## MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS

Educational Institution
BELARUSIAN STATE MEDICAL UNIVERSITY

APPROVED

hy Rector of the Educational Institution (Belarusian State Medical University)

S.P.Rubnikovich

15, 11. 2023

Reg. # UD-*0912-01-03/232*/edu.

Контрольный экземпляр

#### BIOPHARMACEUTICAL ETHICS AND COMMUNICATION

Curriculum of the educational institution in the academic discipline for the specialty

7-07-0912-01 «Pharmacy»

Curriculum is based on the educational program «Biopharmaceutical Ethics and Communications», approved 15.11.2023 registration # УД-0912-01-03/2324/уч.; on the educational plan in the speciality 7-07-0912-01 «Pharmacy», approved 17.05.2022, registration # 7-07-0912-01/2324/mf.

#### **COMPILERS:**

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#### **RECOMMENDED FOR APPROVAL:**

by the Department of Organization and Economics of Pharmacy of the educational institution «Belarusian State Medical University» (protocol # 5 of 01.11.2023);

by the Scientific and Methodological Council of the educational institution «Belarusian State Medical University» (protocol # 11 of 15.11.2023)

## **EXPLANATORY NOTE**

«Biopharmaceutical Ethics and Communications» is an academic discipline of the Communication Module containing systematized scientific knowledge about the theoretical foundations and organizational principles of biopharmaceutical ethics and communication in the field of pharmaceutical activity.

The curriculum for the academic discipline «Biopharmaceutical Ethics and Communications» of the Communication Module is aimed at studying the latest scientific data in the field of biopharmaceutical ethics; modern moral foundations that regulate the activities of pharmaceutical workers and moral problems generated by the latest achievements of modern pharmacy, medicine and biology; ethical and legal regulation of the circulation of medicines and communications in the field of pharmacy.

The purpose of teaching and studying the academic discipline «Biopharmaceutical Ethics and Communications» of the Communication Module is to form students' moral values, a conscious moral attitude to human life and health, as well as communication skills, developing strategies for the interaction of pharmaceutical workers with doctors, patients, and mass media on issues of drug provision of the population.

The objectives of the discipline «Biopharmaceutical Ethics and Communications» are to form students' scientific knowledge about:

basic concepts of ethical and legal aspects of medical and pharmaceutical activities;

basic principles and rules of biopharmaceutical ethics;

the main issues of biopharmaceutical ethics;

bases and principles of communication with patients, doctors and between pharmaceutical workers;

skills and abilities necessary for:

the use in professional activities of methods and means of forming public opinion aimed at maintaining health;

improving communicative competencies.

The academic discipline «Biopharmaceutical Ethics and Communications» is designed to become the basis for the formation of the moral position of students in the study of specialized pharmaceutical disciplines and in their further professional activities — in the field of circulation of medicines, medical devices and other pharmacy products. The content of the discipline focuses on understanding the value bases of pharmaceutical knowledge and activities. The study of the proposed academic discipline is aimed at the conscious acceptance by students of moral and bioethical norms and rules, the understanding of the basic methodological principles and methods of communication in pharmacy.

The knowledge, abilities, and skills acquired in the study of the academic discipline «Biopharmaceutical Ethics and Communications» are necessary for the successful study of the following academic disciplines: «Psychology of Professional Communication. Conflictology», «Management in Pharmacy», «Pharmaceutical Care».

Studying the educational discipline «Biopharmaceutical Ethics and Communications» should ensure the formation of students' specialized competencies:

SC-2. Carry out professional activities in accordance with ethical norms and moral principles of pharmaceutical ethics and deontology, develop a team strategy to achieve the set goal, establish and maintain psychological contact.

As a result of studying the academic discipline «Biopharmaceutical Ethics and Communications» the student should:

#### know:

fundamentals of the legislation of the Republic of Belarus and international law in the field of healthcare, including pharmaceutical activity, the modern concept and prospects for the development of healthcare, pharmaceutical activity and drug safety of the Republic of Belarus;

basic principles and rules of bioethics and biopharmaceutical ethics;

the essence of the main problems of bioethics (life and death, family planning, abortion and reproductive technologies; euthanasia and palliative medicine; transplantology; medical genetics and genetic engineering; biomedical experiment) and their refraction in biopharmaceutical ethics;

originality and problematic field of biopharmaceutical ethics (bioethics of creation, testing, production, circulation of medicines, drug supply, pharmaceutical consulting of the population and medical workers);

moral norms of relationships in the pharmaceutical team, the norms of the relationship «pharmacist-doctor», «pharmacist-pharmacy visitor»;

ethical and legal documents regulating the professional activities of a pharmacist;

essence and main types of communications;

basic methodological principles of communication in pharmacy;

trends, directions and programs for the development of communication in healthcare, pharmaceutical activities and drug provision of the population;

