

- the Ministry of Health of Ukraine;
- the State Service of Ukraine on Medicines and Drugs Control;
- the State Expert Center of the Ministry of Health of Ukraine.

Licensing as an instrument of state regulation of pharmaceutical activity

Licensing is one of the fundamental means of state regulation of economic activity.

In accordance with the Law of Ukraine "**On Licensing of Economic Activities Types**" dated 02.03.2015 No. 222-VIII:

Licensing is a means of state regulation of the production of economic activities aimed at ensuring the safety and protection of the economic and social interests of the state, society, rights and legitimate interests, human life and health, environmental safety and environmental protection.

License is the right of a business entity to carry out a type of economic activity or part of a type of economic activity, which is subject to licensing.

Licensing is carried out through the procedures for issuing, reissuing and revoking licenses, maintaining license files and license registers, monitoring compliance by licensees with license conditions, issuing orders to eliminate violations of license conditions, as well as orders to eliminate violations of legislation in the field of Licensing.

Licensing conditions is a regulatory legal act of the Cabinet of Ministers of Ukraine, one more authority, authorized by the law, the provisions of which establish an exhaustive list of requirements for conducting business activities that are subject to licensing, mandatory for the licensee to comply with, and the exhaustive list of

documents attached to the application for a license.

The licensing authority in the field of drug circulation is the State Service of Ukraine on Medicines and Drugs Control.

The main functions of licensing in the field of drug circulation are:

Control. The determination and control over the availability of conditions for the provision of a certain level of medical care, confirmation of the compliance of the pharmacy institution with the established criteria and guarantees of the high quality of professional activity;

Accounting. The accounting of all business entities that have received a license;

Information. The maintenance and preservation of the registration file of the enterprise;

Statistical. The analysis of the dynamics of the drug market development, study of the market environment;

Security. The protection of the rights and interests of both business entities (by creating equal conditions for them to carry out a certain type of activity) and patients (by creating conditions for dispensing high-quality, safe and affordable drugs).

Economic activity related to the circulation of narcotic, psychotropic substances and precursors is a type of activity that is also limited by law and is subject to licensing.

The main task of the State Service (the licensing body in the field of circulation of narcotic, psychotropic substances and precursors) is to control the activities of pharmaceutical institutions involved in the manufacture, storage, transportation, acquisition, sale (dispensation), importation into the territory of Ukraine, exportation from the territory of Ukraine, transit through the territory of Ukraine, the use, destruction of narcotic, psychotropic substances and precursors with the obligatory obtaining of a license to conduct relevant activities.

The concept of a set of good practices as international standards governing pharmaceutical activities

A set of Good Pharmaceutical Practices (Standards) *(Good X Practice GXP)* is a set of rules for organizing the production, storage and quality control of medicines, their wholesale and retail, as well as planning, performing, monitoring, evaluating and

documenting laboratory studies and clinical trials; engineering and technical support of production, conscientious presentation of information about medicinal products and the creation of pharmaceutical education adequate to the needs of society.

Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and wellbeing of trial subjects are protected and that clinical-trial data are credible.

Good manufacturing practice (GMP) describes the minimum standard that a medicines manufacturer must meet in their production processes. The European Medicines Agency (EMA) coordinates inspections to verify compliance with these standards and plays a key role in harmonising GMP activities at European Union (EU) level.

Any manufacturer of medicines intended for the EU market, no matter where in the world it is located, must comply with GMP.

GMP requires that medicines:

- are of consistent high quality;
- are appropriate for their intended use;
- meet the requirements of the marketing authorisation or clinical trial authorisation.

Good Distribution Practice (GDP) is a system for providing quality storage of medicals in warehouses and distribution centers.

Good Distribution Practice Standards provides a description of special measures for proper storage and transportation of pharmaceutical products.

According to international GDP rules and national legislation, pharmaceutical products' distributors must comply with these standards. Companies must ensure that all employees who have access to medical products and are involved in storage and distribution activities familiar with GDP principles. Storage and transportation of pharmaceutical materials and products as per GSP should be considered at all stages of medical products circulation thus

involving almost all participants of the pharmaceutical market.

Good Regulatory Practice **(**GRP) is a set of principles and rules for regulatory activities to ensure the effectiveness, safety, quality and availability of drugs.

Good Pharmacy Practice is the practice of pharmacy aimed at providing and promoting the best use of drugs and other health care services and products to patients and members of the public. It requires that the welfare of the patient is the pharmacist/s prime concern at all times.

PRACTICAL ASSIGNMENTS

Task 1. Give a description of the relevant state regulatory bodies in the field of drug supply to the population of Ukraine (indicate the purpose of the activity, tasks and functions). Provide the results in the form of a table.

Table 1. Main organizational structures carrying out state regulation in the field of medical provision of the population of Ukraine

NAMED	THE PURPOSE OF THE ACTIVITY	TASKS	FUNCTIONS
Ministry of Health of Ukraine			
State Service of Ukraine for Medicinal Products and Drug Control			
State Expert Center of the Ministry of Health of Ukraine			

Task 2. Give a description of GMP, GDP, GSP, GPP. Provide the results in the form of a table.

Table 2. Main organizational structures carrying out state regulation in the field of medical provision of the population of Ukraine

NAMED	FIELD OF APPLICATION	ESSENCE OF THE STANDARD
GMP		
GDP		
GSP		
GPP		

After completing the practical task, the student should acquire practical skills and abilities:

• application of normative legal acts regulating pharmaceutical activity;

• application of the principles of the national medicine policy;

• application of the principles of public administration in the field of medicines circulation (licensing, registration, certification of medicines).

SELF CHECK TESTS

1

Ukraine is forming the National Medical Policy. Specify its main goals:

A. **Availability, quality and rational use of medicines**
B. Implementation of scientific research into practice
C. Application of professional ethics and deontology
D. Rational use of budget funds
E. Application of treatment standards

2

Subjects of pharmaceutical activity must comply with the requirements of international standards. Good Pharmacy Practice (GPP) sets the rules:

A. **On retail sale and rational use of medicinal products**
B. Production of extemporaneous medicines
C. Placement of the pharmacy network
D. Storage of medicines in a pharmacy
E. Supply of medicines and medical products

3

What international standard of various types of pharmaceutical activity is a set of rules and requirements for distribution. In accordance with them, the quality of medicinal products is ensured in the process of managing and organizing their wholesale sale at all its stages?

A. **GDP (Good Distribution Practice)**

B. GPP (Good Pharmaceutical Practice)

C. GMP (Good Manufacturing Practice)

D. GLP (Good Laboratory Practice) GCP (Good Clinical Practice)

4

Which Law of Ukraine regulates legal relations related to the creation, registration, production and quality control of medicinal products?

A. **Law of Ukraine "On Medicinal Products"**

B. Law of Ukraine "On the Protection of the Population from Infectious Diseases"

C. Law of Ukraine "On Ensuring Sanitary and Epidemic Welfare of the Population"

D. Law of Ukraine "On Entrepreneurship"

E. Law of Ukraine from "On Property"

5

The state-owned pharmacy obtains and sells narcotic medicinal products on the basis of a license. Which state body develops and revises the list of such drugs approved for use in Ukraine?

A. **State Service of Ukraine for Medicinal Products and Drug Control**

B. State Inspection for Quality Control of Medicinal Products

C. State Pharmacological Center

D. State joint-stock company "Medicines of Ukraine"

6

The State Medical Service of Ukraine periodically checks pharmacies' compliance with licensing conditions. What types of checks do you know:

A. **Planned and unplanned**

B. Disposable and reusable

C. Annual and quarterly

D. Sudden and predictable

E. Pharmacies are not subject to inspection

7

At the court hearing, the lawyer did not name the Law of Ukraine, which regulates legal relations related to the creation, registration, production and quality control of medicinal products. Name him:

A. **Law of Ukraine "On Medicinal Products"**

B. Law of Ukraine "On Property"

C. Law of Ukraine "On Entrepreneurship"

D. The Law of Ukraine "On the Protection of the Population from Infectious Diseases"

E. Law of Ukraine "On Ensuring Sanitary and Epidemic Welfare of the Population"

8

In accordance with WHO recommendations, each country creates a National List of Essential Medicinal Products. This list includes:

A. **Effective and safe medicines and medical devices for the prevention, diagnosis and treatment of the most common pathological conditions**

B. Drugs approved for use in Ukraine

C. Medicines used in state targeted programs, medicines purchased with state funds

D. Over-the-counter drugs (OTC drugs)

9

Developed in accordance with WHO recommendations, the list of Essential Medicinal Products that meet the needs of the majority of the population and must be available at any time, in adequate quantities at an affordable price, is -

A. **National list of Essential Medicinal Products**

B. Budget list

C. State register of drugs

D. State drug formulary

10

In order to rationally use medicines in Ukraine, a formulary system has been implemented. The state formulary of medicinal products includes:

A. **Medicinal products with proven effectiveness, an acceptable level of safety, the use of which is economically acceptable**

B. Medicines undergoing clinical trials

C. Medicines for which the registration period has expired

D. Medicines available without a prescription

E. All drugs registered in Ukraine

TOPIC 3
ORGANIZATION OF PHARMACIES AS HEALTH CARE INSTITUTIONS

Student should know: the basic principles of the organization of the work of the pharmacy and its structural divisions, classification of pharmacy in European county, the main requirements for the sanitary and anti-epidemic regime and personal hygiene of employees that manufacture drugs in the conditions of the pharmacy, retail trade of drugs.

Basic terms and concepts: pharmacy establishments, pharmacy, pharmacy point, manufacturing of medicinal products under the conditions of a pharmacy, license, licensing, license conditions, licensee, material responsibility, contract, retail sale (trade) of medicinal products, pharmacist, sanitary and hygienic requirements.

QUESTIONS

1. The concept of pharmacy establishments. Classification of pharmacies.

2. Tasks and functions of pharmacies.

3. Retail trade of medicinal products, basic requirements for conducting business activities.

4. Pharmacy staff. Types of financial responsibility of pharmacy employees and the procedure for drawing up contracts.

5. Organization of a sanitary regime in the pharmacy.

SELF-CHECK QUESTIONS

1.The concept of a pharmacy, pharmacy establishments.

2.Tasks and functions of pharmacies.

3.Classification of pharmacies.

4.Organizational requirements for the activity of pharmacies.

5.Nomenclature of full-time positions in pharmacies and pharmacy establishments.

6.Types of financial responsibility of pharmacy employees and the procedure for

drawing up contracts.

7.General provisions of the Instructions on the sanitary and anti-epidemic regime of pharmacy establishments.

8.General requirements for premises and equipment of pharmacy establishments.

9.General sanitary and hygienic requirements for cleaning the premises, care for the equipment of pharmacy establishments.

10. Requirements for personal hygiene of pharmacy staff that do not manufacture medicinal products.

OVERVIEW

According to Ukrainian legislation, trade in medicinal products should take place only through pharmacy establishments.

Pharmacy establishments - pharmacy warehouses (bases), pharmacies, and their structural subdivisions.

A pharmacy is a healthcare institution. Its main task is to provide the population, healthcare institutions, enterprises, institutions, and organizations with medicines.

The pharmacy, entrusted with the organizational and methodical management of the district (city) pharmacies, is called the **central district (city) pharmacy**.

A pharmacy, which is intended for the primary provision of one or more hospitals, or other healthcare institutions, as well as the population with medicines and medical items, is called **a hospital or inter-hospital pharmacy**.

A pharmacy point is a structural subdivision of a pharmacy, which is created in medical and preventive institutions and functions together with the pharmacy in accordance with License Terms. Its main task is to provide the population with medicines through retail trade.

Pharmacy warehouse (base) - a health care institution. Its main task is to provide medicines to other subjects of wholesale or retail trade, health care institutions, and manufacturers of drugs by carrying out wholesale trade.

The activity of the retail trade of drugs in Ukraine is possible only if there is a license for the retail business of medicinal products.

The effect of these License Terms applies to all economic entities: to legal entities

registered in accordance with the procedure established by law, regardless of their organizational and legal form and form of ownership; natural persons - entrepreneurs who conduct economic activities (production of medicinal products, wholesale and retail trade, import of medicinal products (except active pharmaceutical ingredients).

The licensee is obliged to fulfill the requirements of the Licensing Conditions of the Resolution of the CMU dated 30.11.2016 No. 929, and the license applicant must comply with them.

Functions of pharmacies:

- Production function (production of medicines according to individual prescriptions and requirements of health care (medical and preventive) institutions);
- Trade function (sale of prescription and over-the-counter drugs and medical devices to the population, health care institutions, other organizations, and enterprises in accordance with regulatory acts;
- Information function (organization of sanitary and educational activities among the population, pharmaceutical care for patients, and provision of informational assistance to hospitals on pharmaceutical issues);
- Social function (provision of first aid and dispensing of drugs, and medical devices on discounted and free prescriptions).

Features of pharmacies placement.

To ensure retail activity, a pharmacy must:

1. To be located in a separate building removed from the housing stock or in a built-in (attached) isolated room on the first floor with a separate independent exit from the trading hall.

2. Placement of pharmacies is allowed only in real estate objects. Their property rights are subject to state registration in accordance with legislation.

3. It is allowed to set up a common entrance vestibule in public buildings (except for schools, preschool education institutions, and entrances of residential buildings), subject to free access to the pharmacy is ensured and sanitary and hygienic requirements established for pharmacies. The area of the general entrance vestibule is not included in the minimum and total area of the pharmacy.

4. If the pharmacy occupies isolated multi-story (including basement, semi-basement, or ground floor) premises and has several halls for serving the public, one of these halls is located on the first floor with the mandatory organization of one workplace for dispensing medicines.

5. It is allowed to place a public service hall not only on the first floor if its floor level is not lower/higher than the planned ground level by more than 0.5 meters.

6. It is allowed to place a pharmacy in the premises of sanatoriums and resorts, hotels, airports, train stations, and isolated premises on the first floor without arranging a separate independent exit to the outside, subject to compliance with the requirements of the Licensing conditions dated 30.11. 2016 No. 929.

7. It is allowed to place a pharmacy in an isolated room on any floor of shopping centers, without arranging a separate independent exit to the outside if that shopping center is equipped with passenger elevators (inclined or vertical lifting platforms, etc.). These lifts have to be in a technically sound condition in compliance with the requirements specified in the Licensing conditions dated 30.11.2016 No. 929.

8. It is allowed to place a pharmacy in an isolated room on any floor without arranging a separate independent exit to the outside in the premises of healthcare institutions,

9. It is also allowed to place a pharmacy in public buildings (except for schools, preschool education institutions, and entrances to residential buildings), in the premises of the village (village) council, and in postal companies without arranging a separate independent exit to the outside in rural areas.

10. Have a public service hall and production premises (necessary area and/or premises for receipting medicines, premises (areas) for storing different groups of medicines in accordance with the requirements specified by the manufacturer). The passage to the production premises cannot be carried out through the premises of general use (corridors, vestibules, etc.). The minimum total area of premises for the storage of medicinal products cannot be less than 10 square meters.

11. It is allowed to arrange a hall for the public service with free access of consumers to OTC medicinal products according to the list of medicinal products

approved for use in Ukraine and related products by pharmacies and their structural subdivisions, if specialist consultants (pharmacists) are available in halls.

12. It is allowed not to have a hall for serving the public for pharmacies that are located in healthcare institutions and carry out the manufacture (production) of medicinal products in the conditions of a pharmacy and the dispense of finished medicinal products only to the branches of healthcare institutions, if there is an expedition room. Such pharmacies can create pharmacy points in order to carry out the retail trade of medicines in these healthcare institutions.

13. To have service and household premises - premises for staff, a toilet with a wash basin. It is allowed to locate the toilet outside the pharmacy (for pharmacies located in rural areas and settlements where there are no communications (water supply, sewerage), while the pharmacy must be equipped a separate place for sanitizing hands), a room or cabinet for storing cleaning supplies.

14. Passage to service and residential premises cannot be carried out through production premises. It is allowed to pass in technological clothes and shoes from service, residential premises and additional premises to the public service hall through the medicine storage room and back, when the staff of the pharmacy uses a separate service entrance from the outside.

15. There must be a sign indicating the name of the managing entity or the body authorized by it on the facade of the pharmacy, as well as information about the working hours, the address of the nearest and the on-duty pharmacy. The operating mode of the pharmacy is established by business entities in agreement with local authorities.

Requirements for pharmacies.

1. The premises of the pharmacy consist of a public service hall, production, and service premises (personnel premises, a room or cabinet for inventory storage for cleaning, restroom with a hand basin).

2. The area of the pharmacy should be at least 50 square meters in cities, 40 square meters in urban-type settlement, and 30 square meters in villages.

3. The area of the public service hall for cities, urban-type settlements, and villages should be no less 18 square meters, and 10 square meters for villages.

4. The area of premises for the storage of medicinal products must be at least 10 square meters (for villages - at least six square meters).

5. The accommodation area for staff cannot be less than 8 square meters (4 square meters for villages).

6. The area of the pharmacy point must be at least 18 square meters.

Nomenclature of stuff positions of the pharmacy and pharmacy establishment.

Pharmacies and their structural subdivisions must have a full staff of employees with appropriate pharmaceutical education.

Employees of pharmacies and their structural subdivisions undergo a medical examination and subsequent periodic medical examinations during employment.

The licensee approves the job descriptions of employees whose activities are directly related to the production (manufacturing) of medicinal products in the conditions of a pharmacy, or retail trade of medicinal products. There are the main functions, powers, professional knowledge, competence, and other requirements for employees.

Persons who directly carry out the production (manufacturing) of medicinal products in the conditions of a pharmacy, or retail trade of medicinal products, must have:

- a document on higher education not lower than the first (bachelor) level in the specialty "Pharmacy";
- for specialists with a higher education not lower than the second (master's) level;
- specialist pharmacist certificate issued by a post-graduate education institution, or a certificate of assignment (confirmation) of the relevant qualification category.

Specialist pharmacists, clinical pharmacists, and pharmacists in compliance with the requirements of the law can dispense medicines.

Specialists who have undergone special training in educational institutions of foreign countries are allowed to carry out professional activities in accordance with the procedure determined by the Ministry of Health.

Specialists who have not worked for more than five years after obtaining diplomas, and certificates of a specialty, are allowed to carry out activities related to the production (manufacturing) of medicinal products in the conditions of a pharmacy, or retail sale of medicinal products only after passing retraining.

The positions of pharmacy managers and representatives of pharmacy managers are filled by persons who have a higher education certificate not lower than the second (master's) level in the specialty "Pharmacy" and a certificate of a pharmacist specialist in the specialization "Organization and management of pharmacy" or certified in this specialization with the assignment (confirmation) of the appropriate category and at least two years of experience in the specialty.

For pharmacies located in villages and urban-type settlements, the positions of pharmacy manager, and representative of the pharmacy manager can be used by persons who have a document of higher education not lower than the first (bachelor's) level in the specialty "Pharmacy".

It is not allowed to hold the position of manager of a pharmacy on a part-time basis.

Material responsibility in the pharmacy.

In order to ensure the preservation of material values belonging to the pharmacy, contracts are concluded with employees who have reached the age of 18, hold positions, or perform work directly related to the storage, processing, dispensing, transportation, or use in the production process of the transferred values on full financial responsibility.

Material responsibility is a principle of economic calculation that requires an obligation to compensate the company for losses caused by the fault of the employee, the materially responsible person. Chapter IX of the Labor Code of Ukraine regulates relations regarding the financial responsibility of employees. The legislation provides for limitations and full material responsibility, its size, and the procedure for determining it. Types of contracts are concluded with materially responsible employees, which provide for the obligations of individuals and the administration. The organizational structure of the pharmacy determines the contingent of persons and the nature of the material responsibility that rests on them. According to the contingent of persons who

are entrusted with full material responsibility, it can be divided into **individual and collective (team)**.

Individual material responsibility occurs in those cases when it is possible to clearly define the material and monetary values that are at the disposal of a certain person (for example, the responsibility of the manager of a pharmacy point for property).

When it is impossible to determine the financial responsibility of each person (employees jointly perform certain types of work related to the preservation, processing, sale of goods, and other operations), **collective (team) financial responsibility** is introduced. This form is more common in large pharmacies that have independent departments.

Limited material liability is borne by employees for damage caused by them, but not more than their average monthly earnings for damage or destruction of materials, semi-finished products, products, tools, and measuring devices issued by the enterprise to the employee for use. The heads of enterprises, structural subdivisions, and their deputies, whose fault caused damage (no more than their average monthly earnings) are also financially responsible.

Requirements for the premises, equipment of pharmacy establishments and sanitary and hygienic requirements for the production (manufacturing) of medicines in the conditions of a pharmacy.

The location of the production premises of pharmacies engaged in the production (manufacturing) of medicinal products, in accordance with their functional purpose, should exclude opposing production flows. The production premises of pharmacies engaged in the production (manufacturing) of medicinal products must also meet the following requirements:

- manufacture (production) of sterile medicinal products must be carried out in clean zones (premises) in aseptic conditions;
- the aseptic unit consists of a sluice, an aseptic assistant, a room for receiving water for injections, packaging, sealing and sterilization of medicines. It is possible to combine an assistant and packaging room;

- the premises of the aseptic block should be maximally isolated from other premises of the pharmacy. Also, they have to rationally interconnected to ensure direct work processes and reduce the flow of drugs in the process of their production (manufacturing); equipped with airlocks that protect the air of the aseptic assistant from contamination from the outside;

- windows in the aseptic assistant room must be hermetically closed;

- aseptic bloc is equipped supply and exhaust ventilation with a pre-extraction air flow advantage that provides no less than 10 times air exchange per hour. The air ventilation system should take into account: the size of the room, the equipment, the personnel staying in it, and have appropriate filters.

In front of the entrance to the aseptic block, preparation (defection room), assistant room, there should be rubber mats moistened with a disinfectant solution on the floor.

To wash the hands of the personnel in the locks of the aseptic block, preparation, assistant, washing and toilet, sinks (hand basins) should be installed, which should be equipped with pedal taps with elbow drives, photocells, etc. Directly near the sinks, devices are installed, which must always have hand sanitizers and detergents. Hand drying is carried out with electric towels or single-use towels (the latter - in the case of the manufacture of medicines under non-sterile conditions). Persons who are not engaged in the process of manufacturing and packaging medicines are prohibited from using sinks in production facilities.

Sinks for washing dishes intended for the preparation of injection solutions and eye drops, drugs for internal use, and external dosage forms should be allocated and marked in the washroom. Dishes used in the manufacture of these dosage forms are washed in these same sinks. Do not use these sinks for hand washing.

The materials used in the decoration of "clean" premises must have mechanical strength, which contributes to their sanitary treatment without damage, minor water absorption. They do not corrode, are easy to clean, wash and disinfect.

Ceilings, walls and floors of premises for preparation of medicines in aseptic conditions should be decorated in such a way that there are no protrusions, cornices,

cracks, and covered with materials that allow wet cleaning and disinfection. Doors and windows should fit tightly and have no gaps.

Sterilization of individual objects is carried out in sterilizers. Control over the effectiveness of sterilizers is carried out with the help of maximum thermometers, as well as chemical and biological indicators of industrial manufacture, registered by the Ministry of Health of Ukraine and approved for use in Ukraine. Control results are recorded in accordance with the manufacturer's instructions.

In order to achieve sterility, all items, equipment and furniture that are brought into the aseptic block are first disinfected in accordance with the instructional and methodical documents approved by the Ministry of Health of Ukraine, using a specific disinfectant. It is strictly forbidden to store unused equipment in an aseptic block.

Cleaning of the premises for the production of medicinal products in aseptic conditions is carried out at least once per shift at the end of the work using a wet method with the use of disinfectants.

Once a week, general cleaning of the aseptic block is carried out, strictly following the sequence of stages of cleaning the aseptic block.

They start cleaning from the aseptic assistant room. First, the ceiling is washed and disinfected, then the walls and doors from the ceiling to the floor. Next, stationary equipment is washed and disinfected, and lastly, the floor, using a disinfectant solution. For wiping the floor, cloth rags with wrapped edges are used. For wiping ceilings, walls and equipment, foam sponges and nylon napkins are recommended. After each cleaning of aseptic premises, the material that was used is disinfected, dried and stored in clean, labeled containers with tightly closed lids.

If an aseptic block of fungi is detected in the air during treatment of the premises and equipment with a solution of hydrogen peroxide with detergents, its concentration is increased to 4%, and in the presence of spore-forming microflora - to 6%.

Persons involved in the production of medicines in aseptic conditions, upon entering the airlock, put on special shoes, wash and disinfect their hands, put on a sterile gown, a four-layer gauze mask, which is changed every 4 hours, a cap (at the same time, the hair is carefully removed), shoe covers.

It is optimal to use a pantsuit with a hood or overalls.

After putting on sterile process clothing, personnel should rinse their hands with water for injections and treat them with a disinfectant solution.

Sterile surgical gloves should be worn on the treated hands of personnel engaged in the area of manufacturing, packaging and capping of solutions that are not subject to thermal sterilization.

For washing hands, it is optimal to use such varieties of toilet soap that have a high foaming capacity. You should not use varieties of soap to which special components have been added (sulsene, tar, carbolic, boronthymol).

Hands are washed with warm water and treated with emollients, after finishing the work,

The personnel of the aseptic unit must strictly observe the rules of personal hygiene.

Entry from the airlock to the room in which medicines are manufactured and packaged in aseptic conditions, in non-sterile technological clothing is prohibited. It is also forbidden to go outside the aseptic block in sterile technological clothing.

If it is necessary to leave the aseptic block, the personnel must go through the airlock and remove the technological clothing. Upon return, personnel must undergo full processing again.

The personnel working in the aseptic block must be instructed at least once a year in accordance with the requirements established for work in the specified premises. After conducting the briefing, the staff must confirm in writing the fact that it was conducted by signing and indicating the date.

Technological clothing is sterilized in boxes and stored in a closed state, but no more than 3 days.

Shoes are disinfected from the outside before starting and at the end of work and stored in locks in closed cabinets and boxes.

It is allowed using disposable sterile bandage (respirators), technological clothing and special footwear.

Medicinal and auxiliary substances, which are used for the manufacture of

medicines in aseptic conditions, are stored in an aseptic block in tightly closed cabinets in racks according to their physical and chemical properties, in conditions that prevent their contamination. The straws are washed and sterilized before each filling.

Pharmacy dishes are washed according to the technological instructions approved by the business entity in compliance with the requirements for washing pharmacy dishes.

The presence of detergent residues on the dishes and the degree of cleanliness of the dishes are checked according to the methods approved by the business entity. After washing, the dishes are sterilized, sealed and stored in tightly closed cabinets, painted from the inside with light oil paint or covered with plastic.

The term of storage of sterile dishes (including cylinders) used for the manufacture and packaging of medicines in aseptic conditions is no more than 24 hours.

Large-capacity cylinders, as an exception, may be disinfected with hot steam for 30 minutes after washing. After sterilization (or disinfection), the containers are closed with sterile stoppers, foil or tied with sterile parchment and stored for no more than 24 hours in conditions that prevent contamination.

The preparation and washing of corks and aluminum caps for sealing solutions for injections and eye drops is carried out in accordance with the technological instructions approved by the business entity, observing the requirements for processing and quality control of the processing of utensils and corks.

Auxiliary material (cotton wool, gauze, parchment paper, filters, etc.) is sterilized in boxes or jars with a ground cork and stored in a closed state for no more than 3 days. Labels with the dates of sterilization indicated on them must be attached to the biks and cans. After opening the bix or cans, the materials can be used within 24 hours.

Sampling is carried out with sterile tweezers, which, in order to ensure sterility, are contained in a disinfectant solution. At the same time, it should be borne in mind that the auxiliary material for sterilization must be placed in boxes (cans) in a ready-to-use state (parchment and filter paper, gauze cut into pieces of the required size; cotton wool is used to make tampons). The use of small mechanized means for the production of solutions for injections and eye drops is allowed, provided that there is a possibility

of their disinfection and sterilization.

Concentrated solutions, semi-finished products, intra-pharmacy preparations are made in aseptic conditions and stored in accordance with their physical and chemical properties and established expiration dates in conditions that exclude their contamination.

When working in an aseptic block, pre-cut sheets of vegetable parchment or tracing paper are used for records. Paper is stored in plastic folders or bags. You can write only with a ballpoint pen, which is wiped with 70% ethyl alcohol or an alcohol-ether mixture once per shift.

Records are made on a table located near the local exhaust system.

It is prohibited to use an aseptic assistant for conducting studies on sterility control and other microbiological work.

Personnel who do not work in the aseptic block are strictly prohibited from entering these premises.

It is prohibited to reuse pharmacy utensils and corks for the production (production) in the conditions of the pharmacy of injectable drugs, unless otherwise provided by the relevant regulatory and technical documentation.

Requirements for the personal hygiene of the staff of pharmacy establishments engaged in the production (manufacturing) of medicinal products.

The staff of pharmacy establishments that produce (manufacture) medicinal products additionally perform the following:

- personnel engaged in the production and packaging of medicines must be provided with clean towels for personal use before the start of the shift;

- production personnel are prohibited from keeping personal items, except a clean handkerchief, at workplaces and in the pockets of their gowns;

- in order to prevent the spread of microorganisms, all cases of diseases (skin, colds, abscesses, cuts, etc.) should be immediately reported to the pharmacy administration by the pharmacy staff. All messages must be recorded;

- during the production, control, and packaging of medicines, employees must have their nails trimmed, not covered with varnish, and there must be no rings on their fingers.

Sanitary and hygienic requirements in the manufacture of non-sterile dosage forms.

Medicinal products used for the manufacture of non-sterile dosage forms must be stored in tightly closed containers (or other containers) in conditions that exclude their contamination.

Glass jars used to store medicines are washed and sterilized before filling.

The auxiliary material necessary for the manufacture and packaging of medicines is prepared, sterilized and stored in accordance with the requirements of this Instruction.

Pharmacy dishes are washed and sterilized according to the technological instructions approved by the business entity, observing the requirements for sterilization of individual objects.

The storage period of sterile dishes used for the manufacture of non-sterile dosage forms is no more than three days.

Polyethylene stoppers for closing medicines, which are manufactured and packed in pharmacies, as well as plastic screw stoppers are washed, sterilized and stored in accordance with the technological instructions approved by the business entity, observing the processing requirements and quality control of the processing of pharmacy dishes and stoppers.

Means of small mechanization, which are used in the manufacture and packaging of medicines, are washed and disinfected according to the instructions attached to them. If there are no instructions on this matter in the instructions, after the end of the operation, the equipment is disassembled, the working parts are cleaned of the remaining medicinal substances, washed with hot water (55 +- 5) degrees. C, after which they are disinfected or sterilized depending on the properties of the material from which it is made. Disinfection solution is washed off the equipment with hot water, rinsed with purified water and stored in conditions that prevent contamination.

At the beginning of each weight change, spatulas, scissors and other small

pharmacy equipment are wiped with a 3% hydrogen peroxide solution or an alcohol-ether mixture (1:1).

Burette units and pipettes are washed at least once every 10 days with hot water (55 +/- 5) degrees after freeing them from the concentrate. C with a suspension of mustard powder or a solution of 3% hydrogen peroxide with 0.5% detergent, then rinse with purified water with mandatory control of the rinse water for residual amounts of detergent.

Drain taps of burette units are cleaned of layers of salts from solutions, extracts, and tinctures before starting work and wiped with an alcohol-ether mixture (1:1).

After each weighing or measurement of medicinal substances from the dipstick, the neck and stopper of the dipstick, as well as hand scales, are wiped with a disposable gauze napkin. It is forbidden to wipe barbells and weights with a personal towel.

During the filtering or filtering of liquid medicines, as well as mortars with powder or ointment mass for mixing and placing in containers, they are covered with disinfected plastic or metal plates.

To extract ointments or powders from mortars, use plastic plates or X-ray film freed from emulsion.

The use of cardboard is not allowed.

Paper and wax capsules, spatulas, threads, rubber bands, etc., used for work, are stored in the drawers of the assistant (packaging) table, which must be washed daily.

Auxiliary materials are stored in a storage room, in closed cabinets, chests in conditions that exclude their contamination.

The procedure for monitoring compliance with the sanitary and anti-epidemic regime in pharmacies.

The quality and effectiveness of sanitary and anti-epidemic measures carried out in pharmaceutical establishments engaged in the production (manufacturing) of medicinal products are determined by the results of sanitary and bacteriological control.

State sanitary-epidemiological supervision with sampling for sanitary-bacteriological control is carried out by institutions of the state sanitary-epidemiological service at least once a quarter, as well as according to epidemiological indications.

The objects of bacteriological control in pharmacies are:

- purified water and water for injections;
- medicinal products produced (manufactured) in a pharmacy;
- pharmacy utensils, corks and other auxiliary materials;
- inventory, equipment used in the premises for the production (manufacturing) of medicinal products;
- hands and clothing of personnel, what directly involved in the process of production (manufacturing) of medicinal products;
- air environment in premises for the production (manufacturing) of medicinal products.

PRACTICAL ASSIGNMENTS

Task 1. Present the types of material responsibility in the pharmacy as a diagram.

Task 2. To carry out the classification of the premises of the pharmacy that deals with production and retail sale of medicines (Table 1). To perform the task, you need to use "EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use" https://health.ec.europa.eu/system/files/2016-11/chapter_3_0.pdf

Premises	The list and the main functions

After completing the practical task, the student should receive practical skills and abilities:

- Determination of the rational organizational structure of the pharmacy (pharmaceutical
- firms);
- rational equipment and equipment of pharmacies (pharmaceutical companies);
- completion of contracts on individual (collective) material
- responsibility of pharmacy workers;
- compliance with the general organizational requirements of the sanitary regime in pharmacies
- institutions;
- compliance with special requirements of the sanitary regime in pharmacies;
- application of the principles of sterilization of individual objects;
- control of temperature modes of operation of sterilizers;
- control of temperature regimes of operation of steam sterilizers, control
- temperature modes of operation of pharmacy equipment and devices;
- quality control of processing pharmacy utensils and corks.

SELF CHECK TESTS

1

According to the current legislation, pharmaceuticals can be sold through pharmacies and their structural units. Specify the products that pharmacies are NOT allowed to purchase and sell

A. **Reagents for control and analytical** laboratories
B. Products for medical purposes
C. Disinfectants
D. Repellents
E. Medicines

2

The pharmacy carries out retail sale of drugs and medical devices. According to current legislation, which products cannot be purchased and sold by pharmacies?

A. **Perfumes and decorative cosmetics**
B. Natural and artificial mineral waters
C. Literature on health care and pharmacy
D. Functional food products
E. Special clothing for medical and pharmacy workers

3

The activity of pharmacies is subject to licensing. The term of validity of the license for the right to sell drugs and medical devices is:

A. **Indefinitely**
B. One year
C. Two years
D. Four years
E. Three years

4

A geriatric center started functioning in the city under regional control. A pharmaceutical company is opening a pharmacy next door. What type of specialization should be used in her work?

A. **By the nature of the group of patients served**
B. By the specifics of production activity
C. According to the specifics of the sales activity
D. According to the specifics of the delivery
E. According to the specifics of taxation

5

The pharmacy prepares medicines according to individual prescriptions. Specify the frequency of wet floor cleaning in the production premises of pharmacies?

A. **At least once per shift**
B. At least once a week
C. At least once every 10 days
D. At least once every 5 days
E. At least once every 3 days

6

The sanitary regime in pharmacies is regulated by relevant regulatory documents. How often should a sanitary day be held?

A. **At least once a month**
B. At least once a week
C. At least once every 3 days
D. At least once every 10 days
E. At least once every 5 days

7

The pharmacy prepares intra-pharmacy preparations, semi-finished products and concentrates. What license does she need to have for this?

A. **For the production (manufacturing) of medicinal products in the conditions of a pharmacy**

B. For the production of medicinal products (industrial)

C. For the wholesale trade of medicinal products

D. For the import of medicinal products (except for active pharmaceutical ingredients)

E. For the retail trade of medicinal products

8

According to the current legislation, all premises in which medicinal products are received, stored, controlled and dispensed are related to production. Which of the premises is NOT industrial?

A. **Trading hall**

B. Assistant room

C. Material room for storing medicinal herbs

D. Material room for medicinal products

E. Aseptic block

9

The order of the Ministry of Health of Ukraine dated July 6, 2012 No. 498 expanded the list of pharmacy products. Specify a group of goods that is NOT included in this list?

A. **Stationery goods**

B. Literature on medicine, pharmacy and healthy lifestyle

C. Baby care items not registered as medical devices

D. Special clothing for medical and pharmacy workers

E. Devices for the purification of drinking water and replaceable cartridge filters for them

10

Determine which of the departments of the pharmacy is responsible for receiving the goods in terms of quantity and quality, storing them, and releasing them to

other departments of the pharmacy:

A. **Stock department**

B. Recipe and production department

C. Department of finished medicinal forms

D. Non-prescription department

E. Medical cosmetics department

TOPIC 4
SUBJECT: ORGANIZING THE WORK OF THE PHARMACY WITH STOCKS

Student should know: the concept of "stocks", their classification, the organization of the work of a pharmacy with stocks, methodological principles of the formation of information about stocks, sources of stock formation, stock management in a pharmacy, determining the need for pharmacy products, demand and consumption.

Basic terms and concepts: stocks, goods, invoice, power of attorney.

QUESTIONS

1. Concept of reserves and their classification.
2. Types of basic operations with stocks in the pharmacy.
3. Documentation of stock supply.
4. Organization of reception and delivery of pharmacy products in the drug store.
5. Organization of storage of pharmacy products in the chemists shop.

SELF-CHECK QUESTIONS

1. Definition of the term "reserves".
2. Classification of stocks of pharmacy assortment.
3. The order of storage in the pharmacy of various groups of medicines and medical products.
4. General requirements for the organization of storage in a pharmacy of various groups of medicinal products and medical products.
5. Basic organizational principles of storage of medicines and medical products in accordance with the requirements of regulatory documentation.
6. Types of basic operations with stocks in the pharmacy.
7. Staff and functions of staff working with stocks in the pharmacy.
8. Organization of reception and delivery of pharmacy products in the pharmacy.

9. Duties of the authorized person regarding the incoming quality control of medicinal products in the pharmacy.

10. Documentation of receipt and release of stocks in the pharmacy.

OVERVIEW

According to the National regulation (standard) of accounting 9 "Reserves" **stocks are** assets that:

- are held for further sale under the conditions of ordinary economic activity;
- are in the process of production for the purpose of further sale of the production product;
- contained for consumption during the production of products, performance of work and provision of services, as well as management of the enterprise.

Stocks include:

- raw materials, main and auxiliary materials and other material values, which are intended for the production of products, provision of services, etc.;
- unfinished production in the form of incomplete processing and assembly of parts, assemblies, products and unfinished technological processes;
- finished products, which are manufactured at the enterprise, are intended for sale and meet the technical and quality characteristics stipulated by the contract or other regulatory legal act;
- goods in the form of material values that are purchased (received) and are kept by the enterprise for the purpose of further sale;
- low-value and perishable items that are used for no more than one year or the normal operating cycle if it is longer than one year.

Stocks are the basis of activity of any pharmacy. The efficiency of the pharmacy depends on their presence (or absence). The correct organization of the receipt of stocks contributes to a rational economic process in all spheres of activity of the business entity.

The procedure for accepting stocks and their documentation depends on the conditions of supply specified in the contract, namely: the place of acceptance (at the

supplier’s warehouse, from transport companies, at the buyer’s warehouse), its nature (in terms of quantity, quality and completeness), conformity of quantity and quality of purchased stocks, terms of the contract and accompanying documents.

Various delivery documents drawn up by both suppliers and buyers are used for registration of stocks arriving at the buyer's warehouse. These documents, depending on the conditions of delivery, the order of calculations of the conditions of acceptance and delivery of goods, can be:

- invoice
- waybill;
- railway waybill;
- specification, etc.

Let's briefly consider each of them.

The invoice is the most universal document and is currently quite widely used and issued at the place of storage. Usually, an invoice is issued when there is no need for special transportation (trucking, rail, air transportation, etc.) for the delivery of the goods. Often, in this case, the buyer delivers the purchased stocks on his own (in his hands, by taxi, personal or company car). Minimum of 2 copies.

Waybills are used for road freight transport and are usually issued in four copies:

- the first copy remains with the consignor and is the basis for write-off of goods and material values. Other copies certified with signatures and printing (stamps) are given to the driver;
- the second is an accompanying document for the transportation of goods and is intended for registration by its recipient;
- the third copy (which is the basis for making calculations for the performed transport services) with the charging data and the signature of what the charging carrier sends to the customer of the vehicle for payment;
- the fourth copy together with the waybill of the truck remains with the carrier for accounting of its transport work.

The peculiarity of the waybill registration is that this document can be issued both by the consignor and the consignee.

When delivering stocks by rail, the supplier draws up a special waybill, which is an accompanying document and is issued to the consignee at the destination station.

The specification can be used as an additional, clarifying document attached to one of the above-mentioned main shipping documents.

In some cases, documents confirming the quality of delivered goods, quality certificates, quality certificates, and the like can also be added directly to the product documents.

Stocks are released to the buyer's representative in the presence of duly executed powers of attorney.

The power of attorney to receive the goods is a document that confirms the right of the authorized person to receive valuables on behalf of the business entity. Such a power of attorney has the same nature as any other power of attorney.

The power of attorney specifies a sample of the person's signature and his/her passport data, name and quantity of stocks (goods) to be obtained. All these data are certified by the manager's signature and seal (optional). The power of attorney for the supplier is a guarantee that the goods are not issued to a person from the street, but to an authorized representative of the buyer.

The recipient of the goods puts his signature on the invoice, which also indicates the power of attorney number. This is a kind of explanation why the signature is not of the director, but of another person.

If such a product was accepted by the manager himself, then there is no need to issue any power of attorney.

To manage the business activities of the enterprise (pharmacy), the owner appoints a manager (directors) who, without a power of attorney, acts on behalf of the enterprise, represents its interests, including in relations with legal entities and citizens.

Therefore, the manager (director) managing the pharmacy practically always and everywhere represents his institution to third parties without a power of attorney, since he has the authority to do so granted to him by the founding documents. He himself signs any contracts, acts, invoices on behalf of the pharmacy and seals them with his signature and seal (if desired).

The head of the pharmacy can come to the supplier's warehouse and receive any goods without a power of attorney. His signature on the invoice indicates that he personally received these values.

However, it is unlikely that the manager will visit the warehouses himself. He usually instructs another person to receive the goods. Such another person is issued a power of attorney, which is signed by the head of the enterprise.

Incoming quality control of pharmaceuticals and medical equipment is carried out by an authorized person.

In order to accept from suppliers of narcotic drugs, psychotropic substances and precursors, by order of the head of the pharmacy, a commission is created for the acceptance, accounting and destruction of these drugs consisting of at least three people, chaired by the head of the pharmacy or his deputy. The commission must carry out continuous checks of narcotic drugs, psychotropic substances and precursors that have arrived at the pharmacy, for compliance of their names, quality, quantity, and weight with the data indicated in the accompanying documents of the suppliers. The results of the inspection of these products are reflected in the Act on the acceptance of narcotic drugs, psychotropic substances and precursors in pharmacies.

In accordance with the Resolution No. 929 "On approval of licensing conditions for conducting business activities in the production of medicinal products, wholesale and retail trade of medicinal products, import of medicinal products (except for active pharmaceutical ingredients)", an authorized person who has a document of higher education is determined not lower than the second (master's) level in the specialty "Pharmacy", a specialist pharmacist's certificate issued by a post-graduate education institution, or a certificate of assignment (confirmation) of the relevant qualification category and work experience in the specialty "Pharmacy" for at least two years (obligations are allowed duties of an authorized person responsible for the functioning of the system of ensuring the quality of medicinal products in a pharmacy located in a village, settlement, urban-type settlement, per person,who has a document of higher education not lower than the first (bachelor) level in the specialty "Pharmacy" and does not have work experience in this specialty).

Incoming quality control of medicines in pharmacies is carried out by an authorized person who must have a higher or secondary pharmaceutical education. her name, contact phone number and contact form (phone, fax, e-mail) should be reported to the regional (city) State Inspectorate for Quality Control of Medicines (hereinafter referred to as the territorial inspectorate). The competence of the authorized person includes the preparation and drawing up of a conclusion on the results of incoming quality control of batches of medicinal products with a note on their transfer to sale.

The main duties of an authorized person are:

- checking of medicinal products that arrive at the pharmacy and accompanying documents - invoices (with mandatory indication of the name, dosage, dosage form, series number, quantity, name of the manufacturer), quality certificates of manufacturers, data on the registration status of the medicinal product;
- execution of the conclusion of the incoming quality control of medicinal products;
- maintaining a register of medicinal products that have arrived at the subject of economic activity;
- checking the presence of low-quality and falsified batches of medicines in the pharmacy according to the information of the territorial inspection;
- provision of reports to the territorial inspection about found low-quality and falsified medicinal products or about which there is suspicion regarding their quality. Suspension of trade in such medicinal products;
- approval of the internal procedure for the circulation of medicinal products.

In accordance with the basic conditions for the supply of medical products, medicinal products must be released to the pharmacy with a remaining shelf life of at least 60%, and bacterial preparations - at least 40%.

All medicinal products, depending on their physical and physico-chemical properties, the effects of various environmental factors on them, are divided into the following:

- which require protection from light;
- which require protection from moisture;

- which require protection against evaporation;
- which require protection against elevated temperature;
- which require protection against low temperature;
- which require protection from the action of gases contained in the environment;
- fragrant, colorful;
- disinfectants.

PRACTICAL ASSIGNMENTS

Task 1. Determine the quantity of the necessary order medicines, provided that stock checks are carried out every 5 days, two of the day is spent on searching for suppliers, placing an order and receiving drugs, the reserve stock is the average sales rate of a specific drug per day. To complete the task, it is necessary use the specified formula (1) and table 1.

$$QOO = (PICP + PRO) * ADSS + RS - E,$$

where, QOO is the quantity of the order

PICP - periodicity of inventory checks in the pharmacy

PRO - the period of receiving the order

ADSS - the average daily standard of sale of the medicinal product

RS is his reserve stock

E - estimated balance on the day of delivery.

Table 1 to task 1. Calculation of the quantitative volume of the order

No	The name of the medicinal product, the form of release, dose	Predicted remainder	Average sale for day	Necessary number
1	Glucose, kg	3	7	
2	Ethambutol, tab. 0.4 No.50	3	2	
3	Etiotrast district d/in 3 ml amp No. 10	9	6	
4	Coldflu, tab. No.4	0	10	
5	Pilocarpine hydrochloride dr. ophthalmic. 1% fl. 10 ml.	1	10	
6	Prodein 30, tab. No.100	1	1	
7	Relief, sup. No. 12	1	2	

Task 2. Organize the storage of received medicines.

Take into account that the drug was received by the pharmacy on September 1, 2020 in accordance with the Order Ministry of Health of Ukraine dated 16.03.1993 No. 44 "On organization of storage in pharmacies of various groups of medicines and medical devices":

- taking into account toxicological properties (poisonous and narcotic substances, potent substances and the general list) (Table 2);
- according to pharmacological groups (Table 3);
- in accordance with the third, fourth, fifth and sixth storage principles (Table 4);
- taking into account the established expiration dates for medicinal products (Table 5).

Table 2 for task 2 (a). Storage of medicines taking into account toxicological properties

No	Name of medicines	Storage conditions in a pharmacy.
1	Glucose, kg	
2	Ethambutol, tab. 0.4 No.5	
3	Etiotrast r/n d/in 3 ml amp No. 10	
4	Coldflu, tab. No. 4	
5	Pilocarpine hydrochloride, cap. eyes 1% fl. 10 ml.	
6	Prodein 30, tab. #100	
7	Relief, soup. No. 12	
8	Sedasen tab. No.50	
9	Herd grass, pack of 50 g.	
10	Phosphalugel, gel pack 16 g. No. 20	

Table 3 for task 2 (b). Storage of medicines by pharmacological groups

No	Name of medicines	Pharmacological group
1	Glucose, kg	
2	Ethambutol, tab. 0.4 No.5	
3	Etiotrast r/n d/in 3 ml amp No. 10	
4	Coldflu, tab. No. 4	
5	Pilocarpine hydrochloride, cap. eyes 1% fl. 10 ml.	
6	Prodein 30, tab. #100	
7	Relief, soup. No. 12	
8	Sedasen tab. No.50	
9	Herd grass, pack of 50 g.	
10	Phosphalugel, gel pack 16 g. No. 20	

Table 4 for task 2 (c). Storage of medicines according to the third, fourth, fifth and sixth storage principles

No	Name of medicinal product, release form, dose	The principle of storage			
		Depending on the method using (internal, external)	Drug in mass in mass "engro" by aggregate state	In accordance with the physical chemical properties and influence factors external environment	Taking into account the nature of different medicinal forms
1	Glucose, kg				
2	Ethambutol, tab. 0.4 No. 50				
3	Etiotrast district d/in 3 ml amp No. 10				
4	Coldflu, tab. No. 4				
5	Pilocarpine hydrochloride, cap. eyes 1% bottle of 10 ml				
6	Prodein tab. No.100				
7	Relief, soup. No. 12				
8	Sedasen tab. No. 50				
9	Herd grass, pack of 50g.				
10	Phosphalugel, gel pack 16 g No. 20				

Table 5 for task 2 (d). The remaining expiration dates for medicinal products are also established

No.	Name of medicinal product, release form and dose	Factory series	Expiration date		
			According to AND	Residual	
				In months	in %
1	Glucose, kg	10101012	5 years		
2	Ethambutol, tab. 0.4 No.50	27705013	5 years		
3	Etiotrast district d/in 3 ml amp No. 10	3606014	2 years		
4	Coldflu, tab. No. 4	8803014	3 years		
5	Pilocarpine hydrochloride, cap. eye 1% fl. 10 ml.	308014	2 years		
6	Prodein 30, tab. No.100	0901012	5 years		
7	Relief, sup. No. 12	702012	2 years		

Continuation of table 5

8	Sedasen tab. No.50	140213	3 years		
9	Herd grass, pack of 50g.	311013	2 years		
10	Phosphalugel, gel pack 16 g. No. 20	221113	3 years		

Table 6 for task 2 (d). Journal of medicinal products with a limited shelf life

No	The name of the medicine drug, release form and dose	Factory series	Number of packages	Expiration date			Completion term suitable	Measures taken for implementation
				On AND	In months	in %		
1								
2								
3								

After completing the practical task, the student should receive practical skills and abilities:

- Application of normative and legislative documents regulating organization of work with stocks in the pharmacy;
- documentation of economic transactions with stocks of the warehouse;
- performance of the tasks and functions of the full-time staff of the pharmacy performing the work with stocks in the pharmacy;
- compliance with the rules for receiving, storing and releasing stocks in the pharmacy;
- order of storage in the pharmacy of various groups of medicines and medical devices.

SELF-CHECK TESTS

1

2 liters of 10% sodium benzoate solution were prepared in the pharmacy to fill the burette unit. Specify the accounting register in which this operation is registered?

A. **In the journal of accounting for laboratory work**
B. In the journal of accounting of the recipe
C. In the product report
D. In the recipe journal
E. In the cash book

2

According to the basic terms of supply of medical products, medicinal products in the pharmacy must be dispensed with a residual expiration date of at least %, and bacterial preparations - no less %

A. **60%, 40%**
B. 80%, 60%
C. 50%, 40%
D. 40%, 20%

E. 60%, 30%

3

Pharmacy No. 2 received a batch of goods. During the reception process, it was discovered that the goods arrived without accompanying documents. What needs to be done?

A. **Make a certificate of acceptance of the goods and leave the goods in responsible storage in the pharmacy**

B. Hand over the goods for sale

C. Return to stock

D. Draw up an act of destruction of the batch of goods

E. Return to the manufacturer

4

During the reception of the goods, a shortage was discovered in the pharmacy: instead of 40 boxes of ampicillin - 38 boxes. In what terms is it necessary to draw up the "Act on establishment of discrepancies in quantity and quality upon acceptance of goods"?

A. **On the day when a shortage was detected**

B. Within 3 days

C. Within 5 days

D. Within 7 days

E. Within 2 days

5

Determine which of the departments of the pharmacy is responsible for receiving the goods in terms of quantity and quality, storing them, and releasing them to other departments of the pharmacy:

A. **Inventory department**

B. Prescription and production department

C. Department of finished medicinal forms

D. Department of over-the-counter sales

E. Department of medical cosmetics

6

According to the accompanying documents, the pharmacy received the goods. Who is responsible for maintaining the register of medicinal products that have arrived at the subject of economic activity?

A. **Authorized person Chief accountant**

B. Pharmacy pharmacist

C. Materially responsible person

D. Trustee

7

Medicines arrived at the pharmacy according to the invoice. Who carries out incoming quality control of drugs in the pharmacy:

A. Authorized person appointed by order of the head of the pharmacy

B. Pharmacist of the pharmacy

C. Pharmacy manager

D. State Inspector of the Territorial Inspection for Quality Control of Medicinal Products Tax Inspector

8

Which department of the production pharmacy carries out the determination of the current need for drugs and medical devices, timely submission of orders for them, acceptance of goods by quantity and quality, ensuring proper storage, carrying out laboratory and packaging work, releasing goods to other departments and medical and preventive institutions:

A. **Inventory department**

B. Recipe and production department

C. Department of finished dosage forms
D. Department of over-the-counter sales
E. Department of storage and orders

9

The pharmacy receives goods from the pharmacy warehouse by truck. Which document is the main one when the goods are sold in the pharmacy, received from the supplier?

A. **Waybill**
B. Register of medicines
C. Bill of lading requirement
D. Assignment
E. Invoice

10

Certain principles are followed in the pharmacy when storing goods. Which placement principle cannot be used for medicinal products:

A. **Alphabetically**
B. According to pharmacological groups
C. According to toxicological groups
D. According to physicochemical properties
E. According to the type of dosage form

CONTENT SECTION 2
RETAIL SALES ORGANIZATION MEDICINES

TOPIC 5
REGULATION OF RELEASE OF PRESCRIPTION DRUGS IN PHARMACIES

Student should know: general rules of excerption of recipes on medicinal facilities and wares of the medical setting, form of compounding forms, feature in relation to filling of compounding forms, terms of action of recipes, concept of electronic recipe, rule of excerption of electronic recipe, order of account of recipes are in a pharmacy, their expiration dates.

Basic terms and concepts: retail realization, recipe, compounding form of form №1 (F-1), special compounding form of form №3 (F-3), compounding medicinal facilities, over the counter medicinal facilities, medicinal facilities that is made in the conditions of pharmacy.

QUESTIONS

1. The concept of a recipe. General rules for prescribing.
2. Forms of prescription forms and features of their filling.
3. Rules for issuing prescriptions for medicinal products that are dispensed free of charge or on preferential terms.
4. Rules for issuing prescriptions for medicinal products, which are subject to reimbursement, for chronic patients and for special purposes.
5. Rules for writing prescriptions for drugs manufactured in a pharmacy.
6. The procedure for receiving, recording, storing and destroying prescriptions in the pharmacy.
7. The procedure for dispensing medicines and medical products from pharmacies and their structural subdivisions
8. The mechanism for reimbursement of costs for medicinal products in the health care system

SELF-CHECK QUESTIONS

1. The concept of a recipe. General rules for prescribing.

2. Forms of prescription forms and features of their filling.

3. Rules for issuing prescriptions for medicinal products that are dispensed free of charge or on preferential terms.

4. Rules for issuing prescriptions for medicinal products, which are subject to reimbursement, for chronic patients and for special purposes.