#### be able to:

identify and justify the importance of bioethical and communicative knowledge for the analysis of theoretical and practical aspects of pharmaceutical activity;

analyze the correlation of moral values, principles and norms of traditional pharmaceutical ethics and biopharmaceutical ethics;

assess the influence of risk factors, possible errors and conflict situations in pharmacy in the implementation of communicative activities, establish and maintain psychological contact;

apply modern technologies and communication models in practical and scientific activities;

plan and conduct communication;

#### master:

the conceptual apparatus of the discipline;

the skill of applying the basic ethical and deontological rules of pharmaceutical consultation of the population and medical workers;

the ability to effectively use the basic principles and methods of organizing communication in the field of pharmaceutical activity;

methods of analysis, forecasting, planning and development of communication campaigns aimed at solving the problems of modern healthcare in the field of maintaining health and providing medicines to the population.

**Total number** of hours for the study of the discipline is 200 academic hours. Classroom hours according to the types of studies: lectures – 20 hours (including 7 hours of supervised student independent work), practical classes – 89 hours, student independent work (self-study) – 91 hours.

Intermediate assessment is carried out according to the syllabus of the specialty in the form of a credit (2<sup>nd</sup> semester) and examination (3<sup>rd</sup> semester).

Form of higher education – full-time.

# ALLOCATION OF ACADEMIC TIME ACCORDING TO SEMESTERS OF STUDY

			Nui	nber of a	cademi	c hours		
				ir	ncluding	3	S.	
Code, name of the specialty	semester	total	in-class	lectures (including supervised independent work)	supervised student independent work	practical classes	out-of-class self-studies	Form of intermediate assessment
<b>-</b> 0 <b>-</b> 001 <b>-</b> 01	2	110	61	10	4	51	49	credit
7-07-0912-01 «Pharmacy»	3	90	48	10	3	38	42	examination
<i>y</i>		200	109	20	7	89	91	

# THEMATIC PLAN

Section (topic) name		of class urs
	lectures	practical
I. Biopharmaceutical ethics	10	51
1. Bioethics and biopharmaceutical ethics: status, essence and basic principles	2	6
1.1. Moral guidelines of pharmaceutical knowledge and		3
activity		J
1.2. Biopharmaceutical ethics: theoretical foundations and principles	2	3
2. The phenomenon of life and death from the standpoint of bioethics. The main ethical problems in the development of transplantation and genetics		15
3. Problems of biopharmaceutical ethics	6	21
3.1. Bioethics and foundations of state policy in the field of health care and drug provision		3
3.2. Bioethics of drug circulation. Ethical and legal aspects of drug development	2	3
3.3. Ethical and legal bases of preclinical research and clinical trials of medicines	2	6
3.4. Bioethics of registration and production of medicines		3
3.5. Ethical and legal aspects of the sale of medicines and the provision of pharmaceutical care	2	6
4. Deontological problems in the context of biopharmaceutical ethics	2	9
4.1. Modern pharmaceutical deontology		3
4.2. The role of the pharmaceutical employee in the health care system	2	6
II. The communications in pharmaceutical activity	10	38
5. The communication as a phenomenon of reality and a subject of study. The communication as a social practice	2	2
6. Organizational communication links in pharmacy	2	3
7. Subject areas of communication in pharmacy	2	6
7.1. The information as the basis of the communication process in pharmacy	2	3
7.2. Professional communications in pharmacy: significance for the current stage and development prospects	2	3
8. The business communication tools in pharmacy	2	9
8.1. The non-verbal tools of business communication in pharmacy	2	3
8.2. The verbal tools of business communication in		6

Section (topic) name		of class ours
	lectures	practical
pharmacy		~
9. The applied aspects of communication in pharmacy	2	18
9.1. Communication with pharmacy visitors. Basic principles		6
9.2. The communication with colleagues and management. The business ethics and effective means of professional communications in pharmacy	2	6
9.3. The search, preparation and interpretation of information messages in the activities of pharmaceutical organizations		6
Total hours	20	89

### CONTENT OF THE EDUCATIONAL MATERIAL

- I. Biopharmaceutical ethics
- 1. Bioethics and biopharmaceutical ethics: status, essence and basic principles

## 1.1. Moral guidelines of pharmaceutical knowledge and activity

The originality, purpose and moral foundations of pharmacy as knowledge and activity. Preservation of life and strengthening of human health as moral guidelines for the activities of a pharmacist.