5. Rules for writing prescriptions for drugs manufactured in a pharmacy.

6. The procedure for receiving, recording, storing and destroying prescriptions in the pharmacy.

7. The procedure for dispensing medicines and medical products from pharmacies and their structural subdivisions

8. The mechanism for reimbursement of costs for medicinal products in the health care system

OVERVIEW

One of the priorities of the National Medicines Policy, along with ensuring the availability and quality of medicines, is their rational use. The relevance of this problem is explained by objective circumstances:

- limitation of budget funds for the purchase of medicinal products;
- irrational prescription of drugs;
- uncontrolled drug use;
- the development of medical technologies, the constant increase in the number of pharmacotherapeutic alternatives;
- lack of a system of mandatory medical insurance, etc.

Prescription dispensing of drugs allows to some extent to settle the issue of their rational use and to avoid undesirable consequences of uncontrolled use of drugs during self-medication.

According to the current legislation, drugs are divided into two categories:

- Prescription drugs;
- Medicines that are available without a prescription.

The criteria for determining the categories of drug release have been determined for Order of Ministry of health protection of Ukraine No. 185 dated 17.05.2001 «On the approval of the criteria for determining the categories of medicinal products». In Ukraine, in contrast to international practice, over-the-counter dispensing is subject to regulation: the list of pharmaceuticals allowed to be dispensed without a prescription from pharmacies and their structural units is approved by the Ministry of Health of Ukraine and systematically reviewed taking into account data on pharmaceutical registration. At the moment – this Order of Ministry of health protection of Ukraine 05.05.2023 No. 848 «On the approval of the List of medicinal products approved for use in Ukraine, which are dispensed without a prescription from pharmacies and their structural subdivisions».

In accordance with the current legislation, all other pharmaceuticals are dispensed from pharmacies and pharmacy points according to doctors' prescriptions.

General requirements for prescriptions for medicinal products and medical products

The main regulatory document that regulates the prescription of solvents is Order of ministry of health protection of Ukraine 07.19.2005 No. 360 «On the approval of the Rules for issuing prescriptions for medicinal products and medical products, the Procedure for dispensing medicinal products and medical products from pharmacies and their structural subdivisions, Instructions on the procedure for storing, recording and destroying prescription forms»

First of all, a Prescription is a written request from a doctor to a pharmacist about the manufacture and dispensing of drugs.

The prescription must be written in accordance with the current regulatory framework and have a traditional structure.

Prescriptions are issued for medicinal products registered in Ukraine, except for cases provided for by current legislation.

Prescriptions must be issued to:

1) medicinal products that, according to the instructions for medical use, are subject to prescription and the full cost of which is paid from the consumer's funds and/or other sources not prohibited by law, except for budget funds;

2) medicinal products and medical products subject to reimbursement;

3) medicines and medical products, which are sold on preferential terms;

4) extemporaneous medicines.

Prescriptions for medicinal products or medical products (hereinafter - prescriptions) are issued by doctors in accordance with the medical specialties under which medical practice is carried out in accordance with the license obtained by the business entity, and the corresponding medical positions.

A paramedic of a separate structural subdivision of an outpatient clinic of a primary medical (medical and sanitary) care center (hereinafter referred to as a paramedic) has the right to issue paper prescriptions for patients, except for prescriptions for narcotic drugs, psychotropic drugs, poisonous and potent drugs, specifying his position , by certifying the prescription with one's own signature and seal of the dispensary or the center of primary medical (medical and sanitary) care.

Prescription forms of form No. 1 (f-1) are used for writing paper prescriptions for medicinal products, except for narcotic (psychotropic) medicinal products, and medical products .

Special prescription forms of form No. 3 (f-3) are used for writing paper prescriptions for narcotic (psychotropic) medicinal products in their pure form or mixed with indifferent substances .

In the case of prescribing a narcotic (psychotropic) medicinal product, which is dispensed on preferential terms, along with writing out a paper prescription on a special prescription form No. 3 (f-3), a paper prescription is additionally written on a prescription form No. 1 (f-1) .

Paper prescriptions are written on prescription forms of forms No. 1 (f-1) and No. 3 (f-3) , which are made on paper media using the printing method.

At the same time, special prescription forms of form No. 3 (f-3) for paper prescriptions are made on pink paper with a size of 75 × 120 mm and are numbered

through. Control over their accounting and use is entrusted to the responsible person, who is determined by the order of the business entity.

After issuing a paper prescription, it is provided to the patient (his representative), except for the tear-off part of the prescription form form No. 1 (f-1) , which remains with the business entity whose medical worker issued the prescription.

An electronic prescription is issued for each name of the medicinal product according to the international non-proprietary name of the medicinal product or for each name of the medical product separately. The trade name is indicated if the medicinal product does not have an international non-proprietary name, belongs to medicinal products of biological origin or similar biological medicinal products (biosimilars).

After issuing an electronic prescription, the patient (his representative) is provided with information about the number of the issued electronic prescription and a confirmation code for dispensing drugs and medical products from a pharmacy using an electronic prescription.

At the request of the patient (his representative), he is provided with an information certificate in paper form, which is generated by the system and contains information about the number of the issued electronic prescription, a confirmation code, the date of issuance of the electronic prescription, as well as information about the prescribed medicine or medical product (hereinafter - the information certificate). An information certificate issued in accordance with this paragraph is not considered an electronic prescription and is for informational purposes only.

It is allowed to issue a prescription for a medicinal product in the amount required for a course of treatment, with the exception of medicinal products dispensed in accordance with the norms for the dispensing of medicinal products by prescription (hereinafter referred to as the dispensing norms).

Paper prescriptions for combined medicinal products containing narcotic drugs, psychotropic substances or precursors in an amount that does not exceed their maximum permissible norm are written on prescription forms of form No. 1 (f-1).

For combined medicinal products in original packages containing narcotic drugs, psychotropic substances or precursors in an amount exceeding their maximum

permissible norm, it is allowed to prescribe one package of such a medicinal product in one prescription, but no more than fifty tablets.

The term of validity of the prescription from the date of its issuance is:

for paper prescriptions on special prescription forms form No. 3 (f-3) and electronic prescriptions for narcotic (psychotropic) medicinal products - ten calendar days;

for paper prescriptions on prescription forms form No. 1 (f-1) and electronic prescriptions for medicinal products (except narcotic (psychotropic) medicinal products) and medical products - thirty calendar days.

The date of issuance of an electronic prescription is the date on which the doctor affixes a qualified electronic signature to the electronic prescription in the system.

16. A prescription written in violation of the requirements of these Rules and/or containing incompatible medicinal products and/or errors, in particular in the dosage of the medicinal product, and/or whose validity period has expired, is considered invalid.

A business entity, whose medical worker issued a prescription in violation of the requirements of these Rules, and/or which contains incompatible medicinal products and/or errors, in particular in the dosage of the medicinal product, is obliged to ensure that a new prescription is issued for the patient.

Peculiarities of prescribing for certain categories of patients

If necessary (business trip, vacation, etc.), it is allowed to prescribe to patients in one prescription drugs (except narcotic (psychotropic) drugs) in the amount prescribed for a course of treatment of up to ninety calendar days, taking into account leave norms.

Patients with chronic diseases are allowed to write a prescription for a drug containing phenobarbital in an amount that does not exceed the maximum permissible, mixed with other drugs that are dispensed from pharmacies according to a prescription, for a course of treatment of up to thirty calendar days, while paper prescriptions are issued on prescription forms of form No. 1 (f-1).

In case of carrying out substitute maintenance therapy of persons with mental and behavioral disorders due to the use of opioids in accordance an electronic prescription for a narcotic (psychotropic) medicinal product is issued to the patient with reference to

the treatment plan indicated as a prescription in the medical record, and a new electronic prescription for a narcotic (psychotropic) medicinal product with the same international non-proprietary name is issued to the patient no earlier, than three days before the date of the end of the previous course of treatment of the patient according to the electronic prescription for such a medicine specified in the Register.

In the event that a patient who has an acute or chronic disease or needs continued treatment based on a previously established diagnosis and treatment plan indicated as a prescription in the medical record (with the exception of the conduct of RRT) applies to a doctor by means of electronic communications, the specified doctor must the right to issue an electronic prescription in accordance with these Rules without a personal appointment of the patient.

Dissemination of information by a business entity or a medical worker, directly or through another person, to one, several persons or an unspecified circle of persons, in particular in advertising, about the issuing of electronic prescriptions for medicinal products and medical devices without the need for a personal appointment and/or examination of the patient is prohibited.

Peculiarities of filling out prescription forms for paper prescriptions

Paper prescriptions are filled out clearly and legibly by hand with a ballpoint pen, with mandatory filling in of the information provided for in the corresponding form of the prescription form. Corrections in the paper prescription are not allowed.

The name of the medical product or the international non-proprietary name of the medicinal product shall be indicated on the paper prescriptions. The trade name is indicated if the medicinal product does not have an international non-proprietary name, belongs to medicinal products of biological origin or similar biological medicinal products (biosimilars).

It is forbidden to abbreviate ingredients that are similar in name, which can lead to misunderstanding about which medicine is prescribed.

It is allowed to write no more than three names of medicinal products on the prescription forms of form No. 1 (f-1) , except for the cases specified in the second paragraph of this subsection.

One name of the medicinal product or medical product is written on the prescription form No. 1 (f-1) in the case of prescribing a medicinal product or medical product that is dispensed on preferential terms, or in the case of prescribing a medicinal product or medical product in accordance with paragraph 7 of this section, which are subject to reimbursement.

The last name, initials and age of the patient to whom the prescription is being written are indicated in the paper prescription.

The name and initials of the medical worker who writes the prescription shall be indicated in the paper prescription. A paper prescription issued by a doctor is certified by the signature and personal seal of the doctor who issued the prescription. A paper prescription issued by a paramedic is certified by the paramedic's signature indicating his position and the seal of the dispensary or the center of primary medical (medical and sanitary) care. Medical workers are prohibited from signing incomplete prescription forms and/or certifying them with a seal.

Features of filling out paper prescriptions for extemporaneous medicinal products:

1) paper prescriptions for extemporaneous medicinal products are filled out in expanded form;

2) the names of narcotic (psychotropic) and poisonous medicines are written at the beginning of the paper prescription, followed by all other medicines (ingredients);

3) when prescribing narcotic (psychotropic), poisonous and potent drugs in doses exceeding the highest single doses, the doctor is obliged to write the dose of this drug in words and put an exclamation mark;

4) the amount of solid and loose medicines is indicated in grams (0.001; 0.01; 0.5; 1.0), liquid - in milliliters, grams, drops;

5) if there is a need for immediate dispensing of medicines to the patient (his representative), the mark "cito" (quickly) or "statim" (immediately) is placed at the top of the paper prescription;

6) on the reverse side of the prescription form, the stamp of the pharmacy that produced the medicinal product, the number of the dosage form of individual

manufacture is affixed. In the columns "Checked", "Dismissed", "Accepted", "Produced", the names, initials and signatures of the pharmaceutical workers who fill these columns are indicated.

The procedure for dispensing pharmaceuticals and medical supplies from pharmacies and their structural divisions.

Pharmacies, their structural subdivisions and pharmacy warehouses (bases) may dispense medicinal products only registered in Ukraine in accordance with the established procedure, except for medicinal products manufactured in a pharmacy and packaged in accordance with the established procedure, provided a copy of the certificate certified by the supplier in accordance with the law is available quality of the producer, which is kept by the subject of economic activity.

Prescription and over-the-counter medicines are dispensed from pharmacies and drug stores.

Narcotic (psychotropic) medicinal products, which are prescribed on special prescription forms f-3, are dispensed through pharmacies that have the appropriate license for activities in the circulation of narcotic drugs, psychotropic substances and precursors.

Dispensing of prescription medicinal products is carried out taking into account the norms of dispensing, namely the maximum allowable quantity of medicinal product for dispensing per Prescription.

If necessary, it is allowed to break the secondary industrial packaging in order to dispense a smaller amount of the medicinal product. Violation of the original packaging of the medicinal product is not allowed.

Prescriptions for medicinal products remain and are stored in the pharmacy:

- which contain a narcotic drug, psychotropic substance or precursor prescribed on special prescription forms form No. 3 (f-3);
- which are poisonous or potent;
- the cost of which is subject to state reimbursement;
- which are released on preferential terms (free of charge or with additional payment);

- combined, which contain ephedrine (except medicines in the form of syrups), tramadol, pseudoephedrine and dextropropoxyphene.

Other Prescriptions, when medicines are dispensed for them, are stamped "Dispensed" and returned to the patient.

When dispensing drugs made in a pharmacy that contain poisonous, narcotic (psychotropic) drugs, patients are issued a signature with a yellow stripe in the upper part and the inscription "Signature" in black font on it instead of a prescription.

Prescription storage period in pharmacies:

1. Prescriptions for dispensed medicinal products written on special prescription forms f-3 are kept for five years (not including the current year).

2. Prescriptions (f-1) for medicinal products issued free of charge or on preferential terms, and for medicinal products, the cost of which is subject to state reimbursement, are stored for three years (not including the current year).

3. Prescriptions for dispensed medicinal products, prescribed for poisonous and potent medicinal products, for combined medicinal products containing ephedrine (except medicinal products in the form of syrups), tramadol, pseudoephedrine and dextropropoxyphene are stored for one year (not counting the current year).

4. Electronic prescriptions are stored in the information (information and telecommunications system) in accordance with the storage terms of the correspondingly issued paper prescriptions.

Medicinal products and medical products of appropriate quality, released from pharmacies and their structural subdivisions, are not subject to return, which must be announced in the service hall.

PRACTICAL ASSIGNMENTS

Task 1. Describe the rules for filling out the prescription form f-1

Task 2. Describe the rules for filling out the prescription form f-3

After completing the practical task, the student should acquire practical skills and abilities:

• Rules for issuing prescriptions for medicinal products and medical products;

• receiving prescriptions;

• dispensing of medicines and medical products according to doctors' prescriptions.

SELF-CHECK TESTS

1

The pharmacy received a prescription for powders with an overestimated single dose of phenobarbital, without the appropriate registration. How should a pharmacist act?

A. **Put the stamp "Prescription invalid" on the prescription and return the prescription to the patient Dispense 1/3 of the highest single dose**

B. Dispense a higher single dose multiplied by the number of powders

C. Dispense a higher single dose

D. Dispense 1/3 of the higher single dose multiplied by the number of powders

2

A visitor came to the pharmacy with a prescription written on form f-1, on which chloroethyl in ampoules was written, with a dentist's signature and personal seal. What are the pharmacist's actions?

A. **Dispensing the drug from pharmacies is prohibited**

B. The drug is dispensed in the specified quantity, the prescription remains in the pharmacy

C. The drug is dispensed in the specified quantity, the prescription is returned to the visitor

D. Ampoule of the drug is dispensed, the prescription is returned to the visitor

E. Ampoules of the drug are dispensed, the prescription remains in the pharmacy

3

The pharmacy, which is engaged in the individual production of medicinal forms, received rubber stoppers that were in use in the infectious department of the hospital. Are they allowed to be reused or not?

A. **No, it is not allowed**

B. Yes, it is allowed

C. Yes, but after disinfection

D. Yes, but after disinfection followed by sterilization

E. Yes, but after sterilization

4

The pharmacist must urgently, out of turn, hand over the prescription for the manufacture of the medicinal product, if the doctor has placed at the top of the prescription:

A. **"CITO" or "Statim"**

B. Exclamation mark

C. Two exclamation marks

D. Three exclamation marks

E. Release date

5

For three years, excluding the current one, pharmacies store prescriptions for:

A. **Medicines issued free of charge or on preferential terms**

B. Anabolic steroids at full cost

C. Narcotics in pure form at full cost

D. Psychotropic drugs at full cost

E. Clofelin in tablets at full cost

6

The pharmacy received a prescription written on prescription form F-3. The pharmacist, having performed the incoming control of the prescription, noticed the lack of appropriate information. This prescription form must contain:

A. **Signature and personal seal of the doctor**

B. Healthcare institution's stamp, doctor's seal and signature, signature of the head of the institution, healthcare institution's seal

C. Signature of the head of the institution or his deputy in charge of medical work

D. Stamp of the healthcare institution, signature of the head of the institution, seal of

the healthcare institution

E. Healthcare institution's stamp, seal and signature of the doctor, signature of the head of the institution

7

Prescriptions for narcotic (psychotropic) medicinal products in pure form or mixed with indifferent substances are issued free of charge or on preferential terms at:

A. **On prescription forms f-1 and f-3**

B. On prescription form f-1

C. On prescription form f-3

D. On prescription form f-1 in two copies

E. On two prescription forms f-3

8

During the inspection of the pharmacy on 02/25/2023, the inspector found the drug NIMESIL 0.1 No. 30, the registration certificate of which expired on 02/24/2023. Does the pharmacy have the right to sell it?

A. **Does not have Has**

B. Has, with the permission of the State Inspectorate

C. Has, with the permission of the head of the pharmacy

D. Has, with the permission of the Pharmacopoeia Center

9

The pharmacy received a prescription for a dosage form containing phenobarbital as part of a combined dosage form. Specify the required form of prescription form:

A. **Form No. 1**

B. Form No. 1 in two copies

C. Form No. 2 in duplicate

D. Form No. 3

E. Form No. 3 in duplicate

10

A visitor came to the pharmacy with a prescription for Tramadol tablets. Specify the expiration date of such a recipe:

A. **10 days**

B. 5 days

C. 1 month

D. The validity period is not set for 14 days

TOPIC 6
FEATURES OF RELEASE AND ACCOUNTING OF PRESCRIPTION DRUGS FOR SOME CATEGORIES OF PATIENTS

Student should know: general rules of excerption of recipes on medicinal facilities and wares of the medical setting, form of compounding forms, feature in relation to filling of compounding forms, terms of action of recipes, concept of electronic recipe, rule of excerption of electronic recipe, order of account of recipes are in a pharmacy, their expiration dates.

Basic terms and concepts: preferential categories of patients, palliative care, reimbursement, electronic health care system, a doctor who provides primary medical care (PMC).

QUESTIONS

1. General Rules for issuing prescriptions to preferential categories of patients.

2. Rules for issuing prescriptions for medicinal products that are dispensed free of charge or on preferential terms.

3. The procedure for receiving and recording prescriptions for medicinal products that are dispensed free of charge or on preferential terms.

4. Rules for issuing prescriptions for medicinal products subject to reimbursement.

5. The mechanism of reimbursement of costs for medicinal products in the health care system.

SELF-CHECK QUESTIONS

1. Specify the regulatory framework that regulates the preferential sale of medicinal products.

2. Name the population groups that benefit from medical care benefits.

3. Name the categories of diseases for which free dispensing of medicines is indicated.

4. Explain the features of prescriptions for drugs that are dispensed free of charge

or on preferential terms.

6. Rules for prescribing medicinal products subject to subject-quantitative accounting free of charge or on preferential terms.

7. The procedure for registering free and discounted prescriptions received at the pharmacy.

8. Specify the maximum number of medicines (if necessary) that is allowed to be prescribed to privileged categories of patients.

9. Name the rules for prescribing drugs that are subject to reimbursement.

10. Which doctors and under what conditions have the right to write prescriptions for medicinal products that are subject to reimbursement?

11. The mechanism for reimbursement of the cost of medicinal products to pharmacies.

OVERVIEW

Medical workers who have the right to prescribe Prescriptions are responsible for prescribing medicines to the patient and observing the rules for prescribing Prescriptions in accordance with the legislation of Ukraine.

Prescriptions for medicinal products issued on preferential terms, with additional payment or free of charge, except for narcotic (psychotropic) medicinal products, are issued in 2 copies on the prescription form No. 1 (f-1) (except for electronic prescriptions).

In the case of prescription of narcotic (psychotropic) drugs free of charge, with additional payment or on preferential terms, together with the Prescription on form f-3, a Prescription on form f-1 is also issued.

Lists of population groups and categories of patients who have the right to free and subsidized drug delivery approved from Resolution of cabinet of ministers of Ukraine dated August 17, 1998 No. 1303 «On regulating the free and subsidized supply of medicines according to doctors' prescriptions in the case of outpatient treatment of certain population groups and for certain categories of diseases».

According to this Resolution, medicinal products registered in Ukraine in

accordance with the established procedure and included in the industry standards in the field of health care are issued free of charge and on preferential terms.

Medicines are dispensed free of charge and on preferential terms in the case of outpatient treatment of persons by pharmacies according to prescriptions issued by doctors of medical and preventive institutions at the place of residence of these persons.

Persons who are served in departmental medical and preventive institutions and have the right to free or discounted medication, receive them in pharmacies attached to these institutions.

Medicines are dispensed free of charge to children with disabilities according to doctors' prescriptions, regardless of the place of residence of these children, but within the boundaries of the Autonomous Republic of Crimea, the region, the cities of Kyiv and Sevastopol. In this case, the costs associated with the payment of the cost of medicinal products are borne by the health care authorities at the place of their release.

Expenses related to the dispensing of medicines free of charge and on preferential terms are carried out at the expense of appropriations provided for by the state and local budgets for health care.

Determining the right for individual groups of the population to receive benefits regarding the provision of medicinal products in the case of outpatient treatment based on doctors' prescriptions, which are issued depending on the average monthly total income of the family, is carried out in accordance with the procedure determined by the Cabinet of Ministers of Ukraine.

The resolution consists of two Lists.The first is a list of population groups, in the case of outpatient treatment of which medicinal products are dispensed free of charge or on preferential terms according to doctors' prescriptions. It consists of two points:

- population groups, in the case of outpatient treatment of which medicinal products are dispensed free of charge according to doctors' prescriptions;

- population groups, in the case of outpatient treatment of which medicinal products are dispensed according to doctors' prescriptions with payment of 50 percent of their cost.

The second is a list of categories of diseases, in the case of outpatient treatment

of which medicinal products are dispensed free of charge.

Free dispensing of medicines for the listed categories of diseases is carried out only in the case of outpatient treatment of the main disease, for which patients are granted benefits. Patients with AIDS and HIV-infected patients, regardless of the main disease, have the right to receive medicines free of charge if they have any other diseases.

Prescriptions for medicinal products, which are issued on preferential terms, with additional payment or free of charge, are stored in the pharmacy for 3 years, not counting the current one. These prescriptions are registered in the "Journal of accounting for unpaid and preferential leave", then grouped in the "Register" and "Consolidated register", based on the data of which an "Invoice" is issued for payment to the medical and preventive institution.

Peculiarities of prescribing for certain categories of patients

In case of carrying out substitute maintenance therapy of persons with mental and behavioral disorders due to the use of opioids in accordance an electronic prescription for a narcotic (psychotropic) medicinal product is issued to the patient with reference to the treatment plan indicated as a prescription in the medical record, and a new electronic prescription for a narcotic (psychotropic) medicinal product with the same international non-proprietary name is issued to the patient no earlier, than three days before the date of the end of the previous course of treatment of the patient according to the electronic prescription for such a medicine specified in the Register.

In the event that a patient who has an acute or chronic disease or needs continued treatment based on a previously established diagnosis and treatment plan indicated as a prescription in the medical record (with the exception of the conduct of RRT) applies to a doctor by means of electronic communications, the specified doctor must the right to issue an electronic prescription in accordance with these Rules without a personal appointment of the patient.

Dissemination of information by a business entity or a medical worker, directly or through another person, to one, several persons or an unspecified circle of persons, in particular in advertising, about the issuing of electronic prescriptions for medicinal

products and medical devices without the need for a personal appointment and/or examination of the patient is prohibited .

Peculiarities of issuing electronic prescriptions for medicinal products and medical devices that are subject to reimbursement

Electronic prescriptions for medicinal products and medical products that are subject to reimbursement are issued:

1) by doctors specializing in "Endocrinology", "Pediatric endocrinology" (hereinafter referred to as endocrinologists) for insulin preparations and medicines for the treatment of diabetes insipidus;

2) doctors specializing in "Psychiatry", "Child Psychiatry" for medicinal products for the treatment of mental and behavioral disorders;

3) doctors in the specialties of "Psychiatry", "Child Psychiatry", "Neurology", "Child Neurology" for medicinal products for the treatment of epilepsy;

4) doctors specializing in "Neurology" for medicines for the treatment of Parkinson's disease;

5) doctors who obtained a higher education of the second (master's) level in the field of knowledge 22 "Health care" with the specialties "222 Medicine" or "228 Pediatrics" or the field of training "Medicine" with the specialty "Medical business" or "Pediatrics" and hold the position of transplant coordinator (or are authorized by the economic entity to perform the function of transplant coordinator) for medicinal products for patients in the post-transplant period.

Electronic prescriptions for insulin drugs, drugs for the treatment of diabetes insipidus, which are subject to reimbursement under the program of state guarantees of medical care for the population, can be issued on the basis of a prescription entered into the system by a doctor who provides primary medical care, which is created on the condition that the system has a previous similar appointment created by a doctor specializing in "Endocrinology", "Pediatric Endocrinology".

A new electronic prescription (except for prescriptions issued in violation of the requirements of these Rules and/or containing incompatible medicinal products and/or errors, in particular in the dosage of the medicinal product) for a medicinal product or a

medical product that is subject to reimbursement, with the same international non-patented the name of the medicinal product or the same name of the medical product may be prescribed no earlier than:

for seven calendar days before the end of the term for which a preliminary electronic prescription for a medicinal product or medical product was issued, if such term is or exceeds twenty one calendar days;

three calendar days before the end of the term for which the previous electronic prescription for a medicinal product or medical product was issued, if such term is less than twenty-one calendar days.

Electronic prescriptions for medicinal products and medical devices that are subject to reimbursement, issued before the terms specified in this clause, are considered valid provided that their cost is paid in full from sources not prohibited by law, except for funds allocated from the budget for the reimbursement of medicinal products and medical products under agreements on reimbursement.

PRACTICAL ASSIGNMENTS

Task 1. Describe the features of prescriptions for drugs and medical devices that are subject to reimbursement

Task 2. Rules for writing prescriptions for medicinal products that are dispensed free of charge or on preferential terms.

After completing the practical task, the student should acquire practical skills and abilities:

- organization of medical support for outpatients at the expense of public consumption funds;
- features of prescribing for certain categories of patients;
- rules for issuing prescriptions to preferential categories of patients;
- rules for issuing prescriptions for medicinal products that are subject to reimbursement;
- peculiarities of dispensing and accounting of medicines for some categories of patients.

SELF-CHECK TESTS

1

The department of finished medicinal products of pharmacy No. 1 received a prescription for "Farmazolin" nasal drops for a 2.8-year-old child. Specify the price for which the medicine will be issued?

A. **Free of charge**
B. With payment of 50% of their cost
C. For the full cost
D. With payment of 30% of their value
E. With payment of 70% of their value

2

The pharmacy provides medical care for various categories of patients. Which group of children by age in the case of outpatient treatment receives medicines free of charge?

A. **Up to 3 years**
B. From 3 to 6 years
C. Up to 6 years
D. Up to 16 years old
E. Up to 1 year

3

The pharmacy received a prescription for a discount drug. Which document is filled out based on data from the record book of discounted and free prescriptions?

A. **Consolidated register**
B. Recipe journal
C. Record book of incorrectly written prescriptions
D. Receipt book

4

A doctor wrote a prescription for phenobarbital in its pure form to a disabled person from childhood. Specify the necessary forms of prescription forms on which it must be issued:

A. **On prescription forms F-1 and F-3**
B. On two prescription forms F-1
C. On prescription form F-3
D. On prescription form F-1
E. On two prescription forms F-3

5

Determine the expiration date and storage in the pharmacy of the prescription for zopiclone tablets, which was issued free of charge to a schizophrenic patient:

A. **month, 3 years, excluding the current**
B. 10 days, 1 month, excluding the current
C. 5 days, 1 month, excluding the current
D. 5 days, 3 years, excluding the current
E. 5 days, 5 years, not counting the current

6

The pharmacy received a prescription for "Cyclodol" tablets for a psychiatric

patient. How should a prescription be written for poisonous medicinal products when they are dispensed free of charge or on preferential terms?

A. **On prescription form f-1 in two copies**
B. On two prescription forms f-1 and f-3
C. On prescription form f-1
D. On prescription form f-3
E. On prescription form f-3 in two copies

7

The city pharmacy received a prescription for ethyl alcohol. What amount of alcohol can be given to a patient with diabetes who makes injections independently, free of charge?

A. **100 g per month**
B. 150 g per month
C. 50 g per month
D. Not rationed
E. 200 g per month

8

The doctor prescribed diazepam tablets to a war invalid who has the right to free medication. Indicate the forms of the prescription forms on which the prescription must be written:

A. **On prescription forms No. 1 and No. 3**
B. On two prescription forms No. 3
C. On prescription form No. 3
D. On two prescription forms of form No. 1
E. On prescription form of form No. 1

9

In order to reimburse the cost of the released medicinal products to customers on

preferential terms, an invoice is drawn up for the treatment and prevention institution. In which document are accounts registered?

A. **Register of issued accounts**

B. Act

C. Invoice

D. Registration of retail turnover

E. Cash book

10

The pharmacy received a prescription for phenobarbital in tablets from a schizophrenic patient. On which prescription forms should this prescription be written?

A. **Form No. 3 + Form No. 1**

B. Form No. 1 in two copies

C. Form No. 3 in two copies

D. Form No. 3 + Form No. 1 in two copies

E. Can be issued without a prescription

TOPIC 7
ORGANIZATION OF PRODUCTION OF MEDICINES AND INTERNAL PHARMACY QUALITY CONTROL

Student should know: rules for the production of extemporaneous (compounded) medicinal products, manufacturing (production) of intra-pharmaceutical preparations, the essence and types of in-pharmacy quality control of drugs.

Basic terms and concepts: production (manufacturing) of extemporaneous (compounded) medicinal products, intra-pharmaceutical preparations, assistant premise, written control, survey, organoleptic control, qualitative and quantitative chemical control, physical control, control at release.

QUESTIONS

1. General requirements for the production of medicinal products in the conditions of a pharmacy - individual production of medicinal products according to doctors' prescriptions.
2. Production (manufacturing) of an intra-pharmaceutical preparations.
3. Organization and importance of internal pharmacy quality control of medicines.Qualification requirements of a pharmacist-analyst.
4. Preventive measures and their role in improving the quality of medicines.
5. Types of internal pharmacy quality control of medicines.

SELF-CHECK QUESTIONS

1. General requirements for the manufacture of medicinal products in a pharmacy.
2. General requirements for premises for the manufacture of medicinal products.
3. Requirements for the staff of the pharmacy, which manufactures medicinal products.
4. Rights and duties of a pharmacist-analyst of a pharmacy, organization of his workplace.
5. Preventive measures carried out to improve the quality of medicines.

6. The essence of written control, the procedure for filling out the passport of written control.

7. Rules for survey control.

8. Methodology of organoleptic control.

9. The essence of physical control, rules of conduct.

10. Methodology of chemical control.

11. Control at release.

12. Issuing the results of internal pharmacy control.

OVERVIEW

A licensee who conducts economic activity in the production (manufacturing) of medicinal products in the conditions of a pharmacy, retail trade of medicinal products, ensures the availability of a material and technical base, technical equipment, and their compliance with the requirements of regulatory documents regarding the production, storage, quality control, and trade of medicinal products.

The activity of production (manufacturing) of medicinal products in the conditions of a pharmacy and retail sale of medicinal products is carried out in compliance with the requirements of the legislation regarding the quality of medicinal products, including those intended for clinical research, during their production, transportation, storage, wholesale and retail trade.

Activities of storage of medicinal products during production (manufacturing) of medicinal products in the conditions of a pharmacy and retail trade of medicinal products are carried out in compliance with the requirements of Good storage practices.

A business entity engaged in the production (manufacturing) of medicinal products in a pharmacy must ensure:

- conformity of the material and technical base, the availability of production and auxiliary premises for the production (manufacturing) of medicinal products and storage of raw materials, intra-pharmaceutical preparations, concentrates, semi-finished products, medicinal products produced (manufactured) in stock, all produced (manufactured) medicinal products by their physic and chemical properties and

requirements of The State Pharmacopoeia of Ukraine (SPhU), other regulatory documents;

- the quality system of medicines, which includes preventive measures, quality control, requirements for employees, premises and equipment, documentation, active substances (substances) and auxiliary substances, packaging, and technological process;
- compliance with sanitary norms and rules, sanitary-hygienic and anti-epidemic regime, and these Rules;
- implementation of all types of quality control of produced (manufactured) medicinal products;
- serviceability and accuracy of all measuring equipment through regular metrological verification by legislation;
- conducting incoming quality control of active ingredients (substances) and auxiliary substances, and packaging materials by legislation;
- presence of an authorized person;
- the presence of an urgent action plan for removal, if necessary, from the circulation of produced (manufactured) medicinal products with their subsequent utilization or destruction, in particular, those whose expiration date has expired;
- proper storage conditions of produced (manufactured) medicinal products;
- availability of SPhU, technological instructions, and other normative legal acts of the Ministry of Health of Ukraine, which regulate the production (manufacturing) and quality control of medicinal products in pharmacies;
- regular self-inspections, which are part of the quality assurance system;
- consideration of claims for produced (manufactured) and sold medicinal products by the written procedure;
- systematization of reports on adverse reactions and side effects of medicines to identify low-quality medicines and prevent similar cases.

In the production (manufacturing) of medicinal products for oral and external use, it is possible to use ready-made medicinal products, if this is indicated by the doctor in the prescription for individual production.

Medicinal forms consisting of solid individual dry particles of varying degrees of

fineness, produced (manufactured) in pharmacies, must comply with the requirements of the article "Extemporaneous non-sterile medicinal products" of the SPhU.

The technology of production (manufacturing) of medicinal products for infants and children up to one year must ensure their quality by the requirements of regulatory documents. The production (manufacturing) of medicinal products is carried out in aseptic conditions (or using a laminar box) by the SPhU and other normative legal acts of the Ministry of Health of Ukraine according to the rules of the technology of the corresponding medicinal forms. Solutions for internal use for infants and children up to one year are prepared by mass-volume method in sterile purified water or water for injections in aseptic conditions without adding stabilizers or preservatives.

For the production (manufacturing) of intravenous infusion drugs, injection drugs that are not subject to thermal sterilization, it is necessary to use "sterile water for injections".

For the production (manufacturing) of eye drops, which are subject to further thermal sterilization, it is necessary to use "purified water in containers".

For the production (manufacturing) of drops and lotions that are not subject to sterilization, "purified water" sterile or "water for injections" is used.

All active ingredients (substances) must be stored in original containers in storage rooms (areas) until the integrity is violated, and after opening the containers - in specially designated clean rooms (areas), which can be equipped in the assistant room - in glass bottles (shtanglasses), which must be clean (washed and sterilized) and marked accordingly.

On all glass bottles (shtanglasses) with active ingredients (substances) and auxiliary substances contained in storage rooms, it is necessary to indicate their name, country, name of the manufacturer, serial number of the manufacturing plant, analysis number of the certified laboratory, expiration date, date of filling of the glass bottles and signature of the person, which filled it.

All glass bottles with active ingredients (substances) and auxiliary substances in the assistant's office must have the date of filling, and signatures of the persons who filled in and checked the identity of the substance.

The percentage of moisture should be indicated on the glass bottles with active ingredients (substances) and auxiliary substances that contain moisture, and on the cylinders with liquids (hydrogen peroxide solution, formaldehyde solution, ammonia solution, etc.) - the actual content of the active substance.

Bottles with solutions, tinctures, and liquid semi-finished products, if necessary, are provided with normal droppers or pipettes. The number of drops in the specified volume is determined by weighing and noted on the glass bottles. Small quantities of liquid medicines, which are indicated in the prescription in standard drops, should be measured with an empirical dropper (eye dropper) calibrated for the corresponding liquid.

All utensils used in the production (manufacturing) of medicines must be washed by the requirements of the Ministry of Health order No. 275, sterilized, sealed, and stored in tightly closed cabinets.

The storage period of sterile dishes used in the production (manufacturing) of non-sterile medicinal products is no more than three days. Containers and lids that meet the requirements of the SPhU and the technical documentation for them should be used for packaging injection and intravenous infusion drugs. The term of storage of sterile dishes (including cylinders) used for the production (manufacturing) and packaging of medicinal products in aseptic conditions is no more than 24 hours. The results of sterilization are recorded in the registration log of sterilization of medicines, auxiliary materials, dishes, etc.

The production (manufacturing) of a series of medicinal products, intra-pharmacy preparations, and medicinal products for stock in pharmacies is carried out by technological instructions.

Medicinal products produced (manufactured) in the pharmacy are released only after their quality has been checked and permission for sale has been granted by an authorized person, and in the absence thereof - by other employees.

During the production (manufacturing) of medicinal products in pharmacies, the business entity provides:

- Conducting incoming quality control of active ingredients (substances), medicinal plant raw materials, and auxiliary materials, namely: checking accompanying documents, invoices, manufacturer's quality certificates, data on registration status, etc. For imported medicinal products, a conclusion regarding the quality of the medicinal product imported into Ukraine is mandatory.

- Carrying out constant control over the content of all prescriptions and orders of medical and preventive institutions received by pharmacies, correctness of registration, compatibility of ingredients included in the composition of medicinal products, and conformity of prescribed doses taking into account the age of the patient.

- Implementation of serial production (manufacturing) of medicinal products, which are produced (manufactured) in reserve, according to previously developed and approved technological instructions.

- Quality control of medicinal products by the regulatory acts of the Ministry of Health of Ukraine.

- Microbiological control with a sampling of air, purified water and water for injections, washes from equipment and equipment, hands and clothing of personnel directly involved in the technological process of production (manufacturing) of medicinal products, pharmacy utensils, and produced (manufactured) medicinal products, which should be carried out in the order of scheduled supervision once a quarter.

The following are included in the in-pharmacy control of medicines according to the SPhU:

written, survey, organoleptic, physical, chemical, and release control by the requirements of regulatory documents.

All medicines produced (manufactured) according to a doctor's prescription for a specific patient or by order of medical and preventive institutions must be subject to organoleptic (visual), written survey control, and control upon release. They are usually not subject to physical and chemical control, they are prepared under the supervision of a responsible person.

Physical and chemical control is mandatory for medicines produced

(manufactured) according to a doctor's prescription for a specific patient or according to the orders of medical and preventive institutions containing potent, poisonous, narcotic, psychotropic substances, and electronic devices for infants and children under one-year-old. As an exception, the production (manufacturing) of medicines for babies and children under one year according to complex prescriptions, aromatic waters, and in-pharmacy preparations of medicines for external use containing tar, ichthyol, sulfur, naphthalene oil, collodion, etc., the control of which cannot be carried out in the conditions pharmacies, is conducted in the presence (under the supervision) of a pharmacist-analyst.

Written control consists of filling out from memory the written control passport (hereinafter - WCP) immediately after the production (manufacturing) of the medicines.

The entry in the WCP reflects the technology (the order of introduction of the ingredients) and is executed in Latin by the person who produces (manufactures) the medicinal product.

The date, prescription number (requirements), substances taken, and their quantity are indicated in the WCP; total mass or volume of the dosage form, number of doses; the signature of the person who produced (manufactured), packaged, and checked the medicinal form is affixed.

When using semi-finished products and concentrates, their concentration, quantity taken, and series are indicated in the WCP.

In the production (manufacturing) of powders and suppositories, the mass of individual dosage units and their number are indicated. The amount of suppository mass is indicated both in the WCP and in the recipe.

If the medicinal product includes poisonous, narcotic, psychotropic substances and substances that are subject to quantitative accounting, as well as when the medicinal product is produced (manufactured) according to a prescription that provides for the dispensing of the medicinal product free of charge or on preferential terms, the WCP is filled out on the back of the prescription, that remains in the pharmacy. In the WCP, the coefficients of water absorption used in the calculation for medicinal plant raw materials, and the coefficients of the increase in the volume of aqueous solutions when dissolving

medicinal substances are indicated.

WCP is stored in the pharmacy for two months.

Produced (manufactured) medicines, prescriptions, and completed WCP are handed over to the responsible person for verification. The control consists of checking compliance with the rules of the technology, compliance of the entries in the WCP with the prescription in the recipe, and the correctness of the calculations. If an error is detected, the medicines are subject to physical and chemical control. In the absence of methods of analysis, medicines are manufactured (manufactured) anew. If physical and chemical control of medicines is carried out, then the analysis number and the signature of the person who conducted the analysis are inserted in the WCP.

In the production (manufacturing) of injectable medicinal products and intravenous infusion medicinal products, all stages of production and quality control are registered in individual registration logs for infusion drugs.

In the production (manufacturing) of concentrates (semi-finished products), intra-pharmacy preparation, and packaging of medicinal products, all records are made in the journal of registration results control medicines, produced (manufactured) in pharmacies, intra-pharmacy blanks, and ethyl alcohol.

Extemporaneous powders for external and oral use must meet the requirements of the general articles of the SPhU "Powders for external use" and "Powders for oral use".

When conducting a survey control, the responsible person names the first ingredient that is included in the medicines and its quantity, after which the person who carried out the production (manufacturing) names all the ingredients taken by him for the production (manufacturing) of the medicines and their quantities, and when using semi-finished products (concentrates) also names their composition and concentration. If an error is made, the medicines are subject to physical and chemical control. In the absence of methods of analysis, medicines are manufactured anew.

Organoleptic control consists of checking the appearance, color, smell, homogeneity of mixing, the absence of mechanical inclusions in the test conditions, and the quality of the plugging of the medicines.

Physical control consists of checking the total weight or volume of the electronic

device, and the number and weight of individual dosage units (at least three doses.

Chemical control consists of the identification and determination of the quantitative content of substances included in the composition of electronic devices. Chemical control is carried out according to pharmacopoeial methods.

Identification is subject to:

- medicines for a specific patient or by order of a medical and preventive institution containing potent, poisonous, narcotic, psychotropic substances, and medicines for infants and children under one-year-old;

- concentrates (semi-finished products) and liquid medicinal products in a burette unit and dipsticks with empirical droppers in the filling station, including matrix tinctures, triturations, solutions, dilutions, as well as each series of medicinal products packaged in a pharmacy. The results of the analyses are registered in the journal.

The following are subject to identification and quantitative analysis:

- all injection and intravenous infusion drugs before and after sterilization (stabilizing substances are determined before sterilization);

- eye drops and ointments according to individual prescriptions containing poisonous substances;

- all dosage forms for infants and children up to one-year-old (in the absence of methods of quantitative analysis). These dosage forms must be verified by qualitative analysis. As an exception, the production (manufacturing) of dosage forms for infants and children under one year, complex in composition, which do not have methods of identification and quantitative analysis, is carried out in the presence (under the supervision) of a pharmacist-analyst or a pharmacist;

- solutions of hydrochloric acid (for internal use), atropine sulfate and silver nitrate;

- all concentrated solutions, semi-finished products, medicinal products made for stock, intra-pharmacy preparation (each series);

- concentration of ethyl alcohol in water-alcohol solutions (determined by alcohol meter or refractometric method);

- stabilizers used in the production (production) of solutions for injections and

buffer solutions for eye drops.

The results are recorded in the log. All cases of low-quality production (manufacturing) of medicinal products are recorded in this journal. Low-quality medicinal products based on the decision of an authorized person are removed from "Quarantine", disposed of, or destroyed by the procedure established by law.

Control at release is carried out for all medicines.

Control during release consists of checking compliance:

- medicines packaging - physicochemical properties of the ingredients included in its composition;

- registration of medicines - according to the requirements of regulatory documents;

- doses specified in the prescription poisonous, narcotic, psychotropic, and potent substances - the patient's age;

- prescription numbers and label numbers; the name of the patient on the receipt and the name on the label, in the prescription or its copy;

- the composition of the medicines specified in the WCP in the prescription.

The person who dispensed the medicine must put his signature and the date of dispensing on the back of the prescription (order) and in the WCP.

Two terms are used to assess the quality of a medicinal product:

"Satisfactory" or "Not satisfactory".

Dissatisfaction with medicines is determined by non-compliance with one of the types of internal pharmacy control.

PRACTICAL ASSIGNMENTS

Task 1. In pharmacy No. 1 in Zaporizhzhia during the working day 15 medicines were produced. Specify which of them is mandatory subject to physical or full chemical control. To complete the task, you need to fill in table 1.

Table 1 The need for physical and chemical control

No	Medicines	Physical control	Chemical control
1	Atropine sulfate solution 1% - 10.0 eye drops		
2	Novocaine solution 2% - 20.0 for external use		
3	Hydrochloric acid solution 1% for internal use		
4	Glucose solution 5% - 100.0 for newborns for internal application		
5	Hydrogen peroxide solution 3% - 30.0 for external use		
6	Ethylmorphine hydrochloride eye ointment 10% - 10.0		
7	Kvater potion for internal use		
8	Lugol's solution (water) for external use		
9	Eye drops with chloramphenicol 0.25% - 10.0 60		
10	Sodium sulfacyl solution 20% - 10.0 eye drops		
11	Furacilin solution 0.02% - 100.0 for external use		
12	Silver nitrate solution 1% - 10.0 for external use		
13	Powders with sodium ethaminal 0.01 No. 10 for for internal use		
14	Atropine sulfate solution 0.1% - 10.0 for internal use		
15	Potassium permanganate solution 1:5000 - 200.0 for external use		

Task 2. Characterize and describe the main components of a written control passport

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After completing the practical task, the student should acquire practical skills and abilities:

- search and systematization of regulatory legal acts that regulate essential types of in-pharmacy quality control of drugs;
- rules for the production of extemporaneous medicinal products;
- production (manufacturing) of intrapharmacy preparations;
- internal pharmacy quality control of medicines.

SELF-CHECK TESTS

1

During the working day, the pharmacist prepares medicines. Which of them requires full chemical control?

A. **Glucose solution 40% for injections**
B. Ethonium solution 2% for external use
C. Mixture Pavlov
D. Anti-inflammatory liniment
E. Antipruritic ointment

2

A pharmacy with the right to manufacture sterile drugs that received the goods from the supplier. For which medicinal products a certificate of laboratory analysis is mandatory:

A. **Substances intended for the manufacture of ophthalmic dosage forms**
B. Products for medical purposes
C. Medicinal cosmetics
D. Biologically active supplements
E. Baby food

3

The pharmacy has a license to manufacture sterile medicinal products. Who is responsible for organizing the operation of the aseptic block and preparation of sterile medicinal products?

A. **The head of the pharmacy**
B. Pharmacist-analyst
C. Reception pharmacistprescriptions and release of medicinal products
D. Authorized person
E. Pharmacist

4

Pharmacy enterprise No. 1 has a licensefor the production of medicinal products according to doctors' prescriptions. What types of internal pharmacy quality control are mandatory for all medicinal products manufactured in the pharmacy?

A. **Written, organoleptic, survey, release control**
B. Chemical, physical
C. Questionnaire, written, chemical
D. Physical, organoleptic
E. Control upon release, written, survey

5

An internal document of the business entity must be developed for medicinal products that are produced in a pharmacy in series and are subject to sale, namely:

A. **Technological instruction**
B. Quality certificate
C. Analysis of medical form
D. Medical device register
E. Regulatory documentation

6

The pharmacy had a question about the sterile storage periodutensils used for individually manufactured non-sterile medicines. Name the term of storage of such dishes:

A. **No more than 3 days**
B. 36 hours
C. No more than 2 days
D. 24 hours
E. Unlimited

7

The pharmacist of the pharmacy makes medicinal forms with poisonous substances. Their stocks in the assistance room should not exceed:

A. **Five-day needs**
B. One-day needs
C. Two-day needs
D. Three-day needs
E. Ten-day needs

8

The pharmacy has a license for the right to manufacture medicines. Specify the document in which accepted prescriptions for individually manufactured medicinal products are accounted for:

A. **Recipe journal or receipt book**
B. Cash book
C. Reversible information
D. Accounting book of settlement transactions
E. Register of tax invoices

9

A student-intern asked the manager of the pharmacy to explain the structure of the retail price of individually prepared medicines. This price consists of:

A. **Costs of ingredients, packaging and tariff**
B. Costs of ingredients and packaging
C. Costs of ingredients and profit
D. Valuespackaging and tariff
E. Prices of ingredients and trade markup

10

The pharmacy prepares extemporaneousmedicinal products. Indicate who sets the retail prices and tariffs for manufactured medical products?

A. **By the pharmacy independently**
B. By the Regional State Administration
C. By the Price Inspection
D. Inspectionon quality control of medicines by the Ministry of Health

TOPIC 8
ORGANIZATION OF SUBJECT-QUANTITATIVE ACCOUNTING OF MEDICINAL PRODUCTS

Student should know: organization and documentation of subject-quantitative accounting (SQA) in the pharmacy.

Basic terms and concepts: subject-quantitative accounting of medicines, narcotics, psychotropic substances, precursors, poisonous medicines, potent medicines.

QUESTIONS

1. Characteristics of the legislative and regulatory framework that regulates the circulation of narcotic and psychotropic drugs and precursors.

2. The procedure for licensing economic activity in the circulation of narcotic drugs, psychotropic substances and precursors.

3. State regulation of circulation of narcotic drugs, psychotropic substances and precursors.

4. Rules for prescribing narcotic (psychotropic), potent and poisonous drugs and precursors.

5. Features of storage and transportation of narcotic (psychotropic) drugs and precursors.

SELF-CHECK QUESTIONS

1. Specify the rules for prescribing narcotic and psychotropic drugs, precursors.

2. Specify the rules for prescribing poisonous and potent drugs.

3. Specify the rules for issuing prescriptions for medicinal products that are subject to subject-quantitative accounting free of charge and on preferential terms.

4. Specify the rules for writing prescriptions for medicinal products that are subject to subject-quantitative accounting and are manufactured in the conditions of a pharmacy.

5. Explain the procedure for storing and accounting for prescription forms.

6. Specify the order of destruction of prescription forms.

7. Give examples of narcotic drugs, psychotropic substances and precursors of list № 1.

8. Name poisonous and potent drugs.

9. State the norms for one-time dispensing of medicines that are subject to SQA.

10. Documentation of subject-quantitative accounting in the pharmacy.

OVERVIEW

Control over activities related to the circulation of narcotic drugs, psychotropic substances and precursors is carried out by the relevant state bodies within the limits of the powers defined by the laws of Ukraine.

State quality control of medicinal products during their wholesale and retail trade is carried out by the central executive body, which implements state policy in the areas of quality control and safety in the circulation of narcotic drugs, psychotropic substances and precursors, combating their illegal circulation, and its territorial bodies during inspections economic entities, regardless of their organizational and legal form and form of ownership, which are engaged in wholesale or retail trade of medicinal products, to check their compliance with the requirements of the legislation on ensuring the quality of medicinal products.

Rules for prescribing narcotic (psychotropic) medicinal products and precursors.

Prescriptions for narcotic (psychotropic) medicinal products in their pure form or mixed with indifferent substances are written on special prescription forms of form No. 3 (f-3).

Special prescription blanks of form No. 3 (f-3) are made on pink paper measuring 75x120 mm, numbered through. Control over their accounting and use is entrusted to the responsible person, who is appointed by order of the business entity.

In case of prescription of narcotic (psychotropic) drugs free of charge, with additional payment or on preferential terms, together with the Prescription on form f-3, a Prescription on form f-1 is also issued.

Prescription combined medicinal products containing narcotic drugs,

psychotropic substances or precursors in an amount that does not exceed their maximum permissible rate are prescribed by medical workers on prescription forms f-1.

It is forbidden to prescribe in one Prescription f-1 combined medicinal products, in the composition of which the amount of narcotic drugs, psychotropic substances or precursors exceeds the maximum permissible amount.

In case of receipt of these drugs in original packages containing narcotic drugs, psychotropic substances or precursors in an amount exceeding their maximum permissible norm, it is allowed to prescribe 1 package of medicinal product in 1 Prescription, but no more than 50 tablets.

Prescriptions for medicinal products issued on special prescription forms form No. 3 (f-3) are valid for ten days from the date of issuance.

The validity period of the electronic prescription corresponds to the validity period of the Prescription written on the prescription form form No. 3 (f-3).

One name of the medicinal product is prescribed in the case of prescribing: medicinal products on a special prescription form No. 3 (f-3); when prescribing narcotic (psychotropic), poisonous and potent drugs in doses exceeding higher single doses, the medical worker is obliged to write the dose of this drug in words and put an exclamation mark.

Rules for filling out a special prescription form No. 3 (f-3)

1. In the upper part of the form for health care institutions, the name of the health care institution, its location, the number and date (number, month, year in numeric format) of the issuance of a license for conducting economic activity from medical practice or the number and date are indicated (number, month, year) decision of the licensing authority to issue a license for conducting business activities in medical practice;

2. In the upper part of the form for the sole proprietor, the surname, first name and patronymic of the sole proprietor, whose doctor prescribes the Prescription, the location (place of activity) of the sole proprietor, the registration number of the taxpayer's registration card or series (if available) and the passport number (for individuals, who, due to their religious beliefs, refuse to accept the registration number of the tax payer's

registration card and have notified the relevant supervisory body about it and have a mark in their passport), the number and date (number, month, year in numeric format) of the issuance of a license to conduct economic activity in the field of medical practice or number and date (number, month, year) of the licensing authority's decision to issue a license for medical practice business activity;

3. In the "Prescription" part, the series and number, the date (month, month, year) of the prescription, the name, initials and age of the patient, the card number of the outpatient or inpatient patient are indicated;

4. The Prescription contains the name and initials of the doctor who writes the Prescription. The prescription is certified by the doctor's signature and personal seal.

5. It is forbidden to certify prescription forms that have not been filled in and not signed by a doctor with a doctor's seal;

6. In the "Place of marking" column, the markings "Chronicly ill", "For special purpose" are indicated, which are additionally certified by the doctor's signature and seal on the paper prescription forms.

Table 1. Norms for dispensing prescription drugs

The name of the medicinal product	The maximum allowable amount of the product for dispensing per Prescription
Amfepramon (fepranon)	
dragee 0.025 g	50 dragees
Buprenorphine	
tablets 0.2 mg	0.017 g
tablets 0.4 mg	0.017 g
tablets 2 mg	0.112 g
tablets 4 mg	0.112 g
tablets 8 mg	0.112 g
ampoules 0.3 mg - 1 ml	20 amp.
ampoules 0.6 mg - 2 ml	10 amp.
transdermal patch	10 patches regardless of dosage
tablets 5 mg, 15 mg, 30 mg, 60 mg	12 tables
Morphine	
tablets 5 mg	40 tables
tablets 10 mg	20 tables
oral solution 2 mg / 1 ml	100 ml
ampoules 1% - 1 ml	10 amp.
Sodium oxybutyrate and others salts of oxybutyric acid	
ampoules 20% - 5, 10 ml	10 amp.
bottles of 66.7% - 50 ml	1 fl.
Omnipon	
ampoules of 1 ml	10 amp.
Psychotropic drugs*	10–12 tables, 10 amps.
Trimeperidine hydrochloride	
ampoules 20 mg/ml	10 amp.
tablets 25 mg	10 tables
Triazolam (halcyon)	
tablets 0.25 mg	30 tables
Ethylmorphine hydrochloride**	
tablets 10 mg, 15 mg	0.2 g of the total amount of ethylmorphine on an anhydrous basis
Prosidol	
tablets 25 mg	10 tables
ampoules 1% - 1 ml	0.25 g of the total amount of prosidol on an anhydrous basis

Tramadol (international non-proprietary name)	
capsules, tablets 0.05 g	30 caps., tab.
ampoules 5% - 1 ml	10 amp.
ampoules 5% - 2 ml	10 amp.
drops of 0.1 g in 1 ml	1 fl. 50 ml
rectal suppositories 0.1 g	20 candles
Atropine and its salts, powder	0.01 g
Tetracaine, powder	1 g
Trihexyphenidyl	0.12 g
Atracurius	0.05 g
Vecuronium	0.004 g
Pipecuronium	0.004 g
Rocuronium	0.05 g
Suxamethonium	0.1 g
Butorphanol (Moradol, etc.)	0.008 g
Diphenhydramine (diphenhydramine), solid forms	2.1 g
Zopiclone	0.075 g
Clonidine (Clofelin), substance, liquid forms	0.015 g
Methandienone	0.05 g
Nandrolone	0.05 g
Promethazine	0.5 g
Hydromorphone hydrochloride	21 table.
Fentanyl in the form of transdermal therapeutic systems with a prolonged effect	10 patches regardless of dosage
Methadone	
tablets 5 mg, 10 mg, 25 mg, 40 mg	1 g
liquid forms, 1 mg in 1 ml	0.3 g
Codeine (codeine phosphate), tablets	2.1 g
Oxycodone	
tablets 10 mg	20 tables
tablets 20 mg	20 tables
tablets 40 mg	10 tables
tablets 80 mg	10 tables

* Classified as psychotropic drugs according to by law of Ukraine "On narcotic drugs, psychotropic substances and precursors".

** Ethylmorphine hydrochloride can be prescribed in eye drops and ointments in the amount of up to 1 g if there is an indication of a medical professional on the prescription "For special purpose".

Table 2. Norms of the maximum permissible quantity of a narcotic drug, psychotropic substance, precursor in the composition of a combined medicinal product for dispensing

Name of narcotic drug, psychotropic substance, precursor	The maximum allowable amount for release in the composition of the narcotic (psychotropic) of combined medicinal product for 1 prescription
Codeine	0.2 g
Dextropropoxyphene	0.6 g
Phenobarbital	1 g
Ephedrine hydrochloride	0.6 g
Pseudoephedrine	0.6 g
Phenylpropanolamine	0.6 g
Ergotamine	0.02 g
Ergometrine	0.002 g

According to the order of the Ministry of Health dated 17.08.2007 No. 490 "On approval of the Lists of poisonous and potent medicinal products", medicinal products included in the following lists are subject to quantitative accounting.

Table 3. List of potent drugs by international non-proprietary or common names

Butorphanol (Moradol, etc.)*	Butorphanol (Moradol)
Diphenhydramine (diphenhydramine) (solid forms)	Diphenhydramine (Dimedrolum)
Zopiclone	Zopiclone
Clonidine (Clofelin) (substance, liquid forms)	Clonidine (Clophelinum)
Matandienone	Methandienone
Nandrolone	Nandrolone
Promethazine	Promethazine

* In addition to the first-aid kits of vehicles, which include a solution of butorphanol tartrate for injections of 0.2% at 1 ml in syringe tubes

Table 4. List of poisonous medicinal products by international non-proprietary or common names

Atropine and its salts (powder)	Atropine
Ketamine	Ketamine
Tetracaine (powder)	Tetracaine
Trihexyphenidyl	Trihexyphenidyl
Myorelaxants of peripheral action, including their salt derivatives:	
Atracurius	Atracurium
Vecuronium	Vecuronium
Pipecuronium	Pipecuronium
Rocuronium	Rocuronium
Suxamethonium	Suxamethonium

Features of storage and transportation of narcotic (psychotropic), potent and poisonous substances, precursors

Strong, poisonous substances, narcotic, psychotropic substances and precursors or products containing them should be stored in safe and protected areas in accordance with the requirements established by law. For powerful, poisonous substances, narcotics, psychotropic substances and precursors or products containing them, subject-quantitative accounting should be kept at all stages of production.

Storage of medicines that contain narcotic, psychotropic substances and precursors, is carried out with a license in accordance with point 22 of the first part of Article 7 of the Law of Ukraine "On Licensing Types of Economic Activities": cultivation of plants included in Table I the list of narcotic drugs, psychotropic substances and precursors approved by the Cabinet of Ministers of Ukraine, development, production, manufacture, storage, transportation, acquisition, sale (issuance), import into the territory of Ukraine, export from the territory of Ukraine, use, destruction of narcotic drugs, psychotropic substances and precursors included in the specified list.

Narcotic drugs, psychotropic substances and precursors are transported in accordance with the requirements of the legal acts that regulate their circulation in Ukraine.

Importation and further circulation on the territory of Ukraine of medicinal

products containing narcotic, psychotropic substances and precursors, are carried out with a license in accordance with point 22 of the first Article 7 of the Law of Ukraine.

"On licensing types of economic activity" (cultivation of plants included in Table I the list of narcotic drugs, psychotropic substances and precursors approved by the Cabinet of Ministers of Ukraine, development, production, manufacture, storage, transportation, acquisition, sale, import into the territory of Ukraine, export from the territory of Ukraine, use, destruction of narcotic drugs, psychotropic substances and precursors included in the specified list).

Instructions on the procedure for storage, accounting and destruction of prescription forms

1. Health care institutions and natural persons - entrepreneurs conducting economic activity from medical practice receive special prescription forms No. 3 (f-3) - through pharmacy warehouses (bases), pharmacies or structural subdivisions of local state health care administrations

2. Prescription forms f-3 are stored by the responsible person of the business entity in locked drawers or safes.

3. The order of the business entity appoints a person who ensures the storage, accounting, issuing of prescription forms, and/or determines the procedure for authorizing employees to issue electronic prescriptions in the information (information and telecommunications) system.

Accounting for special prescription forms No. 3 (f-3) is kept in accordance with forms primary accounting documentation No129-12/o "Journal of registration special prescription forms form No. 3 (f-3) in healthcare institutions", approved by the order of the Ministry of Health of Ukraine dated August 7, 2015 No. 494.

1. The economic entity and medical workers who prescribe medicinal products on prescription forms ensure the safety of these forms.

2. The stock of prescription forms f-1 and special prescription forms form f-3 for the current needs of the business entity cannot be less than one month's need for them.

3. When a medical worker is dismissed, the remaining prescription forms are returned to the place of receipt.

4. The term of storage of the upper part of the prescription form No. 1 (f-1) along the tear-off line or electronic prescription in the information system of the business entity after the prescription is issued is three years (not including the current year).

5. After the end of each quarter, financially responsible persons compile registers of prescriptions (f-3) for narcotic (psychotropic) medicinal products dispensed according to prescriptions on forms No. 3 (f-3) (in paper form) according to which narcotic drugs and psychotropic drugs were dispensed substances (Registers of recipes), which are stored together with recipes (f-3) for the corresponding quarter before their destruction.

6. F-3 electronic prescriptions received by the pharmacy using electronic means are recorded in the Prescription Register, which is created electronically and stored in the pharmacy's information system for five years with the possibility of reproducing the Prescription Register in paper form. Pharmacies can compile in electronic form Registers of prescriptions, which include prescriptions f-3 as in paper, as well as in electronic form (generalized registers) for released narcotic (psychotropic) medicinal products. Generalized registers are stored in the information system of the pharmacy for five years with the possibility of reproducing such registers in paper form.

7. Spoiled prescription forms f-1 and f-3, as well as prescriptions of form No. 3 (f-3) and form No. 1 (f-1), according to which narcotic drugs, psychotropic substances were dispensed in pharmaceutical (pharmacy) healthcare institutions, after the expiration of the storage period are subject to destruction in a way that makes their further use impossible, with the drawing up of an act of destruction of damaged prescription forms

8. No. 1 (f-1) and form No. 3 (f-3) of business entities conducting economic activity from medical practice, or prescriptions according to which narcotic drugs, psychotropic drugs were dispensed in pharmaceutical (pharmacy) health care institutions substances

REGISTER OF RECIPES (f-3),

according to which narcotic drugs and psychotropic substances were released for _____–_____20 _ year (month)

No	The name of the health care facility whose doctors wrote the prescription	Series and recipe number	Prescription date	The name of the narcotic or psychotropic medicinal product issued by prescription

Employee of pharmacy, which is responsible for accounting and storage of narcotics, psychotropic substances _____

(surname, initials)

_____

(signature)

_____ 20_year

PRACTICAL ASSIGNMENTS

Task 1. Indicate to which group these medicines belong. For this, it is necessary to fill in table No. 1

No.	Medicines	narcotic	potent	poisonous	OTC
1	Zopiclone				
2	Morphine				
3	Diphenhydramine (diphenhydramine) (solid forms)				
4	Paracetamol				
5	Tramadol				
6	Phenazocine				
7	Clonidine (Clofelin) (substance, liquid forms)				
8	Laevomicolum oilment				
9	Ketamine				
10	Proheptazine				
11	Trihexyphenidyl				
12	Ibuprofen				
13	Tetracaine (powder)				
14	Matandienone				
15					

Task 2. Describe and characterize the use of prescription form No. 3 and list the main drugs that can be prescribed on this form.

characteris

After completing the practical task, the student should receive practical skills and abilities:

- legislative acts regulating subject-quantitative accounting medicines in pharmacies;
- lists of drugs subject to subject-quantitative accounting;
- organization of subject-quantitative accounting in pharmacies.

SELF-CHECK TESTS

1

The pharmacy is engaged in the retail sale of medicines. Specify the accounting group to which omnipon belongs?

A. **Narcotic drugs**
B. Psychotropic drugs
C. Poisonous drugs
D. Potent drugs
E. Drugs of the general list

2

The inspector checks the correctness of circulation of narcotic drugs, psychotropic substances and precursors. What is the storage period in the pharmacy of the "Logbook of narcotic drugs, psychotropic substances and precursors in pharmaceutical (pharmacy) establishments"?

A. **5 years**
B. Not stored
C. Three years
D. Four years
E. Two years

3

A poisonous medicinal product, which is subject to objective and quantitative accounting, is prescribed free of charge to the patient upon discharge:

A. **In 2 copies on form F-1**
B. In 2 copies on form F-3
C. On form F-3
D. On the F-1 form
E. On form F-3 and form F-1

4

A doctor wrote a prescription for codeine powder to a disabled person from the Great Patriotic War. What is the maximum permissible amount of codeine in the composition of the combined dosage form that can be dispensed under 1 prescription?

A. **0.2 g**
B. 1.0 g
C. 0.6 g
D. 1.2 g
E. 0.1 g

5

In pharmacies, subject-quantitative accounting of some groups of medicines is carried out. Specify the drug that belongs to the narcotic group:

A. **Ethylmorphine hydrochloride**
B. Dikain
C. Analgin Defedrine
D. Clofelin

6

In pharmacies, subject-quantitative accounting of some groups of medicines is carried out. Specify the drug belonging to the psychotropic group:

A. **Elenium (ampoules, tablets) (chlordiazoxide)**
B. Promedol
C. Omnipon
D. Opium medical
E. Atropine sulfate

7

A visitor came to the pharmacy with a prescription for Tramadol tablets. Specify

the shelf life of such a prescription in the pharmacy:

A. **5 years, excluding current**

B. year, excluding current

C. 6 months, excluding current

D. 10 years, excluding current

E. month, excluding current

8

Ethylmorphine hydrochloride belongs to drugs with standardized release. What is the maximum amount of it that can be dispensed by prescription as part of eye drops or ointment "For a special purpose"?

A. **up to 1 g**

B. up to 2 g

C. up to 0.5 g

D. up to 1.5 g

E. up to 3 g

9

The pharmacy has a license to sell narcotic drugs. What is the validity period of the power of attorney for obtaining these drugs from the pharmacy?

A. **The term of validity is set in the power of attorney by the business entity**

B. No more than 1 calendar month from the day of the statement

C. No more than 1 calendar day from the day of discharge

D. No more than one year from the day of discharge

E. No more than 5 calendar days from the day of discharge

10

A visitor came to the pharmacy with a prescription for Tramadol tablets. Specify the shelf life of such a prescription in the pharmacy:

A. **5 years, excluding current**

B. year, excluding current

C. 6 months, excluding current

D. 10 years, excluding current

E. month, excluding current

TOPIC 9
ORGANIZATION OF OVER-THE-COUNTER MEDICINES

Student should know: the main principles of the organization of over-the-counter (OTC) medicines in Ukraine.

Basic terms and concepts: OTC drugs, self-medication, pharmaceutical guardianship, compliance, pharmaceutical-equivalent drugs, bioequivalent drugs, original drug, generic drugs.

QUESTIONS

1. Organization of over-the-counter medication in Ukraine. Legislative and regulatory framework regulating over-the-counter medication in Ukraine.

2. Responsibilities and rights of a pharmacist in dispensing drugs without a prescription. Procedure for dispensing over-the-counter medicines from pharmacies.

3. Criteria for determining the categories of drug release.

4. The concept of responsible self-treatment: prerequisites for the emergence, essence, meaning. The concept of compliance.

5. The essence, conditions and procedure of pharmaceutical guardianship.

SELF-CHECK QUESTIONS

1. Name the category of drugs and the criteria for classifying them as OTC drugs.

2. List the main requirements for over-the-counter drugs.

3. Describe the legislative framework that regulates the lists of drugs allowed for use and dispensed without a prescription in Ukraine.

4. Name the peculiarities and problems of over-the-counter dispensing of drugs from pharmacies and their structural subdivisions on the territory of Ukraine.

5. Procedure for organizing the work of the over-the-counter department.

6. Specify the features of the use of OTC drugs, the rights and duties of a pharmacist in dispensing drugs without a prescription.

7. List the socio-economic prerequisites for the emergence of the concept of responsible self-medication.

8. Describe responsible self-medication and its importance in modern pharmaceutical practice.

9. Describe pharmaceutical guardianship: definition, essence and conditions necessary for its quality implementation.

10. Give the algorithm of actions of a pharmacist who provides pharmaceutical guardianship when dispensing an over-the-counter drug. List the categories of patients that require his increased attention.

OVERVIEW

Over-the-counter drugs (OTC) or without a prescription drugs — a large group of drugs that a patient can buy for self-treatment directly at a pharmacy (and some drugs — and not only at a pharmacy) without a prescription doctor They reach the patient directly from the hands of the pharmacist, bypassing the doctor. OTC drugs is an integral part and at the same time a necessary condition for the successful development of the concept of self-treatment.

They are represented by various pharmacological groups: analgesics, antipyretics, antacids, antihistamines, antitussives, etc. Among them, there is a sufficient number of drugs that can cause significant side effects, especially when they are used irrationally.

OTC drugs must therefore have:

a) low general toxicity, not affect reproductive function, do not show genotoxic or carcinogenic effects;

b) a low degree of risk of severe adverse reactions of type A in the general population;

c) a very low degree of risk of severe adverse reactions of type B; absence of interactions with widely used drugs, which can lead to severe adverse reactions.

It is very important that the risk to the health of consumers is insignificant, even if the consumer uses OTC drugs off-label or using it for a longer period than recommended, exceeding the recommended dose, etc.

OTC drugs particular importance is evidence of their safe use in those groups of patients who usually do not participate in clinical trials, e.g. in the elderly, children, some ethnic groups and patients with certain pathological conditions.

So that the risk to the health of consumers is insignificant, even if the consumer uses OTC drugs off-label or using it for a longer period than recommended, exceeding the recommended dose, etc.

The list of drugs allowed for self-medication may differ significantly in different countries depending on existing health care systems and socio-economic conditions. However, the criteria for the selection of such drugs should be common to everyone and be based on reliable data, therapeutic breadth, and their cost. According to the provisions of the EU Council Directive of November 6, 2001, all drugs must be available for dispensing, except for those dispensed from a pharmacy by prescription.

In practice, it is very important that the patient can objectively assess his condition or symptoms, for which the corresponding OTC drugs is indicated, in order to use it without medical supervision. This means that the consumer must be able to exclude conditions for the treatment of which OTC drugs are not suitable, but are similar to those for which the use of this drug is indicated.

It is also necessary to take into account the availability of relevant sources of information, with the help of which the consumer will be able to distinguish similar conditions (printed products, the possibility of taking advice from a pharmacist or other medical professionals). In this regard, contraindications, interactions with other drugs, warnings and cautions regarding its use should be presented in a form accessible to the consumer.

In Ukraine, work on creating a legislative framework for licensing and a civilized market for the sale of OTC drugs has been carried out since the first days of its independence.

The Ministry of Health of Ukraine periodically approves the updated List of medicinal products approved for use in Ukraine as over-the-counter.

It should be taken into account that the method of application of over-the-counter and prescription drugs differs, even if the indications for their use are the same or if they

belong to the same therapeutic group.

When making a decision, it is worth bearing in mind that the consumer may consider OTC drugs less dangerous compared to similar prescription. The information contained in the annotation-insert and on the package should contribute to its safe and effective use. The instructions should explain how OTC drugs should be used, and information about this should be presented in an accessible form so that patients can correctly assess the possibility of using OTC drugs. The volume of information should be sufficient so that OTC drugs can be used without supervision by a doctor and allow to prevent the risk of using OTC drugs if it is contraindicated or dangerous.

Contraindication, interactions with other drugs, warnings and cautions should be presented in such a form as to attract the attention of the consumer. In order to minimize the risk and maximize the benefit from the use of OTC drugs, it is necessary to indicate in the annotation-insert and on the package when the drug cannot be used, and this information should be no less detailed than the indications for use.

In addition, the consumer needs to know what to do in case OTC drugs does not give the desired effect or causes an adverse reaction. Therefore, the annotation-insert and on the package should contain recommendations about what actions should be taken, e.g. consult a doctor or pharmacist during the time indicated on the insert or on the package of OTC drugs.

In order to minimize the risk and maximize the benefit from the use of OTC drugs, it is necessary to indicate in the annotation-insert and on the package when the drug cannot be used, and this information should be no less detailed than the indications for use. In addition, the consumer needs to know what to do in case OTC drugs do not give the desired effect or causes an adverse reaction.

Therefore, the annotation-insert and on the package should contain recommendations about what actions should be taken, e.g. consult a doctor or pharmacist during the time indicated on the insert or on the package of medicines.

B.p. intended for symptomatic treatment, as they do not affect the cause and mechanism of disease development. All of them are designed to be used for a relatively short period of time. OTC drugs are used mainly for the treatment of mild conditions

that do not require the intervention of a doctor. The main purpose of their use: to quickly and effectively relieve the symptoms of diseases that do not require medical consultation; under the conditions of financial and personnel difficulties of the state health care sector, to give the patient the opportunity to independently relieve minor symptoms in case of poor health, which reduces the burden on medical services; to increase medical care for the population living in remote regions, where obtaining qualified medical consultations is difficult.

Pharmaceutical guardianship is a comprehensive program of interaction between pharmacist and patient, pharmacist and doctor during the entire period of drug therapy, starting from the moment of drug release until the end of its action. It should be carried out by a pharmacist in close cooperation with other health care professionals (doctors, nurses) and patients.

Pharmaceutical guardianship implies the pharmacist's acceptance of responsibility to a specific patient for the result of drug treatment. In light of the requirements of the Good Pharmacy Practice (GPP), the term pharmaceutical guardianship has been established as the name of the ideology of the practice, which defines the patient and society as the primary users of the pharmacist's activity.

It is legitimate to say that good pharmacy practice is one of the most effective ways of implementing pharmaceutical guardianship.

Pharmaceutical guardianship implies the involvement of a pharmacist (pharmacist) together with a doctor in active activities to ensure health and prevent disease of the population. The duty of the pharmacist is to provide the patient not only with high-quality medicines and medical products, but also to promote their rational use. The basis for proper pharmaceutical guardianship is the pharmacist's professional knowledge and experience, norms of professional pharmaceutical ethics, the pharmacist's relationship with the patient, and his duties.

In order to carry out pharmaceutical guardianship when dispensing over-the-counter drugs in a pharmacy, a pharmacist must perform a number of mandatory actions provided for by GPP requirements.

1. Correctly assess the patient's problem. When a patient asks for a prescription or asks to be dispensed a non-prescribed drug, the pharmacist must receive information that allows for a proper assessment of a specific health problem in a given patient. For this, it is necessary to find out who has the problem (to be able to assess whether the patient belongs to the risk group and use this information in further counseling), what are the symptoms, how long has the illness been going on, whether any measures have been taken, other medical drugs. The pharmacist needs to resolve whether the symptoms are related to a serious health disorder; in such a case, the patient should be referred to a doctor for immediate advice. For a less serious health problem, advice should be given,

2. Provide the patient with an over-the-counter drug(s). A pharmacist should make maximum use of his professional knowledge and experience when choosing over-the-counter medicines, taking into account their effectiveness, safety, quality and economic feasibility. When dispensing an over-the-counter drug, provide complete information about the effect of the drug, the method of its use (how, when, in what doses), duration of treatment, possible side effects, compatibility with other drugs and food.

3. Provide the patient with follow-up. The pharmacist should evaluate the effectiveness of the drug with the help of the patient. The pharmacist should advise the patient to consult a doctor if symptoms persist after a certain period of time. Algorithm of the pharmacist's actions in the implementation of pharmaceutical guardianship during the vacation of over-the-counter drugs for the symptomatic treatment of minor health disorders

According to the rules and recommendations of the GPP, for each symptom or ailment that can be treated independently, there is a separately developed algorithm with which the pharmacist working in the pharmacy must be familiar. In general, the pharmacist's actions in the implementation of pharmaceutical guardianship of patients during the leave of non-prescription drugs can be presented in the form of the following algorithms.

1. Determine which symptom is being treated with the medicinal product.

2. Determine on the basis of the patient's survey whether this symptom is a manifestation of a disease that requires the mandatory intervention of a doctor.

3. Determine the pharmacological (pharmacotherapeutic) group of drugs for the treatment of this symptom.

4. Choose the optimal drug for a given patient among drugs of a certain group.

5. Provide the patient with appropriate information about the selected drug.

Practical functions of the pharmacist, which are necessary for the implementation of guardianship

(methodology of medical anamnesis collection, development of a drug side effect monitoring plan, preventive measures regarding the possible manifestation of a side effect, etc.). Medical anamnesis — collection of information about previous drug therapy — is of great importance when choosing a drug for a specific patient. Taking a medical history is necessary, because in some cases, drugs can be the cause of the disease or cause symptoms that simulate the disease.

After choosing an over-the-counter drug, pharmaceutical care includes the following recommendations and consultations for the patient:

- selection of the optimal dosage form and routes of administration;
- rules for the use of various medicinal forms;
- peculiarities of individual dosage;
- features interaction given medicinal drug with other medicines;
- peculiarities of the interaction of this drug with food, alcohol and nicotine;
- time of day, optimal for taking this medication;
- possible adverse effect of drugs on the functions of human organs and systems;
- storage conditions of specific medicines.

To perform the above-mentioned algorithm of pharmaceutical guardianship, a pharmacist must be able to:

- initiate a dialogue with the patient to obtain sufficient data about his illness;
- ask key questions to find out the patient's condition;
- be prepared to recognize specific conditions, symptoms of common diseases;

- within a short time, after asking 3-4 key questions, decide on the possibility of self-treatment;

- convince the patient of the need for a limited period of treatment and consultation with a doctor in case of continuing adverse symptoms;

- convince the patient at detection "threatening" symptoms if a visit to the doctor is necessary;

- ensure the confidentiality of information about the patient's condition;

- to navigate well in the nomenclature of OTS-Preparations;

- know well the chemical, pharmaceutical and pharmacological properties of OTC drugs;

- to provide objective information about the medicine and convey it in a form accessible to the patient;

- use additional sources of information about medicines to meet the urgent needs of the patient;

- to help patients carry out responsible and adequate self-treatment;

- to provide consultations to consumers to take care of their health.

The following conditions are also necessary for high-quality pharmaceutical guardianship:

- Pharmacists must have sufficient information about treatment regimens and the main drugs used to treat the most common diseases.

- Pharmacists must have knowledge of the basics of internal medicine.

- Pharmacists must have the basics of rational use of drugs.

- Pharmacists must know the rules of conducting consultations with patients.

- It is also necessary to control the information that comes to the pharmacist from the drug manufacturer through their representatives and through advertising.

Practical functions of the pharmacist, which are necessary for the implementation of guardianship (Methodology of medical history collection, development of a side effect monitoring plan, preventive measures regarding the possible manifestation of a side effect, etc.) With the development of the concept of self-medication and the expansion of indications for the use of over-the-counter drugs, the role of the pharmacist

in providing primary medical care increases significantly.

Having adequate knowledge in the field of clinical pharmacy, the pharmacist, based on the presence of relevant symptoms, can give the consumer the correct advice on the use of medicinal products.

He can explain which symptoms can be prescribed for self-medication, and which symptoms require you to see a doctor. In mild forms of the disease, a pharmacist can give as qualified advice as a doctor. Since the patient comes to the pharmacy without a doctor's diagnosis, in self-treatment, the starting point is the patient's self-diagnosis. It follows from this that the pharmacist is a competent consultant to the patient who intends to start self-medication. Based on his education, experience and special knowledge, in order to protect the patient, he is fundamentally and professionally obliged to check the expediency of the patient's actions.

The control function of the pharmacist finds its expression in communication, when through a consultation conversation he receives from the patient himself reliable information necessary for starting self-treatment.

At the same time, the pharmacist is in no way a competitor of the doctor, but on the contrary, differentially selects a contingent of patients who are in need of medical care.

In addition, the control function of the pharmacist extends to:

- prevention of the use of drugs that do not correspond to the indications;
- instructions on the conditions of rational use;
- clarification of the risk of unwanted side effects of medicines;
- restrictions on the use of certain categories of drugs.

Criteria for determining the categories of drug release. Medicines are divided into two categories:

1. prescription drugs;

2. medicines that are available without a prescription.

Prescription drugs can be divided into separate groups according to the following classification:

1. medicinal products that are issued by single or multiple prescriptions;

2. medicines that are dispensed according to special prescriptions;

3. medicinal products, which are issued according to prescriptions and have a limited field of application.

Medicinal products that are issued by single or multiple prescriptions:

1. if they may pose a direct or indirect threat to the consumer's health even with their correct use, but without medical supervision;

2. if they are used incorrectly by many consumers, as a result of which there may be a direct or indirect threat to the consumer's health;

3. if they contain substances whose action and/or side effects require further study;

4. if the drug is intended for parenteral administration.

When enrolling medicines in this group, the following factors are taken into account:

1. the medicinal product is classified as narcotic or psychotropic in accordance with current legislation;

2. a medicinal product that, when used incorrectly, may pose a significant risk (abuse, addiction or use of the medicinal product for an illegal purpose);

3. the medicinal product contains a substance that, due to its novelty or pharmacological properties, can be attributed to this group;

4. the medicinal product contains substances included in lists 1 and 2 of table IV of the Cabinet of Ministers of Ukraine resolution dated 05.06.2000 770 "On approval of the list of narcotic drugs, psychotropic substances and precursors".

Medicinal products that are available by prescription and have a limited field of application

The following factors should be taken into account when including medicinal products in this group:

1. the medicinal product due to its pharmacological properties or novelty or in the interests of public health is intended for use only in hospital conditions;

2. the medicine is used for the treatment of diseases, the diagnosis of which can be established in the conditions of a hospital or in institutions with the necessary

diagnostic equipment, although the administration of medicines and follow-up can be carried out in other conditions;

3. the drug is intended for outpatient treatment of patients, but its use can lead to serious side effects, as a result of which it is necessary that the prescription be issued by specialists and the treatment be carried out under medical supervision.

Medicines that are available without a prescription

Medicines are available without a prescription, unless they are prescribed.

Medicinal products are available without a prescription if they contain small amounts of narcotic drugs or psychotropic substances and precursors included in the relevant tables of the Cabinet of Ministers of Ukraine resolution of 06.05.2000 N 770 "On approval of the list of narcotic drugs, psychotropic substances and precursors", and these drugs or substances cannot be extracted from medicinal products by readily available methods in quantities that allow them to be abused.

PRACTICAL ASSIGNMENTS

Task 1. Distribute the information given in the table. 1 drugs by release categories (over-the-counter and prescription). Specify the criterion by which it was determined leave category.

Table 1 Analyzed group of drugs

No	Commercial (international) name of the drug	Release form	Brief pharmacotherapeutic characteristics	Expediency of inclusion in over the counter th list "+"- yes, "-" - there is no and a short argumentation
1	Ampiox	Caps. 0.25 g. No. 20	Antimicrobial (combined) drug used in the treatment of bronchitis, pneumonia, cholangitis, infected wounds, sepsis, etc.	
2	Bromhikum elixir	Elixir 130 g, bottle	Combined herbal preparation containing 5 tinctures. It has an antitussive, expectorant, antimicrobial and antispasmodic effect	
3	Carbolong (activated carbon)	Powder 5.0 in bags	Adsorbent prevents the absorption of poisons.	
4	Canesten (clotrimazole)	Vaginal tablets 0.1 g No. 6	Antifungal drug of a wide spectrum of action	
5	Methindol (indomethacin)	Ointment 5% in a tube of 30 g	NSAIDS It is used for rheumatoid arthritis, osteoarthritis, gout, neuralgia, myalgia, traumatic lesions of soft tissues, etc.	
6	Morphine hydrochloride (morphine)	Injection solution 1% 1ml amp. No. 5	Narcotic analgesic	
7	Solpadein	Table No. 12	Combined drug with analgesic effect. It is used for migraine, neuralgia, cold, flu, pain during menstruation.	

8	Grass herd	Pack of 100.0 g	Anti-allergic, anti-inflammatory effect. It is used both internally (infusion) and externally for various allergic diseases.	
9	Tazepam (oxazepam)	Table 0.01 g #50	Tranquilizer with antiolytic, anticonvulsant, sedative effect. It is used for neuroses, sleep disorders and various psychovegetative disorders.	
10	Epheralgan (paracetamol)	Effervescent table 0.5 g No. 16	It is widely used in the treatment of colds, flu, migraines, neuralgia, etc.	

Task 2. Schematically present the algorithm for providing pharmaceutical guardianship when dispensing over-the-counter medicines from a pharmacy

After completing the practical task, the student should acquire practical skills and abilities:

- determination of the category of medicinal product;
- organization of pharmacotherapeutic replacement of over-the-counter drugs;
- economic assessments of the availability of over-the-counter analogue drugs;
- use of INN and OTC codes to identify trade names, manufacturers and analogues of drugs;
- organization of sanitary and educational work among the population on issues effective use of medicinal products, compliance with terms and conditions their storage, avoidance of food and drug incompatibility, mastering unfamiliar medical terms;

SELF CHECK TESTS

1

Who is responsible for the patient's health in the practice of responsible self-treatment?

A. **Patient**
B. Doctor
C. Pharmacist
D. The company-manufacturer of the drug
E. The head of a business structure that owns a retail point of sale of drugs

2

Which of the following pharmacotherapeutic requirements allow the drug to be classified as an over-the-counter drug?

A. **The drug does not cause direct or indirect harm to health**
B. The drug should be used only in a hospital
C. The drug contains substances, the activity and side effects of which require additional research
D. The drug, the use of which requires a doctor's prescription
E. The drug, which was recently introduced to the pharmaceutical market and has

limited experience of use in practice

3

Which of the following pharmacotherapeutic requirements allows the drug to be classified as an over-the-counter drug?

A. **Drugs does not cause direct or indirect harm to health**

B. Drugs should be used only by inpatients

C. The drug contains substances, the activity and side effects of which require additional studies of the drug, the use of which requires a prescription

D. Medicines with limited experience

4

***Availability*on the market of over-the-counter drugs is a necessary condition of the concept: Prescription dispensing**

A. **Responsible self-treatment**

B. Medical insurance

C. Reimbursement

D. Medical assistance

5

Medicines that meet certain criteria can be dispensed from pharmacies without a doctor's prescription. Which of the listed drugs can be classified as over-the-counter drugs:

A. **Rosehip oil, 50 ml**

B. Atropine sulfate district 1 mg/ml amp. 1 ml, No. 10

C. Phenobarbital, tab. 100 mg, #6

D. Diphenhydramine district 10 mg/ml amp. 1 ml, No. 10

E. Sibazon, tab., 0.005 g, No. 20

6

Indicate which of the following medicinaldrugs can be classified as over-the-counter drugs:

A. **Valerian extract, tab. 0.02, No.10**
B. Tramadol, caps. 0.05 No. 10
C. Ketamine, district d/in., amp. 100 mg/2 ml No. 5
D. Clofelin, amp. 1 ml of 0.01% solution No. 10
E. Norfloxacin, tab., 400 mg No. 10

7

***Medicines of appropriate quality*, released from pharmacies to the public are not subject to:**

A. **Exchange or return**
B. Return at the request of citizens
C. Exchange with a receipt or check
D. Exchange or return before the expiration date
E. Exchange or return if there is a complete package

8

The over-the-counter department is headed by the head of the department. Which of the following does NOT apply to his duties:

A. **Maintenance of subject-quantitative accounting**
B. Accounting for TMC in the department
C. Maintenance of the necessary range of goods.
D. Compliance with the sanitary regime
E. Ensuring conditions for proper storage of goods

9

According to the legislation, there is a clear division of pharmaceuticals into prescription and over-the-counter drugs in Ukraine. Which of the listed drugs

can be dispensed from a pharmacy without a prescription?

A. **Ascorbic acid, 500 mg No. 30**
B. Tramadol, caps. 0.05 #10
C. Clofelin, amp. 1 ml of 0.01% solution No. 10
D. Phenobarbital, tab. 100 mg, No. 6
E. Ketamine 5% 2 ml No. 10

10

Which of the following drugs can be dispensed from pharmacies without a doctor's prescription?

A. **Karsil tab.**
B. Morphine tab.
C. Clophelin eye drops
D. Atropine solution
E. Nitrazepam tab.

TOPIC 10
ORGANIZATION OF PHARMACY ELECTRONIC RETAIL TRADE WORK OF MEDICINES

Student should know: the main principles of the organization of the work of a pharmacy in the electronic retail trade of medicinal products.

Basic terms and concepts: electronic retail trade of medicines, license, licensee, means of economic activity, end consumer, electronic medical information system.

QUESTIONS:

1. Organization of the work of the pharmacy for the electronic retail trade of medicinal products.
2. Legislative and regulatory framework regulating electronic retail trade in Ukraine.
3. The main stages of electronic trade in medicinal products.
4. Procedure for obtaining/extending a license.
5. Requirements for the website and features of its use.

SELF-CHECK QUESTIONS

1. Characteristics of the legislative and regulatory framework regulating electronic retail trade in Ukraine.
2. Distance trade in medicinal products: what should be taken into account.
3. Procedure for obtaining a license.
4. Acceptance of orders for medicinal products.
6. Online pharmacists.
7. Completing and storing ordered medicines.
8. Delivery of ordered medicines.
9. Issuance of ordered medicinal products to the final consumer.
10. Information regarding the website of the business entity.

OVERVIEW

The main stages of electronic trade in medicinal products for the convenience and increase of access to medicines for citizens, the Cabinet of Ministers of Ukraine Resolution No. 1002 of September 22, 2021 allowed the delivery of over-the-counter medicines.

What is e-commerce and does booking an order qualify as e-commerce?

Electronic retail trade of medicines - retail trade of medicines using information and telecommunication systems in a remote way, which includes the reception, assembly, storage and delivery of orders for medicines and dispensing of medicines to end users.

End user (consumer) - a natural person who buys, orders, uses or intends to buy or order a medicinal product for personal needs not directly related to business activities or the performance of the duties of an employee.

Implementation of electronic retail trade of medicinal products involves:

- receiving orders for medicinal products
- order picking
- storage of medication orders
- delivery of ordered medicines
- release of ordered medicines to the final consumer.

Acceptance of orders for medicinal products

An Internet site that accepts orders for medicinal products must be in the address space of the Ukrainian segment of the Internet. It must be reflected in the List of business entities that have received the right to carry out electronic retail trade of medicinal products. The licensee's site may not be used by another licensee to organize such sales. At the same time, it is allowed for the licensee to use other resources (for example, integrator sites) for the purpose of informing consumers about the availability and price of the goods that they can order directly on the licensee's website. The license conditions stipulate that the licensee's website must contain a logo with a hyperlink to the List maintained by Dezhrleksluzhba, and this list will contain complete information: when the license was obtained, which pharmacies of the licensee can carry out electronic retail

trade, from which sites delivery can be made and other.

Online pharmacists

A person who receives and completes an order, as well as provides advice when ordering a medicinal product through the website, must have a document of higher education at least at the master's level in the specialty "Pharmacy, Industrial Pharmacy" and work experience in the specialty for at least two years.

These can be persons (regardless of their number, even if it is a call center) who are obliged to provide appropriate consultation, inform the consumer about the indications for the use of the medicinal product, its retail price, expiration date, conditions of release and storage, interaction with other medicines, conditions of return, payment and delivery.

The licensee is obliged to keep a record of orders and deliveries of medicinal products. Registration and accounting of orders and deliveries of medicinal products can be carried out electronically in accordance with the Law of Ukraine

"About electronic documents and electronic document management". The license conditions determine what information must be contained in the drug order information.

Completing and storing ordered medicines

Completing and storing the ordered medicinal products can be carried out exclusively from the pharmacy establishment of the licensee, information about which is available in the List. This happens regardless of whether we are talking about delivery or release of pre-ordered goods. A pharmacy must have a room and/or an area in the material room for storing completed orders. Order picking is carried out by a person authorized by the licensee.

Delivery of ordered medicines

The delivery of ordered medicinal products can be carried out both by an employee of the licensee's own delivery service and with the involvement of postal operators. The licensee is obliged to ensure and/or control:

- receiving recommendations regarding the storage conditions of medicinal products in accordance with the requirements established by the manufacturer. Medicinal products that require special storage conditions should be transported under

the same conditions using appropriately adapted technical means. Protocols for monitoring transport conditions, such as temperature, should be available for inspection;

- presence of protection against contamination, mixing, contamination and damage of medicinal products (spill, spillage, breaking, etc.);

- protection against exposure to high and low temperatures, light, moisture and other adverse factors that may lead to loss of quality of medicinal products;

- protection against disclosure, theft and/or substitution of medicinal products;

- involvement on the contractual basis of postal communication can be carried out only through the concluded contract, which must correspond to the standard form of the contract on the delivery of medicinal products to the final consumer, approved by the Cabinet of Ministers of Ukraine;

Before entering into such a contract, the licensee checks the business entity that will deliver medicinal products to the final consumer regarding the availability of transport, equipment and the ability to ensure the conditions for transporting medicinal products specified in the clauses of the license conditions.

Engagement of postal operators on a contractual basis includes the shipment of the ordered medicinal product exclusively from a pharmacy, information about which is available in the List.

Obligations of the licensee in accordance with the concluded contract:

- inform the postal operator about the contents of the shipment provided for delivery, including the need to comply with the conditions for the storage of medicinal products specified by the manufacturer and what exactly these conditions are;

- pack the shipment for its preservation during delivery and unloading and loading operations, and, if necessary, also mark it accordingly;

- inform the consumer about the transfer of the shipment to the postal operator for the provision of delivery services, the number of the consignment note and the estimated delivery time of the medicinal products;

- to require the postal operator to comply with the conditions of storage of medicinal products specified by the manufacturer during their delivery to the consumer.

Issuance of ordered medicines to the end user

The customer has the right to refuse the delivered medicinal product upon receipt and has the right to demand a refund from the licensee who sold such medicinal product in the event that:

- the primary and/or secondary packaging of the medicinal product is damaged;
- the expiration date of the medicinal product has passed;
- a ban on the sale and use of the medicinal product has been published by the authorized body;
- the delivered order does not correspond to the ordered one in terms of quantity or composition, name, dosage, release form, price.

All this should be combined into a quality system. The licensee is obliged to approve written standard work methods (standard operating procedures), which describe, in particular, work related to reception, registration, formation, storage, delivery of orders for medicinal products, provision of consultations, as well as dispensing of medicinal products to the end user. These documents must be submitted to the State Medical Service when the entity wishes to obtain the right to electronic trade in medicinal products.

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The procedure for obtaining/extending a license

Business entities must:

- create your own delivery service, ensure the availability of equipment and facilities for compliance with the conditions of storage of drugs during their delivery and/or conclude a contract with a postal operator that has the appropriate equipment and facilities for compliance with the conditions of storage of drugs and is entered in the Unified State Register of Operators postal communication;

- to arrange premises and/or areas in the material room for storing completed orders;

- ensure the availability of an electronic payment system and/or mobile POS terminals for making electronic payments directly at the place of service provision;

- to ensure the availability of its own website in the address space of the Ukrainian segment of the Internet, information about which is included in the List of business entities that have the right to carry out electronic retail trade of medicinal products;

- to appoint at least one person who accepts, completes orders, provides consultations when ordering medicinal products through the website, is in employment with the licensee, has the necessary education and work experience;

- approve written standard work methods that describe work on receiving, registering, forming, storing, delivering orders, providing consultations, and dispensing medicines to the end user;

- ensure registration of completed orders and deliveries of medicinal products with the necessary data, as well as protection and non-disclosure of confidential information, in particular, personal data of customers of medicinal products;

- to ensure compliance with the requirements of good storage practices (Guide to good storage practices for pharmaceuticals — GSP) during the delivery and transportation of ordered medicinal products, and in the case of the involvement of postal operators, to monitor the observance of storage conditions by such operators during the delivery of medicinal products;

- ensure the availability of transport packaging to protect medicines from external influences and conditions for storing medicines during their transportation with the possibility of monitoring unauthorized intervention.

After carrying out the steps indicated above, the business entity, which already has a license to carry out retail trade of medicinal products, applies to the State Service of Ukraine for medicinal products and drug control with an application for obtaining a license for the implementation/expansion of economic activities for production (production) of medicines in the conditions of a pharmacy, wholesale, retail trade of

medicines, electronic retail trade of medicines, adds to such an application information about the availability of material and technical base and qualified personnel, a copy of the contract with the postal operator (if involved).

Documents to be submitted to the State Medical Service:

- statement of the established form;
- information on the availability of the material and technical base and qualified personnel necessary for the electronic retail trade of medicinal products, in the established form;
- a copy of the contract with the postal operator on the delivery of medicinal products to the final consumer, certified by the licensee (in the case of the involvement of postal operators on a contractual basis).

Based on the results of the examination of the application, the State Medical Service makes a decision on the issuance (extension) of a license for the conduct of economic activity in the electronic retail trade of medicinal products or on the refusal to issue it within 10 working days from the date of receipt of the relevant application and the documents attached to it.

Requirements for the website and features of its use

One of the necessary conditions for conducting remote trade in medicines is the presence of the business entity's own website. The relevant website should contain:

- the full name of the legal entity or the surname, first name, patronymic of an individual — an entrepreneur;
- information on whether the business entity has the necessary license;
- a logo with a hyperlink that is displayed on each page of the website and takes the consumer to the page of the List of business entities that have the right to carry out electronic retail trade of medicinal products;
- mode of operation of the licensee and pharmacy establishments through which electronic retail trade of medicinal products is carried out;
- contact data for ordering medicines;
- the option of providing consultation by the licensee's specialist when ordering the medicinal product through the website, indicating the contact details and the mode

of providing such consultation;

- necessary information about drugs available for ordering;
- information about medicinal products that are prohibited for delivery;
- information on the conditions of sale of medicinal products;
- conditions for returning medicines of inadequate quality.

It should be noted that the website must be accessible to users with visual, hearing, musculoskeletal, speech, and intellectual disabilities, as well as with various combinations of disabilities in accordance with DSTU ISO/IEC 40500:2015 "Information technologies.

The website of the licensee may not be used by another licensee to organize electronic retail trade of medicinal products.

Other websites may be used by the licensee exclusively for the purpose of posting up-to-date information on the availability and price of the medicinal product at a specific pharmacy with a hyperlink directly to the website of the licensee, from which the electronic retail trade of medicinal products is carried out.

However, licensees are not limited in receiving orders using electronic medical information systems. The corresponding electronic medical information system must be connected to the central database of the electronic health care system, contain a link to the official website of the licensing authority, which contains the List of business entities that have the right to carry out electronic retail trade of medicinal products and the option of providing advice specialist of the licensee.

Electronic retail trade of medicinal products may be carried out by economic entities in the event of:

1. taking the steps necessary to carry out the relevant type of activity specified above;

2. application to the State Medical Service with an application to obtain a license for the implementation/expansion of economic activity for the production (manufacturing) of medicinal products in the conditions of a pharmacy, wholesale, retail trade of medicinal products, electronic retail trade of medicinal products together with the necessary documents;

3. adoption of a decision by the State Medical Service to issue (extend) a license for the conduct of economic activity in the electronic retail trade of medicinal products for the relevant business entity;

4. entry of the relevant business entity into the List of business entities that have the right to carry out electronic retail trade of medicinal products.

In addition to this, licensees should take into account that the electronic retail trade of medicines can be carried out exclusively from a pharmacy, information about which is available in the List of business entities entitled to carry out electronic retail trade of medicines.

PRACTICAL ASSIGNMENTS

Task 1. Define the terms, according to Resolution of cabinet of ministers of Ukraine dated November 30, 2016 No. 929 « 1. On the approval of the Licensing conditions for conducting business activities for the production of medicinal products, wholesale and retail trade of medicinal products, import of medicinal products (except for active pharmaceutical ingredients)»

Pharmacy establishments:

_____

_____

_____

_____

_____

_____

Pharmacy:

_____

_____

_____

_____

_____

_____

Pharmacy warehouse (base):

Electronic retail trade of medicinal products:

Task 2. Specify the documents to be submitted to the State Medical Service to obtain/extend a pharmacy e-commerce license

After completing the practical task, the student should acquire practical skills and abilities:

- the basic principles of the organization of the work of the pharmacy in the electronic retail trade of medicinal products.

SELF-CHECK TESTS

1

Consumers have the opportunity to independently check the legality of a pharmacy that carries out electronic retail trade of medicinal products, using:

A. **Service of the State Medical Service"E-Trade Check"**
B. FTP service (File Transfer Protocol)
C. Mail Lists service (mailing lists)
D. IRC (Internet Relay Chat) service
E. Telnet service (remote access)

2

Electronic retail trade and delivery to the final consumer of medicinal products, the sale of which to citizens is carried out according to doctors' prescriptions (except for the dispensing of such medicinal products by electronic prescription in accordance with the procedure established by the Ministry of Health):

A. **It is prohibited**
B. Permitted subject to license
C. It is allowed under the conditions of the rules of transportation of medicinal products
D. Allowed only by an authorized person
E. It is allowed under the conditions of the rules for the storage of medicinal products

3

The website of a business entity that has a license for electronic retail trade of

medicinal products must contain the following information, except:

A. **Information about medicinal products that are prohibited for delivery**

B. Information on storage conditions of medicinal products after sale

C. Conditions for returning medicines of inadequate quality

D. Mode of operation

E. Information about phone numbers, e-mail addresses, by which medicines are ordered

4

For the organization of electronic retail trade of medicinal products, the licensee appoints a person who accepts, completes orders, and provides advice when ordering a medicinal product through the website. Such a person must be employed with the licensee and meet the following qualification requirements:

A. **Have a document of higher education not lower than the second (master's) level in the specialty "Pharmacy, industrial pharmacy" and work experience in the specialty for at least two years**

B. Have only a document of higher education not lower than the second (master's) level in the specialty "Pharmacy, industrial pharmacy"

C. Have any pharmaceutical education

D. Have any pharmaceutical education and at least two years of work experience in the specialty Have a medical education and at least two years of work experience in the specialty

5

The standard form of the contract on the delivery of medicinal products to the end user is established:

A. **By the government**

B. Licensee

C. The end consumer

D. Local authorities

E. Postal operator

6

The licensee must be entered intoThe list of business entities that have the right to carry out electronic retail trade of medicinal products, which is maintained and posted on the official website:

A. **Licensing body of the Government**
B. Local authority
C. Postal operator
D. Pharmacy institution

7

Electronic retailing of medicines is retailing medicinal means with usingin formation and telecommunications systems remotely, what includes all of the following except:

A. **Production**
B. Acceptance, assembly
C. Storage
D. Deliveries of orders for medicinal products
E. Dispensing medicines to the end user

8

The licensee is obliged to keep a record of orders and deliveries of medicinal products. Registration and accounting of orders and completed deliveries of medicinal products can be carried out:

A. **Only in electronic form**
B. In paper or electronic form
C. Only in paper form
D. Registration is carried out not by the licensee, but by the postal operator
E. Registration is carried out by the manufacturer of medicinal products, not by the

licensee

9

Ordering and storage of ordered medicines can be carried out:

A. **Exclusively from the pharmacy establishment of the licensee**

B. Exclusively from the drug manufacturer

C. From any pharmacy, if medicines are not available at the licensee

D. From several pharmacies, in which medicines are ordered

E. Exclusively from the state pharmacy

10

Delivery ordered medical means mayto be carried out both by an employee of the licensee's own delivery service, and with the involvement of postal operators. The licensee is obliged to ensure and/or control the following, except:

A. **Delivery time**

B. Obtaining recommendations regarding the storage conditions of medicinal products in accordance with the requirements established by the manufacturer

C. Availability of protection against contamination, mixing, contamination and damage of medicinal products

D. Protection from exposure to high and low temperatures, light, moisture and other adverse factors that can lead to a loss of the quality of medicinal products

E. Protection against disclosure, theft and/or substitution of medicinal products

CONTENT SECTION 3
ORGANIZATION OF MEDICINES WHOLESALE. STATE QUALITY CONTROL

TOPIC 11
ORGANIZATION OF THE PHARMACY WAREHOUSE (BASE)

Student should know: organization of the supply of pharmacies, organizational structure, licensing conditions for the production of economic activities, tasks and functions of pharmacy warehouses (bases), legal regulation of the activities of a wholesale company, the procedure for accepting and dispensing goods and controlling the quality of medicines.

Basic terms and concepts: wholesale trade in medicines and pharmacy products, licensing conditions, legal regulation of wholesale trade, pharmacy warehouses (bases), quality control of medicines, storage departments, supply chain to pharmacies, tasks and functions of pharmacy warehouses (bases), good distribution practice, purchase and sale agreement, incoming quality control of medicines for wholesale.

QUESTIONS

1. Organization of supplies of pharmaceutical products to pharmacies. The concept of distribution and wholesale of drugs. Good Distribution Practice.

2. Licensing conditions for the implementation of economic activities in the wholesale trade of medicines.

3. Pharmacy warehouses (bases): tasks, functions, classification. Organizational structure.

4. Procedure for receiving goods from suppliers. Documentary support of the main operations in the pharmaceutical supply chain

5. The procedure for the implementation of input quality control of the drug in the wholesale.

SELF-CHECK QUESTIONS

1. Organization of supplies of pharmaceutical products to pharmacies.
2. The concept of distribution and wholesale of drugs. Good Distribution Practice.
3. Licensing conditions for the implementation of economic activities in the wholesale trade of medicines.
4. Pharmacy warehouses (bases): tasks, functions, classification.
5. Organizational structure.
6. Procedure for receiving goods from suppliers.
7. Documentary support of the main operations in the pharmaceutical supply chain
8. The procedure for the implementation of input quality control of the drug in the wholesale.

OVERVIEW

The concept of distribution and wholesale of medicines

Distribution begins with the purchase of a large consignment of goods from a manufacturing company.

In accordance with the Decree of the Cabinet of Ministers of Ukraine No. 929:

Distribution (wholesale distribution) of medicines is any activity related to the receipt, storage, supply, transportation and import / export of medicines, with the exception of their sale directly to citizens for personal consumption.

Distributor is a business entity that has a permit (license) for the wholesale trade of medicinal products and carries out appropriate activities for their distribution (wholesale trade).

Distribution of drugs and other pharmacy products in Ukraine is carried out by:

- manufacturing companies,
- pharmacy warehouses (bases),
- wholesale companies of various forms of ownership,
- subsidiaries of foreign pharmaceutical companies.

The wholesale link plays a significant role in the formation of a well-coordinated

system for bringing drugs to the end consumer, ensuring the quality of drugs along this path and in the regulatory procedure for recalling low-quality pharmaceutical products from the pharmaceutical market.

Distributors can be classified according to several criteria:

- the location, they are divided into domestic and foreign.
- the scale of activity, they are national, interregional, regional, local.
- the form of ownership, they are divided into state (or communal), private, collective and mixed forms.
- the status of a legal entity, there are joint-stock companies, state enterprises, business companies with various forms of responsibility, private enterprises, joint companies.
- the business entity, there are manufacturing plants, wholesale pharmaceutical companies, pharmacy bases (warehouses), central pharmacies.

The main criteria for choosing suppliers by pharmacies are:

- business reputation and duration of work in the pharmaceutical market;
- range of medicines and medical products;
- terms of delivery, their speed, periodicity;
- prices, trade margins and discounts;
- form of payment; calculation conditions;
- personnel qualification;
- territorial proximity, method of product delivery.

In accordance with the Decree of the Cabinet of Ministers of Ukraine No. 929, which formalizes the Licensing conditions for various types of pharmaceutical activities (production, wholesale and retail trade of medicines, as well as import of medicines):

Wholesale of medicines is a business reputation and duration of work in the pharmaceutical market; range of medicines and medical products; terms of delivery, their speed, frequency; prices, trade margins and discounts; form of payment; calculation conditions; personnel qualification; territorial proximity, product delivery method.

Good Distribution Practice (GDP) establishes the principles and rules

(requirements) for the wholesale trade of medicines. The requirements and norms of the GDP are closely related to the set of good practices that govern other aspects of pharmaceutical activities.

By the order of the Ministry of Health of Ukraine No. 593 dated August 22, 2014, a regulatory document was put into effect - the Guideline “Medicines. Good Distribution Practice.

This Guide applies to business entities that distribute drugs on the territory of Ukraine, including enterprises that manufacture drugs, regardless of departmental subordination and form of ownership. The regulatory document applies to the distribution of imported drugs, as well as those produced in Ukraine for the domestic market.

Business entities that carry out wholesale trade in medicines must guarantee:

- purchase and sale of drugs which are registered only in the State Register from business entities that have valid licenses for the production or wholesale trade of drugs (copies of licenses must be kept by the authorized person);
- observance of the storage conditions of medicines determined by the manufacturer (including during transportation) and safety of medicines;
- exclusion of the possibility of drug contamination;
- functioning of the system for detecting any products that do not meet the established requirements (technological, analytical and regulatory documentation, current quality standards), and an effective recall procedure.

The order of the Ministry of Health of Ukraine "On Approval of the Procedure for Certification of Enterprises Engaged in Wholesale (Distribution) of Medicinal Products" No. 421 dated August 23, 2005 establishes that all pharmacy warehouses and wholesalers must undergo mandatory certification for GDP requirements.

The certificate is issued for 5 years.

The criteria for certification is the ability of the enterprise:

- to ensure compliance of the material and technical base, technical means and quality assurance system of drugs during their distribution with the requirements established by regulatory legal acts and the Guidelines with GDP (Order of the Ministry

of Health of Ukraine No. 593);

- to ensure the constant availability and turnover of stocks of a range of drugs, in particular, those included in the National List of Essential Drugs, approved by the Decree of the Cabinet of Ministers;

- to fulfill the order of a pharmacy or medical institution of any name of drugs from the above lists to any locality in Ukraine within two days from the date of receipt of the order

Licensing conditions for the implementation of economic activities in the wholesale trade in medicines.

This activity is carried out jointly with manufacturers or their representatives, importers, other wholesale or retail trade of medicines by medical institutions.

In accordance with the Law of Ukraine "On Medicinal Products" dated 04.04.1996 No.123/ 96-VR, wholesale trade in medicines on the territory of Ukraine is carried out by enterprises, institutions, organizations and individual entrepreneurs on the basis of a license issued in the manner prescribed by the law.

Also, in accordance with the Law of Ukraine "On Licensing of Economic Activities Types" dated 02.03.2015 No. 222-VIII, wholesale trade of medicines is subject to compulsory licensing.

Issuance of a license is granting to a business entity the right to carry out a type of economic activity or part of a type of economic activity subject to licensing by the decision of the licensing body to issue a license, which is recorded in the license register.

Wholesale of drugs is carried out through pharmacy warehouses (bases). State regulation and control of activities in the wholesale trade of medicines are ensured through the licensing and certification procedure.

In addition, in accordance with the Decree of the Cabinet of Ministers of Ukraine No. 929 dated November 30, 2016 “On Approval of the Licensing Conditions for the Production of Economic Activities for the Production of Medicines, Wholesale and Retail Trade of Medicines, Import of Medicines (except for Active Pharmaceutical Ingredients)”, the concept of the authorized person is introduced

The authorized person for business entities (engaged in the wholesale trade in

medicines) is a person who has a document of higher education not lower than the second level (Master's Degree) in the specialty "Pharmacy, industrial pharmacy", a certificate of a specialist pharmacist issued by an institution of postgraduate education, or a certificate of assignment (confirmation) of the relevant qualification category and has at least two years of work experience in the specialty "Pharmacy, industrial pharmacy", which is entrusted by a business entity with the responsibility for the functioning of the quality system of medicines during wholesale trade.

In order to obtain a license for the production (manufacturing) of medicines in a pharmacy, wholesale trade in medicines, retail trade in medicines, an enterprise submits an application to the licensing authority (State Service) in the prescribed form.

The application is to indicate all places of production of the licensed type of economic activity.

Attached to the license application are supporting documents for each place of production of the type of economic activity, which is subject to licensing, which is information about the availability of the material and technical base and qualified personnel necessary for the implementation of economic activities in the wholesale trade in medicines in the prescribed form.

The licensee for the implementation of economic activities for the wholesale trade of medicines provides:

- trade only in medicines registered in accordance with the legislation of Ukraine;
- observance of general and specific storage conditions of medicines determined by the manufacturer at all stages of wholesale trade (including during transportation);
- compliance with the requirements of Good Distribution Practice and Good Storage Practice, harmonized with EU legislation;
- implementation, operation and maintenance of the quality system (pharmaceutical system);
- availability of personnel whose qualifications and powers meet the Licensing Conditions;
- availability of the material and technical base and technical means necessary for carrying out economic activities in the wholesale trade of drugs, and its compliance

with the requirements of regulatory documents for the storage, quality control, and trade in drugs;

- documentation of processes, procedures, operations;
- compliance with the quality requirements of medicinal products during their wholesale trade;
- organizing and conducting self-inspections (internal audit) for the implementation and compliance with GDP requirements
- prevention of contamination and confusion of medicines;
- operation of a detection system for any products that do not meet the established requirements (regulatory (analytical, technical, technological) documents, quality control methods, quality standards), and an effective recall procedure.

The basic requirements for doing business in the wholesale trade of medicines.

Trade in substandard or expired medicinal products or for which there is no quality certificate issued by the manufacturer and/or importer is prohibited.

The enterprise is obliged to keep the manufacturer's and/or importer's quality certificates (copies on paper or scanned copies on electronic media) on a series of medicinal products sold by the enterprise for three years from the date of purchase.

When storing quality certificates in the form of scanned copies of certificates, the licensee is obliged to provide (upon request) their hard copies no later than two business days.

Pharmacy warehouses (bases) are located subject to the arrangement of a loading and unloading area for the entrance of cars (ramp with a canopy, etc.) outside the front of the windows of the premises with the constant stay of people on any floor in isolated rooms with a separate independent exit to the outside in separately standing specially equipped capital buildings, as well as in auxiliary buildings of industrial enterprises.

Placing a pharmacy warehouse (base) in residential buildings and public buildings (sports facilities, educational institutions (schools, educational and preschool institutions), cultural, sports and social welfare institutions, medical

institutions, trade enterprises, etc.) is allowed when the corresponding separate buildings are not used for their intended purpose.

On the facade of the building where the pharmacy warehouse (base) is located, according to its purpose, a sign indicating the type of institution is installed. In a conspicuous place in front of the entrance to the pharmacy warehouse (base) information about the name of the licensee, the mode of operation of the pharmacy warehouse (base) is placed.

The pharmacy warehouse (base) is assigned a serial number and, at the request of the licensee, a name.

Pharmacy warehouses (bases) are equipped with central heating devices or autonomous heating systems that meet fire safety standards. This requirement does not apply to licensees engaged in the wholesale trade of medical gases.

It is not allowed to heat rooms with gas appliances with an open flame or electric heaters with an open electric coil.

The licensee ensures the sanitary condition of the premises and equipment of the pharmacy warehouse (base) in accordance with the requirements of the sanitary and anti-epidemic regime of pharmacy institutions.

Premises and equipment are subject to cleaning, disinfection, deratization in accordance with the instructions approved by the licensee.

Walls, ceiling, floor of industrial premises of a pharmaceutical warehouse (base) are covered with materials that allow wet cleaning using disinfectants.

The licensee must have cleaning programs and protocols. Equipment used for washing and cleaning must be selected and used so that it does not become a source of contamination

The licensee takes measures to prevent unauthorized persons from entering the premises. Storage and quality control areas should not be used as walkways for non-working personnel.

The licensee ensures that each person entering the storage areas (zones) wears protective clothing appropriate for the operations it performs.

It is forbidden to eat, drink, smoke, and store food products, drinks, tobacco products and personal medicines in production premises (zones).

The premises (zones) of the pharmacy warehouse (base) must be clearly marked.

Access to production premises (zones) must be allowed to authorized personnel and controlled.

Visitors and/or workers who have not been trained are instructed in advance, in particular on the hygiene requirements for personnel and the use of protective clothing, and are admitted to such premises (areas) if necessary and with appropriate accompaniment.

The licensee must have documents describing the individual stages of the technological process (reception, incoming control, storage, packaging, dispensing / shipment and transportation of medicines) at the pharmacy warehouse (base), approved, signed with the date in the manner prescribed by the licensee.

The licensee must have an urgent action plan to ensure the implementation of the orders of the Ministry of Health and the State Service for Drugs to stop the sale of low-quality and counterfeit medicines, withdraw, if necessary, medicines for sale and take appropriate measures to return these medicines to the supplier (manufacturer) or destroy them (utilization) .

Medicines are purchased exclusively from licensees licensed for the production of medicines, wholesale of medicines, import of medicines (except for active pharmaceutical ingredients)

The wholesaler needs to use all available means to minimize the risk of counterfeit medicines entering the legal supply chain.

Prior to the procurement of medicinal products, it is necessary to carry out the appropriate qualification of suppliers and approve them. This process must be controlled in accordance with the procedure established by the licensee, and the results documented and periodically reviewed.

If a wholesaler obtains medicines from another wholesaler, check that the supplier follows good distribution practices and is licensed to wholesale, for example by using appropriate databases.

When transporting medicinal products, conditions must be observed that ensure their proper quality, safety and integrity, do not allow dust, atmospheric precipitation and the influence of foreign odors to enter them.

Narcotic drugs, psychotropic substances and precursors are transported in accordance with the requirements of regulatory legal acts regulating their circulation in Ukraine.

Pharmacy warehouses (bases) include production facilities: separate premises, areas or for receiving and storing medicines and dispensing/shipping them, auxiliary materials and containers with a total area of at least 250 sq. meters.

Production facilities include premises (zones) where medicinal products are received and stored, premises (zones) for completing and dispensing / shipping medicinal products (forwarding), premises (zones) for storing auxiliary materials and containers, quarantine products.

Mandatory premises of the pharmacy warehouse (base):

Production

- Reception
- Storage
- Options
- Forwarding

Household

- premises for personnel (0.75 square meters per employee of one work shift, but not less than 8 square meters);
- WC (water closet), where there is water supply, sewerage (but not less than 2 square meters);
- wardrobe;
- shower room;
- dining room

Service

• For the preparation of disinfectant solutions, control room, archive, server room, security rooms, classrooms, rooms for storing working tools for loading and unloading operations, rooms or cabinets for storing cleaning items

Auxiliary

• corridors, vestibules, stairwells, elevator shafts, switchboard rooms, boiler rooms, ventilation chambers (shafts).

Requirements for the personnel of the subjects of implementation of economic activities for the wholesale trade of medicines are as follows

The licensee, carrying out economic activities in the wholesale trade of medicines, must have qualified personnel in the amount (depending on the number and capacity of pharmacy warehouses), which allows to perform all the tasks assigned to the licensee.

The licensee must have an approved staff list and job descriptions of employees, which indicate the main functions, powers, professional knowledge, competence and other requirements for employees.

The licensee's personnel must be aware of and comply with the Good Distribution Practices and Good Storage Practices requirements relating to its operations, as well as receive initial and periodic training in accordance with the duties of the personnel, including instruction on the implementation of hygiene requirements.

Persons directly engaged in the wholesale trade in medicinal products must have a document of higher education not lower than the first level (Bachelor’s Degree) in the specialty "Pharmacy, industrial pharmacy".

Specialists who have not been working for more than five years according to the specialty specified in the diploma and specialty certificate are allowed to carry out activities in the wholesale trade in medicines only after undergoing retraining.

The positions of heads of a pharmacy warehouse (base), deputy heads of a pharmacy warehouse (base) can be filled by persons who have a document of higher education not lower than the second level (Master's Degree) in the specialty "Pharmacy, Industrial Pharmacy" and a certificate of a pharmacist-specialist in the specialization "Organization of Management pharmacy” or certified in this specialization with the assignment (confirmation) of the appropriate category and work experience in the

specialty for at least two years.

It is not allowed to hold the position of the head of the pharmacy warehouse (base) in combination (at the same time).

The licensee appoints at least one authorized person responsible for the creation, implementation and operation of the quality system. The authorized person performs his duties and must have for at least two years of work experience in the specialty.

The licensee provides periodic training for personnel whose activities may affect the quality of products, in accordance with the training programs approved by the licensee.

Licensee periodically evaluates the practical effectiveness of the training.

The licensee establishes hygienic requirements corresponding to the type of activity carried out and ensures their observance. These requirements, in particular, include requirements for the state of health of personnel, hygiene procedures and technological clothing. The licensee must have personnel hygiene documentation.

When hiring personnel whose activities may affect the quality of products, they undergo a medical examination, and in the future - periodic medical examinations. The licensee is responsible for the existence of instructions, in accordance with which it is ensured that it is informed about the health status of employees, which may affect the quality of products. The licensee shall take organizational measures to ensure that no worker with an infectious disease or wounds on open areas of the body will be allowed into storage areas (zones) and quality control areas

Pharmacy warehouses (bases): tasks, functions, classification. Organizational structure.

A pharmacy warehouse is an institution of the healthcare and pharmacy system that operates on the basis of a license and a GDP certificate, carries out wholesale of pharmacy products and is a pharmaceutical (pharmacy) institution.

The main task of pharmacy warehouses (bases) is the timely provision of medicines and medical devices to business entities licensed for wholesale or retail trade, as well as medical institutions, drug manufacturers.

Main functions of warehouses (bases)

Trading

- Implementation of wholesale trade of drugs and other pharmacy products

Information

- Information support for trade and intermediary activities in the pharmaceutical market.

For the effective implementation of these functions, the warehouses (bases) must:

- determine the need for drugs and MD (by nomenclature and quantity);
- conclude contracts with suppliers and buyers;
- receive pharmaceutical products from suppliers (manufacturers and wholesalers of various forms of ownership, having the appropriate license);
- carry out incoming quality control of goods;
- ensure proper storage conditions for pharmaceutical products in accordance with the physical and chemical properties and established rules, regulations and requirements;
- organize the rational supply of drugs and MD to the pharmacy network, medical institutions, other organizations and enterprises;
- create the necessary reserve of goods according to the established nomenclature and approved standards;
- ensure the transportation of the released goods in appropriate conditions.

The organizational structure of pharmacy warehouses (bases) included in the structure of an enterprise engaged in the wholesale trade of medicines may be different.

It depends on the amount of work and the functions performed. In general, an enterprise in its structure should have:

- Department (group) of marketing
- Department (group) supply
- Sales department (group)
- Transport department (group)
- Financial department (group)
- Pharmacy composition (base)

Warehouses (bases): should have

- reception department
- expedition department
- operational departments (the number of which depends on the amount of work - up to 16)
- auxiliary divisions (washing, packing, packaging).

The receiving department is the most important structural unit of the pharmacy warehouse (base), which implements reception and posting goods, incoming quality control and distribution of goods entering the warehouse among the relevant operational departments to organize proper storage.

Operational departments are designed to store different groups of goods. On the pharmacy staff, as a rule, the following operational departments are distinguished: narcotic, psychotropic drugs and precursors; finished medicines; injectables; bacterial preparations and blood substitutes; bulk drugs; galenical preparations; antibiotics and vitamins; department of storage of flammable and explosive drugs; dressings; patient care items, etc.

Pharmacy network, medical institutions, other enterprises, organizations, institutions are supplied according to their requirements through the expedition department.

The functions of the **expedition department** include the picking of orders and the execution of relevant documentation (waybills, tax invoices, etc.).

Pharmacy warehouse is equipped with modern means of mechanization, innovative conveyor lines. Picking of orders is carried out by works under the control of operators.

The procedure for receiving goods from suppliers. Documentary support of the main operations in the pharmaceutical supply chain

The acceptance of received goods is carried out by the acceptance committee, the chairman of which is the head of the receiving department or his deputy, and the members of the commission are the heads of the relevant operational departments.

Responsibilities of the Admissions Committee include:

- Determining the good quality of the goods, checking the compliance of the goods with the provided documents (certificates, waybills), checking the expiration dates;
- acceptance of goods according to the nomenclature and quantity;
- execution of the act of acceptance;
- resolving questions about further actions in cases when a low-quality product has arrived or there are disagreements about its quantity;
- transfer of goods to storage departments;
- Carrying out work on customs clearance (release for free circulation on the territory of Ukraine) of MD and MD received from foreign suppliers
- Determining the good quality of the goods, checking the compliance of the goods with the provided documents (certificates, waybills), checking the expiration dates;
- acceptance of goods according to the nomenclature and quantity;
- execution of the act of acceptance;
- resolving issues about further actions in cases when a low-quality product has arrived or there are disagreements about its quantity;
- transfer of goods to storage departments.

When receiving a product, pay attention to the expiration date. Drugs received for the composition must have a shelf life margin of at least 80%, and bacterial preparations - at least 50%.

When shipped from the warehouse, the remaining shelf life must be at least 60% and 40%, respectively.

Received pharmaceutical products, prior to their transfer to the operational departments of the warehouse (base), must undergo an incoming control procedure (checking the compliance of the received drugs with the accompanying documents regarding the quantity, dosage, batch numbers, expiration dates, registration status, name, dosage form, manufacturer, as well as the package integrity and the integrity of the packaging, appearance, labeling (marking)).

Each series of drugs must be accompanied by a quality certificate issued by the

manufacturer

The following groups of drugs are subject to obligatory laboratory testing for compliance with their quality with indicators of **pharmacy warehouse**:

- substances used in pharmacies for the manufacture of parenteral dosage forms and drugs used in ophthalmic practice;
- narcotic drugs, psychotropic substances and precursors
- medicines used for anesthesia, including inhalation (except oxygen and nitrous oxide);
- radiopaque, including barium sulfate;
- anti-tuberculosis (including combined), containing rifampicin, isoniazid, ethambutol, pyrazinamide.

In case of doubt regarding the quality of the medicinal product, the authorized person sends samples to the territorial inspection for laboratory testing. Until the issue is finally resolved, batches of dubious drugs are quarantined separately from other drugs with the designation "Trade is prohibited for separate disposal."

The fact of acceptance of the goods is confirmed by the act of acceptance.

In case of discrepancies between the actual availability of the goods and these accompanying documents, an Act is drawn up on the discrepancies identified in the quantity and quality upon receipt of the goods.

Modern automated control and accounting systems allow to optimize the work of the warehouse, significantly reduce the time for processing the relevant documentation, and improve the inventory management efficiency.

The received pharmaceutical products are in the receiving department until the admission of analysis results confirming their quality, after which they are transferred to the operational departments of the warehouse (base) for storage.

Drugs and M.Devices are stored in operational departments in accordance with their physical and chemical properties and current regulatory documents (Good Storage Practice, Order of the Ministry of Health No. 44 of 16.03.1993).

The premises of the departments must comply with the volume of work and all the requirements that ensure the preservation of the relevant groups of inventory items:

the presence of ventilation, fire and security alarms, compliance with the required temperature regime, lighting, etc.

Thermometers and hygrometers should be installed in warehouses to monitor temperature and humidity. Goods in departments are placed on racks by name, series and expiration date. For each item, a rack card is created, which indicates the series, shelf life, quantity of received and released goods.

The procedure for the implementation of input quality control of the drug in the wholesale

The main duties of the authorized person. They are:

1. Checking drugs and accompanying documents - waybills, quality conclusions, information on state registration.

According to the order of the Ministry of Health No. 677 "On approval of the Procedure for quality control of drugs during wholesale and retail trade"

2. Registration of the conclusion of the input quality control of drugs

3. Maintaining a register of drugs received by a business entity in order to be able to trace the source of a low-quality or falsified batch of drugs

4. Maintaining a register of drugs sold by a pharmacy warehouse (base) in order to be able to recall batches of low-quality or counterfeit drugs.

5. Checking of the presence of low-quality and falsified batches of drugs in the composition according to the information of the territorial inspection.

6. Provision of information to the territorial inspectorates about the detected low-quality and falsified drugs or suspicion of their quality; suspension of vacation and quarantine of such drugs.

7. Monitoring the storage conditions of drugs in accordance with the requirements of the instructions for the medical use of drugs.

8. Granting permission to dispense medicines to business entities and/or other places where the business entity operates.

PRACTICAL ASSIGNMENTS

Task 1. Indicate the tasks and the functions of the main departments of a pharmacy warehouse. Present the results of the work in the table.

№	The name of pharmacy warehouse department	Brief characteristics of the department
1	reception department	
2	expedition department	
3	operational departments	

Task 2. The following medicines were received at the pharmacy warehouse:

1. Nitric oxide cylinder 6 kg.
2. Analgin, kg.
3. Water for injection 10.0 No. 10.
4. White clay, kg.
5. Dermatol, kg.
6. Diazepam tablets 2 mg No. 10.
7. Ephedrine hydrochloride, kg.
8. Crystalline iodine, kg.
9. Sodium chloride, kg.
10. Zinc sulfate, kg.

Indicate for which of them the authorized person of the pharmacy the warehouse must verify the presence of a quality conclusion after a mandatory laboratory test.

№	The name of the medicinal product	Justification of mandatory laboratory testing

After completing the practical task, the student should acquire practical skills and abilities:

- conditions of implementation of the wholesale sale of medicinal products;
- organizational requirements for economic entities engaged in the wholesale trade of medicinal products;
- tasks and functions of pharmacy warehouses (bases);
- responsibilities of the authorized person of the pharmacy warehouse (base) and methods of incoming quality control of medicinal products.

SELF-CHECK TESTS

1

The pharmacy received a license for the right to sell medicinal products wholesale. Name the operation of the release of goods, which refers to wholesale sales.

A. **Release of goods to other subjects of wholesale or retail trade in medicinal products, which have received appropriate licenses for this:**

B. Issuance of over-the-counter medicines

C. Implementation of ready-made medicines

D. Issuance of medicines to chronic patients

E. Release of extemporaneous medicinal forms

2

What is the name of the structural unit of the pharmacy warehouse that receives goods from suppliers and monitors their arrival?

A. **Receiving department**

B. Operational department

C. Shipping department

D. Merchandise department

E. Transport department

3

In the pharmacy warehouse, a warehouse record of medicines and medical products must be kept. Specify what warehouse accounting should provide:

A. **Timely and reliable display of operations on their arrival, movement and exit**

B. Display of operations on their movement

C. Quantitative and qualitative exchange

D. Posting and disposal of pharmaceuticals and medical devices.

E. Display of transactions regarding their receipt and disposal

4

A student of the Faculty of Pharmacy, who is undergoing practice in pharmacy No. 1, had questions regarding the organization of the incoming quality control of medicines in the pharmacy. Specify the period during which the authorized person must apply to the territorial body of the central executive body that implements the state policy in the field of quality control and safety of medicinal products in the event of receiving a negative opinion on the quality of medicinal products:

A. **10 days**

B. 7 days

C. 5 days

D. 1 days

E. 15 days

5

According to the supply contract, the pharmacy receives medicines from the pharmacy warehouse. What is the remaining expiration date of the pharmacy's medicinal products?

A. **At least 60%**

B. At least 40%

C. At least 20%

D. At least 10%

E. Within the main expiration date

6

Goods and material values from JSC "Darnytsia" have arrived at the pharmacy warehouse in accordance with the supply contract. Which warehouse department receives the goods directly?

A. **Reception department**

B. Expedition department

C. Equipment department

D. Storage department

E. Operational department

7

***Leave from the pharmacy warehouse*(sale) of medicinal products is NOT carried out:**

A. **To the population**

B. To business entities that have a license for the retail trade of drugs

C. For the production of medicinal products (for use in production)

D. To business entities that have a license for the wholesale trade of drugs

E. Directly to health care institutions

8

Indicate which regulatory document establishes the qualification, organizational, technological and other special requirements for activities in the wholesale trade of pharmaceuticals:

A. **License conditions**

B. Proper regulatory practice

C. Commercial Code of Ukraine

D. Law "On Medicinal Products"

9

Specify the body that carries out state quality control of medicinal products during wholesale and retail trade:

A. **State Service of Ukraine for Medicinal Products and Drug Control National**

B. Local self-government bodies

C. Cabinet of Ministers of Ukraine

D. State Sanitary and Epidemiological Service

E. Academy of Medical Sciences of Ukraine

10

During the implementation of incoming control, some drugs were found, which raised doubts about the quality. How should the authorized person act?

A. **Samples of questionable pharmaceuticals should be sent for analysis, the batch of goods is in quarantine**

B. Transfers a batch of medicinal products for sale

C. Returns to manufacturer

D. Draws up an act on detected defects and hands it over to the Party of Doubtful Medicines for implementation drugs are disposed of

TOPIC 12
THE STATE SYSTEM OF QUALITY ASSURANCE OF MEDICINAL PRODUCTS

Student should know: the main principles of the organization of the state system of quality control of medicinal products.

Basic terms and concepts: State Register of Medicinal Products of Ukraine, State Pharmacopoeia of Ukraine, pharmacopoeial article, quality of medicinal product, analysis of medicinal product, expiration date of medicinal product, laboratory studies of quality of medicinal products, medicinal products of questionable quality, state control of medicinal product quality, incoming control, low-quality medicinal products, opinion on quality, quality certificate of medicinal product, authorized person, falsified medicinal products.

QUESTIONS

1. Regulations on the State Service of Ukraine for medicinal products and drug control.
2. The procedure for State registration of medicinal products.
3. Quality certification of pharmaceutical products.
4. State quality control of medicinal products during wholesale and retail trade.
5. Incoming quality control of medicinal products during wholesale and retail trade, rights and obligations of the authorized person.

SELF-CHECK QUESTIONS

1. The main tasks and functions of the State Medical Service and drug control.
2. Procedure for State registration (re-registration) of medicinal products.
3. Quality certification of pharmaceutical products.
4. Stages of quality certification of medicinal products for international trade.
5. State quality control of medicinal products during retail trade.
6. State quality control of medicinal products during wholesale trade.
7. Control over the circulation of falsified medicinal products.

8. Organization of incoming quality control of medicines in pharmacies (retail trade).

9. Organization of quality control of medicinal products at business entities that have licenses to carry out economic activity in the wholesale trade of medicinal products

10. The procedure for appointing an authorized person for incoming quality control of pharmaceuticals during wholesale and retail trade, his duties.

OVERVIEW

The State Service of Ukraine for Medicinal Products and Drug Control is the central body of the executive power, the activities of which are directed and coordinated by the Cabinet of Ministers of Ukraine through the Minister of Health, which implements state policy in the areas of quality control and safety of medicinal products, including medical immunobiological preparations, medical equipment and medical devices, and circulation of narcotic drugs, psychotropic substances and precursors, combating their illegal circulation.

The main tasks of the State Medical Service are:

- implementation of state policy in the spheres of quality control and safety of medicines, medical devices and the circulation of narcotic drugs, psychotropic substances and precursors, combating their illegal circulation, as well as making proposals to the Minister of Health on the formation of state policy in the specified spheres;
- licensing of economic activities for the production of medicinal products, import of medicinal products (except for active pharmaceutical ingredients), wholesale and retail trade of medicinal products, circulation of narcotic drugs, psychotropic substances and precursors;
- technical regulation in certain areas;
- implementation of state regulation and control in the spheres of circulation of narcotic drugs, psychotropic substances and precursors and combating their illegal circulation.

Functions of the State Medical Service:

- control over compliance with the requirements for ensuring the quality and safety of medicines and medical devices;
- fulfillment of licensing conditions for conducting economic activities for the production of medicinal products, wholesale and retail trade with such means, regardless of the form of ownership and departmental subordination;
- supervises compliance with the requirements of technical regulations regarding medical devices;
- selects samples of medicinal products and medical products in the prescribed manner to check their quality;
- issues binding prescriptions on the elimination of violations of standards and technical conditions, pharmacopoeial articles and technological regulations, as well as on the elimination of violations during the production, storage, transportation, and sale of medicinal products;
- carries out certification of pharmacists and pharmacists in accordance with the procedure established by law;
- carries out state registration of medical devices, etc.

Procedure for State registration (re-registration) of medicinal products.

Medicinal products are allowed to be used in Ukraine after their state registration.

State registration of medicinal products is carried out on the basis of an application submitted to the central executive body that implements state policy in the field of health care.

In the application for state registration of the medicinal product, the following shall be specified: the name and address of the manufacturer; the address of its location and production facilities; the name of the medicinal product and its trade name; the name of the active substance (in Latin); synonyms; release form; full composition of the medicinal product; indications and contraindications; dosage; conditions of leave; methods of application; term and conditions of storage; packaging information; data on the registration of the medicinal product in other countries, including the name of the country, number and date of registration.

The following are attached to the application: materials of the registration file; materials on methods of quality control of medicinal products; packaging labeling text; a document confirming payment of the registration fee; a graphic representation of the layout of the medicinal product packaging; instruction on the use of the medicinal product.

Information about submitted applications for state registration, the status of document review and decisions made as a result of it is published free of charge on the website of the institution that examines registration materials.

Based on the results of consideration of the specified materials, the central executive body implementing the state policy in the field of health care, within a period not exceeding ten working days, makes a decision on registration or refusal to register the medicinal product.

A certificate is issued to the applicant for a registered medicinal product, which specifies the validity period during which the medicinal product is allowed to be used in Ukraine.

The medicinal product can be used in Ukraine for five years from the date of its state registration. At the request of the person who submitted the application for state registration of the medicinal product, the period during which it is allowed to be used on the territory of Ukraine may be shortened by the decision of the registering body.

In the case of discovery of previously unknown dangerous properties of a medicinal product, the central executive body that implements state policy in the field of health care may decide on a complete or temporary ban on its use.

After the expiration of the period during which the medicinal product was allowed to be used in Ukraine, its further use is possible subject to re-registration. After re-registration, the period of use of the medicinal product in Ukraine is not limited.

Certification of pharmaceutical products

Certification of the quality of medicinal products for international trade is carried out by the State Medical Service by conducting an examination statements about issuing medicinal product certificate / application for licensing status / medicinal product series certificate / confirmation for active pharmaceutical ingredients exported according to

the certification dossier, and conducting laboratory analysis of the quality of medicinal products.

The certification procedure includes the following stages:

- submission of an application and certification dossier to the State Medical Service, and, if necessary, a written request of the applicant regarding the selection of samples in an arbitrary form (in the case of submitting an application for the issuance of a certificate of a medicinal product series);

- verification and processing of the submitted by the State Medical Servicestatements,certification file and, if necessary, issuing a referral for sampling for laboratory analysis;

- sample selection and laboratory control;

- adoption of a decision by the State Medical Service regarding the issuance of a medicinal product certificate and/or an application for licensing status and/or a medicinal product series certificate;

- registration and issuance of a medicinal product certificate and/or an application for licensing status and/or a medicinal product series certificate.

State quality control of medicines

State quality control of medicinal products during their wholesale and retail trade is carried out by the central executive body, which implements state policy in the spheres of quality control and safety of medicinal products, including medical immunobiological preparations, medical equipment and medical products, and circulation of narcotic drugs, psychotropic substances and precursors, combating their illegal circulation, and its territorial bodies.

State quality control of medicinal products is carried out in accordance with the Laws of Ukraine"About medicines", "On the basic principles of the state supervision (control) in sphere economic activity", In order selection samples medical means for laboratory analysis under time implementation state quality control of such means,approved by the resolution of the CMU dated February 3, 2010 No. 260,The procedure for establishing a ban (temporary prohibitions) and renewal circulation medical means on territory of Ukraine,approved by the order of the Ministry of Health

of Ukraine dated November 22, 2011 No. 809, registered in the Ministry of Justice of Ukraine on January 30, 2012 under No. 126/20439, this Order.

The selection of samples of medicinal products for their laboratory analysis is carried out in accordance withIn order selection samples medical means for laboratory analysis during the implementation of state quality control of such means,approved by the resolution of the CMU dated February 3, 2010 No. 260, and is being processedact of selection of samples of medicinal products for laboratory analysis their quality withand the established form. First of all, medicinal products manufactured (under the conditions of a pharmacy), stored, transported and sold in violation of current norms and rules, and in case of doubt about their quality, are subject to selection.

Laboratory research of the quality of medicinal products is carried out by subordinate or authorized laboratories on the basis of referrals from the central executive body, which implements state policy in the areas of quality control and safety of medicinal products, including medical immunobiological preparations, medical equipment and medical devices, and the circulation of narcotic drugs, psychotropic substances substances and precursors, combating their illegal circulation, or its territorial bodies or on the basis of appeals by business entities to the central body of executive power, which implements state policy in the spheres of quality control and safety of medicinal products, including medical immunobiological preparations, medical equipment and medical devices, and the circulation of narcotic drugs, psychotropic substances and precursors, combating their illegal circulation, and/or its territorial bodies. Incoming quality control of medicinal products.

Incoming quality control of medicinal products during wholesale and retail trade is carried out using visual methods by authorized persons of business entities that have licenses to carry out economic activity in the wholesale and retail trade of medicinal products. The authorized person is a specialist with a complete higher pharmaceutical education and at least 2 years of work experience in the specialty, who is entrusted by the business entity with the responsibilities of effective management of the quality system of medicinal products during their wholesale and retail trade, conducting incoming quality control of medicinal products. The fulfillment of the duties of an

authorized person responsible for the effective management of the quality system of medicines in a pharmacy located in a rural area can be entrusted to a person with a pharmaceutical education who has obtained the educational and qualification level of a specialist - junior specialist, bachelor. The fulfillment of the duties of an authorized person in rural areas can be entrusted to specialists without professional experience.

Duties of the authorized person:

1. to check medicinal products received by the business entity and accompanying documents - invoices (with mandatory indication of the name, dosage, dosage form, series number, expiration date, quantity, name of the manufacturer); quality certificates of the medicinal product series issued by the manufacturer (for imported medicinal products - the importer (manufacturer or a person representing the manufacturer of medicinal products on the territory of Ukraine)), conclusions about the quality of the medicinal product imported into Ukraine (for medicinal products of foreign production), conclusions about compliance of MIBP with the requirements of state and state and international standards (for medical immunobiological drugs); information about the state registration of the medicinal product;

2. draw up in paper or electronic form (if there is an appropriate electronic accounting system with user authentication and access restriction) the conclusion of the incoming quality control of medicinal products by marking the result positive/negative, allowed/not allowed for sale on the revenue documents, with the identification of the date of its implementation and the authorized individuals;

3. to keep records of the decisions of the central executive body, which implements state policy in the spheres of quality control and safety of medicinal products, including medical immunobiological preparations, medical equipment and medical devices, and circulation of narcotic drugs, psychotropic substances and precursors, combating their illegal circulation, regarding the quality of medicinal products in electronic and/or paper form with the possibility of forming registers of the movement of medicinal products in response to the requests of the central executive body, which implements state policy in the areas of quality control and safety of medicinal products, including medical immunobiological preparations, medical

equipment and medical products, and circulation of narcotic drugs, psychotropic substances and precursors, combating their illegal circulation, and its territorial bodies;

4. to ensure the possibility of forming registers of the movement of medicinal products, which are sold by the economic entity, in electronic or paper form, in order to be able, if necessary, to recall series of medicinal products;

5. to check the availability of medicinal products, the circulation of which is prohibited in Ukraine; medicines that are not registered in Ukraine and whose expiration date has passed;

6. to provide information to the territorial body of the central executive body, which implements state policy in the areas of quality control and safety of medicinal products, including medical immunobiological preparations, medical equipment and medical devices, and circulation of narcotic drugs, psychotropic substances and precursors, combating their illegal circulation, about detected low-quality medicinal products (with the exception of medicinal products whose expiration date has passed); medicines suspected of being falsified; falsified and unregistered medicinal products. When samples of such medicinal products are detected, take measures to remove them from circulation by placing them in a specially designated, clearly defined, marked quarantine zone (premises), separate from other products, marked "Quarantine" with the possibility of identifying the reasons for removal and the date of placement.

7. For large volumes of quarantined goods, it is allowed to be placed in the general storage area, provided that clear signal marking of quarantined products and additional safety measures (including the use of electronic accounting systems) are provided to prevent shipment of quarantined goods, which are defined in standard operating procedures and legislation;

8. to ensure constant monitoring of the storage conditions of medicines in accordance with the requirements of the instructions for the medical use of the medicine;

9. to grant permission for the sale (issuance) of received batches of medicinal products.

PRACTICAL ASSIGNMENTS

Task 1. Schematically depict the organizational structure of the quality control system of medicinal products in Ukraine.

After completing the practical task, the student should acquire practical skills and abilities:

- conducting incoming quality control of medicines that are delivered to retail and wholesale trade entities;
- performance of the duties of an authorized person during the incoming quality control of drugs arriving at the pharmacy;
- search and systematization of legal acts regulating the organization of the state system of quality control of medicinal products.

SELF-CHECK TESTS

1

During the inspection of the pharmacy, the inspector of the territorial state service for drugs took samples for laboratory analysis. What is the minimum amount of each drug he can take?

A. **At least 2 packages**
B. At least 1 package
C. At least 3 packages

D. At least 4 packages

E. At least 5 packages

2

According to the order on the temporary prohibition of medicinal products, they must be placed in the zone:

A. **Quarantine**

B. Public service halls

C. Closets for storing clothes

D. Staff rooms

E. Premises for storing inventory

3

A batch of Mezim forte #20 tablets arrived at the pharmacy. Upon receiving the goods, the authorized person of the pharmacy discovered that several packages of pharmaceuticals had lost their appearance during transportation. What is the name of drugs that have the appropriate labeling, but which, in the absence of proper conditions of production, transportation and storage, do not meet the established requirements of regulatory documents:

A. **Low-quality**

B. Inappropriate

C. Quality

D. Counterfeit

E. Improper

4

A batch of goods arrived at the pharmacy. In case of doubt in the authorized person during the visual control in the pharmacy about the quality of the product that came from the wholesale pharmaceutical company, is it necessary?

A. **Send samples to the Territorial State Medical Service and Drug Control for**

analysis

B. Write off at own expense

C. Return the goods to the wholesale company

D. Return the goods to the manufacturer's factory

E. Destroy at the company's expense

5

The licensee is obliged to remove from sale, accordingly identify and place in quarantine zones the following medicinal products:

A. **Falsified medicinal products**

B. Registered medicinal products

C. Quality medicinal products

D. Medicinal products allowed for sale

E. Medicinal products without damage

6

The state system of drug quality assurance has three levels. Which of the above refers to the microeconomic level?

A. **Pharmacies of the Ministry of Health of Ukraine**

B. State expert center

C. Regional control and analytical laboratories Ukrainian

D. Pharmaceutical Quality Institute

7

The quality assurance system of medicinal products performs certain functions. What function consists in creating a regulatory and legal field of activity, implementation of licensing mechanisms *pharmaceutical activity*?

A. **Regulatory**

B. Scientific and Methodological

C. Controlling

D. Management

E. Information

8

What is the name of a drug that has not passed the state registration procedure in the relevant authorities and is not entered in the State Register of Medicines?

A. **Unregistered**

B. Counterfeit

C. Substandard

9

An entity of economic activity that has a license for the wholesale trade of medicinal products must ensure:

A. **Incoming drug quality control by an authorized person**

B. Carrying out in-pharmacy quality control of drugs

C. Availability of a control and analytical laboratory

D. Inspection of medicines by a pharmacist-analyst

TOPIC 13
ORGANIZATION OF FOREIGN TRADE ACTIVITIES OF PHARMACY ENTERPRISES

Student should know:basic concepts of foreign economic activity, features of concluding foreign economic contracts (agreements) for the purchase and sale of drugs and other pharmacy products, terms of delivery in accordance with the international rules of INCOTERMS for the import of medicinal products and pharmacy products into Ukraine.

Basic terms and concepts: foreign economic activity (FEA), types of export (import) licenses, customs duty, International Monetary Fund (IMF), International Bank for Reconstruction and Development (IBRD) or World Bank, International Chamber of Commerce (ICC; World Trade Organization (WTO), customs regime) , foreign economic agreement (contract), offer, acceptance, international commercial terms "Incoterms-2010", customs tariff of Ukraine, customs value of goods.

QUESTIONS

1. The concept of foreign economic activity. Instruments of regulation of foreign economic activity.

2. Peculiarities of concluding foreign economic contracts (agreements) for the purchase and sale of medicinal products and other pharmacy products.

3. Terms of delivery according to the international rules of INCOTERMS.

4. The essence and principles of customs regulation of foreign economic activity in Ukraine.

5. Peculiarities of importing medicines and pharmacy products into Ukraine Procedure for declaring imported goods.

SELF-CHECK QUESTIONS

1. Define foreign economic activity. Specify its main types.

2. Who can be the subjects of FEA according to the current legislation.

3. Name the international organizations that regulate world trade, monetary and financial relations.

4. What legal regimes are provided for goods from WTO member countries.

5. Describe the main customs regimes.

6. Name the main principles of customs regulation.

7. Describe the procedure for concluding an international sales contract.

8. Name the main stages of customs control and customs clearance of goods.

9. Name the main methods of determining the customs value of goods.

10. What documents are submitted by a business entity when importing drugs to the territory of Ukraine?

OVERVIEW

Foreign economic activity - the sphere of economic activity of the state, enterprises, firms, companies, including the pharmaceutical industry, related to international trade, foreign loans and investments. Foreign economic activities include: export and import of goods; provision of various types of services to each other by subjects of foreign economic activity; international financial transactions; credit and settlement transactions between entities; joint business activity.

Subjects of foreign economic activity are: natural persons - citizens of Ukraine, foreign citizens and stateless persons; legal entities that are registered in Ukraine and are permanently present on its territory; structural units of subjects of economic activity of foreign countries (subsidiaries, branches, branches, representative offices).

Regulation of foreign economic activity is carried out: by the state in the person of relevant bodies within their competence; non-state economic management bodies (commodity and stock exchanges, chambers of commerce, associations, unions and other organizations of a coordinating type); by the subjects of foreign economic activity themselves on the basis of relevant coordination agreements concluded between them.

With the aim of operational regulation of foreign economic activity, optimal satisfaction of the population in various groups of goods, protection of domestic producers in Ukraine and implementation of concluded international agreements, the

CMU annually approves a list of goods whose export and import are subject to quotas and licensing.

The foreign economic policy of Ukraine promotes both the development of the country's domestic market and the gradual integration of the national economy into the world economy. This general trend is also characteristic of the pharmaceutical industry.

The implementation of foreign economic activity contributes to the development of a competitive domestic pharmaceutical industry, allows the formation of a pharmaceutical market designed to fulfill the most important social task - providing the population with pharmaceuticals and medical products.

The main directions of foreign economic activity in the pharmaceutical industry of Ukraine are:

- establishment of direct relations with partners - leading pharmaceutical companies of the world pharmaceutical market;
- identification of economic conditions of cooperation;
- conclusion of long-term contracts with further cooperation, starting with the purchase of raw materials, substances, obtaining technologies and equipment for their joint production;
- approval of the nomenclature and volumes of import/export of drugs;
- determination of price strategies of import-export operations of drugs;
- provision of production services and conducting research and development work in pharmacy;
- creation of a joint venture for the production of pharmaceutical products and participation in international pharmaceutical associations and organizations;
- purchase of licenses for the production of important pharmaceutical substances and the manufacture of pharmaceutical products at enterprises of Ukraine;
- intensification of market research to identify the real volume of import (export) of drugs;
- expansion of export and import of pharmaceuticals directly by enterprises-producers of pharmaceutical products while maintaining state regulation of these processes.

The pharmaceutical market is multifunctional and advanced in terms of knowledge, capital intensity and significance for the country's economy and society as a whole. The functioning of this market is impossible without effective foreign economic activity.

By the time end consumers buy medicines in a pharmacy, this product goes through a certain path from the manufacturer/importer to wholesale distributors, then from wholesalers to pharmacies (or from the domestic manufacturer to pharmacy chains), and only then reaches the end consumer through the pharmacy , who buys medicine for his own consumption.

The modern Ukrainian market of pharmaceutical products and drugs includes a significant part of imported medical drugs, as well as a majority of the products of outdated, clinically ineffective drugs.

That is, the pharmaceutical market of Ukraine remains import-dependent.

Exchange between producers of different countries is carried out through foreign trade operations. In order for the exchange to take place, it is necessary to carry out appropriate interrelated actions:

1. find a buyer;

2. sign an agreement with them in which to discuss all conditions (goods, their quantity and quality, price, delivery terms, etc.);

3. to fulfill the contract, i.e. to prepare the goods for delivery, deliver them to the buyer, make a payment for the delivered goods.

The totality of these actions constitutes the content of a foreign trade operation, that is, a complex of actions of counterparties of different countries aimed at carrying out trade exchange. Such actions are of a commercial nature, therefore exchange operations become commercial.

A foreign trade operation as a managerial activity involves the presence of entities that carry out this activity and objects to which this activity is directed.

Subjects of foreign trade operations are enterprises, firms, organizations that received from the state the right to enter the foreign market.

The objects of foreign trade operations are material processes that manifest

themselves in the process of exchanging goods, services, and the results of industrial and scientific-technical cooperation. These objects determine the types of foreign trade operations on the world market. Foreign trade operations are divided into main and auxiliary.

The main ones include operations that are carried out on a settlement basis between the direct participants of these operations (counterparts of different countries). These operations:

1. on the exchange of scientific and technical knowledge in the form of trade in patents, licenses, "know-how";

2. on the exchange of goods in tangible form (export-import operations).

Auxiliary foreign trade operations include:

1. for international transportation;

2. transport and forwarding;

3. on cargo insurance;

4. on the preservation of cargo during international transportation;

5. international settlement operations, etc.

Types of foreign economic activity in accordance with the Law of Ukraine "On Foreign Economic Activity" (Article 4) in our country, subjects of foreign economic activity carry out the following types of activities (Appendix D):

- export and import of goods, capital and labor;
- provision of services by subjects of foreign economic activity to foreign subjects of economic activity;
- scientific, scientific and technical, scientific and industrial, production, educational and other cooperation with foreign subjects of economic activity;
- training and training of specialists on a commercial basis;
- international financial transactions and transactions with securities in cases provided for by the laws of Ukraine;
- credit and settlement operations between subjects of foreign economic activity and foreign subjects of economic activity;

- creation by subjects of foreign economic activity of banking, credit and insurance institutions outside of Ukraine; creation by foreign subjects of economic activity of the specified institutions on the territory of Ukraine in the cases provided for by its law;

- joint business activity between subjects of foreign economic activity of Ukraine and foreign subjects of economic activity, which includes the creation of joint enterprises of various types and forms, conducting joint economic operations and joint ownership of property both on the territory

- of Ukraine and beyond;

- entrepreneurial activity on the territory of Ukraine, related to the granting of licenses, patents, know-how, trademarks and other intangible property objects by business entities;

- similar activity outside Ukraine;

- organization and implementation of activities in the field of holding exhibitions, auctions, trades, conferences, symposia, seminars and other similar events, carried out on a commercial basis, with the participation of subjects of foreign economic activity;

- organization and implementation of wholesale, consignment and retail trade on the territory of Ukraine for foreign currency in cases provided for by the legislation of Ukraine;

- commodity exchange (barter) operations and other activities based on forms of counter trade between subjects of foreign economic activity and foreign subjects of economic activity;

- rental, including leasing, operations between subjects of foreign economic activity and foreign subjects of economic activity;

- operations on purchase, sale and exchange of currency at currency auctions, currency exchanges and on the interbank currency market.

If earlier in Ukraine the procedure for organizing and carrying out foreign trade operations was regulated, today it has many gaps and outdated provisions that need to be updated.

The legislation of Ukraine does not contain a definition of an international commercial agreement (contract). However, the Law of Ukraine "On Foreign Economic Activity" defines the concept of "foreign economic agreement (contract)" as a materially executed agreement between two or more subjects of foreign economic activity and their foreign counterparties, aimed at the emergence, change or termination of their mutual rights and obligations in the sphere of foreign economic activity. The parties to the foreign economic contract are under the jurisdiction and on the territory of different states, the goods cross customs borders, and payments are made in foreign currency through an authorized bank (with the exception of commodity exchange agreements).

International organizations regulating world trade, currency and credit operations and financial relations:

- ***International Monetary Fund (IMF)***- controls international currency credit and financial relations;

- ***International Bank for Reconstruction and Development (IBRD) or the World Bank***- contribute to the financing of investment projects in war-torn countries and liberated countries, provide expertise and consultations in the field of development policy;

- ***International Chamber of Commerce***(MTP; Eng. - International Chamber of Commerce, ICC) - an independent non-commercial international organization, created in 1919, which currently unites thousands of enterprises, associations and companies from 140 countries of the world. The activity of MTP is aimed at solving the most urgent issues, including the development of unified rules and standards for conducting business and solving problems related to the liberalization of international trade. Among the ICC documents: Incoterms (Unified Trade Terms of the ICC), Arbitration Rules of the ICC, standard international contracts, etc.;

- ***World Trade Organization (WTO)***- which is based on the General Agreement on Tariffs and Trade (GAAT), concluded in 1947 between 23 countries. Ukraine became a member of the WTO in 2008.

International trade customs, which are usually understood as single (uniform), constantly observed and widely known rules of conduct, which are recognized as legally

binding by trade participants, traditionally play a significant role in the field of regulation of foreign trade and international maritime transport.

One of the most well-known trade customs in international trade is the Rules for the Interpretation of Commercial Terms "Incoterms®" (Incoterms®), adopted by the International Chamber of Commerce (hereinafter - ICC). Currently, the Incoterms 2020 edition (Incoterms® 2020) is used in the contracts. Uniform trade customs also include Rules for sea waybills, Rules for electronic bills of lading, developed by the International Trade Commission.

International commercial terms "Incoterms - 2020":

EXW- ex-factory (indicating the delivery point)

This term is often used in initial price offers for the sale of goods without taking into account any costs. EXW means that the seller provides the goods on his territory or at another specified place (plant, factory, warehouse, etc.). The seller must neither load the goods on the transport for the delivery of goods, nor clear the goods for export.

FCA– freight forwarder (indicating the delivery point)

The term FCA can have two different meanings, each involving different levels of risk and cost for the buyer and the seller. FCA (a) is used when the seller delivers goods cleared for export to a specified place which is his own territory. FCA (b) is used when the seller delivers goods cleared for export to a specified place which is not his own territory. In both cases, the goods may be delivered to a carrier designated by the buyer or to another party designated by the buyer.

CPT– transportation paid to... (indicating the destination)

Under the terms of CPT, the seller pays for the transportation of the goods to the specified destination.

CIP– transportation and insurance are paid until... (indicating the destination)

These conditions are similar to CPT conditions with the exception that the seller must provide minimum insurance for the goods during transportation.

DAP- delivery to the destination (indicating the destination)

In this case, the seller is considered to have delivered the goods if the goods are at the disposal of the buyer on the arriving mode of transport and are ready for unloading

at the specified destination. Under DAP, the seller must manage all the risks associated with the importation of the goods.

DPU– delivery to the destination with unloading (indicating the destination)

According to these Incoterms, the seller must provide the goods in an unloaded form at the specified place. The seller pays all transportation costs (export fees, handling charges, unloading from the main carrier's transport at the destination port and destination port fees) and assumes all risks until arrival at the destination.

DDP- delivery with payment of duty (with the destination indicated)

The seller is responsible for the delivery of the goods to the specified place in the buyer's country and pays all costs related to the transportation of the goods to the destination, including import duties and taxes. The seller is not responsible for unloading.

By agreement of the parties, the contract (contract) may also determine other conditions: insurance, quality guarantees, conditions for the involvement of subcontractors, agents, carriers, determination of loading (unloading) norms, conditions for the transfer of technical documentation for the goods, the procedure for paying taxes, customs duties, the possibility and the procedure for making changes to the agreement (contract), etc.

Ukraine independently determines the customs policy, creates its own customs system and carries out customs regulation on its territory in accordance with the Customs Code (MCU), laws of Ukraine and international treaties with the participation of Ukraine.

Customs regime- a set of interrelated legal norms that, in accordance with the stated purpose of moving goods across the customs border of Ukraine, determine the customs procedure for these goods, their legal status, taxation conditions and determine their use after customs clearance.

A foreign economic agreement (contract) is a materially formalized agreement between two or more foreign economic entities and their foreign counterparties, aimed at defining, changing or terminating their mutual rights and obligations in economic economic relations.

The procedure for concluding and executing sales contracts is regulated by the UN Convention on Contracts for the International Sale of Goods of April 11, 1980 (Vienna Convention), which entered into force for Ukraine on

February 1, 1991.

The conclusion of the contract must go through two main stages:

Offer- the offer to conclude a contract must contain all the essential points of the future contract and be addressed to a specific person or a certain circle of persons (the so-called public offer). The offer becomes effective when the addressee received it.

Acceptance- acceptance of the offer, statement or other behavior of the addressee of the offer, which indicates agreement with the offer.

The structure of the contract of sale:

main sections of the foreign economic sales contract:

1. Name, contract number;
2. Preamble;
3. Subject of the contract (contract);
4. Quantity and quality of goods;
5. Term and date of delivery;
6. Basic conditions of delivery;
7. Price and total value of the contract;
8. Terms of payments;
9. Terms of acceptance and delivery of goods;
10. Packaging and labeling;
11. Force majeure circumstances;
12. Sanctions and claims;
13. Settlement of disputes in court; 14. Location and payment details of the parties;
15. Supplements and annexes to the contract.

The customs tariff of Ukraine contains a list of rates of the national tax - import duty on goods imported into the customs territory of Ukraine and systematized according to the Ukrainian classification of goods of foreign economic activity,

compiled on the basis of the Harmonized system of description and coding of goods. Customs duties on goods and other items are calculated on the basis of their customs value.

Customs value of goods- this is the value declared by the declarant of the goods moving across the customs border of Ukraine, which is calculated at the moment when the goods cross the customs border in accordance with the requirements of the Customs Code of Ukraine. Data on the customs value of goods is used for calculating taxes and fees, maintaining customs statistics, as well as for calculations in the event of the application of fines, other sanctions and penalties established by the laws of Ukraine.

In order to implement the provisions of the Partnership and Cooperation Agreement between Ukraine and the EU, an interdepartmental database "Medical products registered in Ukraine" was created. During the importation of electronic devices into the territory of Ukraine and customs clearance of electronic devices, the customs inspector checks their availability in the specified database. The absence of the LZ in the base is a reason for refusal to move it across the customs border of Ukraine and to refuse customs clearance.

The following types of export (import) licenses are used in Ukraine:

- general - open permission for export (import) operations for a certain product or with a certain country during the period of validity of the licensing regime;
- one-time (individual) - issued for the implementation of each operation by a specific subject of the foreign exchange for the period necessary for its implementation;
- open (individual) - permission to export (import) goods within a certain period of time (not less than a month) with a definition of its total volume.

PRACTICAL ASSIGNMENTS

Task 1. Present in the form of a table (table 1) the purpose of the activities of the main international organizations that regulate world trade, currency, credit and financial relations:

1. International Monetary Fund (IMF);

2. International Bank for Reconstruction and Development (IBRD) or World Bank

3. Bank;

4. International Chamber of Commerce (ICC; English — International Chamber of;

5. Commerce, ICC;

6. World Trade Organization (WTO).

Organization	The purpose of the activities
1. International Monetary Fund (IMF)	
2. International Bank for Reconstruction and Development (IBRD) or World Bank	
3. Bank	
4. International Chamber of Commerce (ICC; English — International Chamber of	
5. Commerce, ICC	
6. World Trade Organization (WTO)	

After completing the practical task, the student should acquire practical skills and abilities:

- application of legislative acts that regulate foreign economic pharmaceutical activity;
- conclusion of foreign economic contracts (agreements) for the purchase and sale of medicines and other pharmacy products.

SELF-CHECK TESTS

1

Which regulatory document governs the mode of conducting barter transactions?

A. P(S)BO 21 “Effect of Changes in Currency Exchange Rates”

B. Law of Ukraine “On Taxation of Corporate Income”

C. Law of Ukraine “On Regulation of Barter Transactions in the Field of Foreign Economic Activity”

D. Law of Ukraine “On Medicines”

E. Law of Ukraine “On Enterprises in Ukraine”

2

In which country are taxes, duties, and fees paid when conducting barter operations?

A. In the country where the contract is concluded

B. In the country that initiated the barter transaction

C. Each party pays in their own country independently without any mutual settlements

D. Taxes, duties, and fees for barter operations are abolished in some countries

E. Taxes, duties, and fees for barter operations are assigned to executive authorities

3

On what date is revenue recognized when conducting a barter transaction?

A. On the date of signing the barter contract

B. On the date of customs clearance of goods

C. On the date of customs clearance of goods, signing the act, or another document confirming the actual provision of services or completion of works

D. On the date of signing the act

E. On the date of signing the contract

4

The only document that confirms the fact of importation is:

A. Invoice

B. Cargo customs declaration

C. Contract and a copy of the contract

D. Declaration

E. Copy of the contract

5

What is foreign economic activity?

A. This is the activity of business entities of Ukraine and foreign entities, based on relations between them, taking place both in Ukraine and abroad

B. This is the activity of business entities of Ukraine and foreign entities, based on relations between them, taking place in Ukraine

C. This is the activity of business entities of Ukraine, based on relations between them, taking place both in Ukraine and abroad

D. This is the activity of business entities

E. This is the activity of foreign entities

6

Foreign economic activity in Ukraine is regulated by:

A. P(S)BO 21 “Effect of Changes in Currency Exchange Rates”

B. Law of Ukraine “On Enterprises in Ukraine”

C. Law of Ukraine “On Foreign Economic Activity”

D. Law of Ukraine “On Taxation of Corporate Income”

E. Law of Ukraine “On Medicines”

7

In which currency is foreign economic activity accounted for?

A. In US dollars

B. In the national currency of Ukraine

C. In the currency of the partner country

D. In various currencies

E. In euros

8

Which regulatory document governs the form and procedure for drafting contracts?

A. Law of Ukraine “On Foreign Economic Activity”

B. P(S)BO 21 “Effect of Changes in Currency Exchange Rates”

C. “Regulation on the Forms of Foreign Economic Contracts”

D. Law of Ukraine “On Foreign Economic Activity”

E. Law of Ukraine “On Medicines”

9

Who and when established the INCOTERMS rules?

A. In 2000 by the International Chamber of Commerce

B. In 2000 by the Verkhovna Rada of Ukraine

C. In 1975 by the United Nations

D. In 2000 by the International Monetary Fund

E. In 2000 by the World Trade Organization

10

Acceptance is:

A. A business letter from the buyer to the seller containing a request for specific information about a possible transaction

B. A business letter from the buyer to the seller specifying the buyer's desire to purchase specific goods and services

C. A commercial document that is the seller's (exporter's) statement of intention to enter into a transaction with an indication of its specific terms

D. The agreement of a natural or legal person to conclude a contract with another person on the terms proposed by the latter

E. A business letter from the seller to the buyer containing a request for specific information about a possible transaction

RECOMMENDED LITERATURE

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