Ethics and morals. Medical ethics and pharmaceutical ethics as types of professional ethics. Professional ethics as a system of moral principles and norms that regulate the behavior of a specialist on the basis of universal moral values, taking into account the specifics of professional activity and a specific situation. Features of professional ethics: corporativity, asymmetry of relations, specificity of the highest moral values, the presence of professional moral norms and values expressed in moral oaths and codes. The oath of the doctor of the Republic of Belarus.

Interrelation and historical stages of development of medical and pharmaceutical ethics. Hippocratic ethics and the principle of «do no harm». Paracelsus' model and the principle of «do good». Deontological model and the principle of «compliance with duty». Bioethics and the principle of «respect for human rights and dignity» in medicine and pharmacy.

The beginning of bioethics as a new type of thinking. Sociocultural prerequisites for the formation of bioethics (the need for ethical regulation in the field of biomedical research and technology, new situations of moral choice, etc.).

Ethical and ideological foundations of bioethics Anthropocentrism and biocentrism. Ethics of «reverence before life» by A. Schweitzer. The concept of «bioethics» in the work of V.R. Potter «Bioethics: bridge to the future». Bioethics as a science of survival.

Bioethics: essence and interdisciplinary nature. Bioethics as a field of knowledge and a social institution. Main directions, goals and objectives of bioethics.

Bioethics as a normative ethics and the doctrine of a value attitude to Life, as a form of spiritual and practical protection of life and fundamental human values - human rights to life, autonomy and freedom of choice. Problem field of bioethics. Differentiation of bioethics. The main sections of bioethics. Ethical committees as a form of institutionalization of bioethics: status, mechanisms of creation, functions and tasks.

# 1.2. Biopharmaceutical ethics: theoretical foundations and principles

The originality of the subject biopharmaceutical ethics, content, structure and functions. Correlation of bioethics, biomedical and biopharmaceutical ethics. Actualization and relationship of problems of biomedical and biopharmaceutical ethics.

Theoretical foundations of biopharmaceutical ethics. The relationship between biopharmaceutical ethics and fundamental ethics. Types of ethical teachings in the history of culture and theoretical forms of bioethics and biopharmaceutical ethics.

Conceptual model of biopharmaceutical ethics. Normative, situational, experimental-practical, institutional, deontological aspects of biopharmaceutical ethics.

Universal principles of bioethics as a theoretical foundation of biopharmaceutical ethics (personal autonomy, informed consent, voluntariness, confidentiality, integrity, vulnerability, tolerance, justice). The principle of «Do no harm» and the rules of biopharmaceutical ethics (truthfulness, voluntary informed consent, privacy). The nature and range of problems of biopharmaceutical ethics.

# 2. The phenomenon of life and death from the standpoint of bioethics. The main ethical problems in the development of transplantation and genetics

Life as the highest value. State program «Health of the people and demographic security» in the Republic of Belarus. Bioethics of family planning and reproductive technologies. Ethical aspects of discussions about the beginning of human life. Abortion as an ethical issue. Ethical and legal components in matters of reproductive technologies, contraception. The problem of motherhood.

Death as an ethical-philosophical and biomedical problem. The moral meaning of death. Death and dying in the era of new medical technologies. The problem of death criteria. Clinical and biological death. Brain death: medical and moral problems. Ethics of resuscitation. Euthanasia as a bioethical problem. Legislative prohibition of euthanasia in the Republic of Belarus. Mercy from the positions of bioethics. Ethical foundations of modern palliative medicine. Hospice movement against the legalization of euthanasia.

Main ethical issues of organ and tissue transplantation. Legal and bioethical foundations of legislation on transplantation of human organs and tissues. Development of transplantation in the Republic of Belarus.

The specificity of moral problems of genetics. Moral problems of obtaining and using genetic information. Genetic counseling, testing, screening. Voluntary receipt and confidentiality of medical genetic information, availability of medical genetic assistance, prohibition of discrimination and stigmatization on genetic grounds.

Ethical problems of the international project « Human genome «. Eugenics and the main risk factors of genetic engineering activities for human health. Stem cells:

types, sources, ethical aspects of use. Cloning problems. Reproductive and therapeutic cloning. Moral problems of human cloning.

Ethical problems of the processes of medicalization and medicalization of society.

## 3. Problems of biopharmaceutical ethics

# 3.1. Bioethics and foundations of state policy in the field of health care and drug provision

The main directions of state policy in the field of circulation of medicines. Drug safety.

Implementation of the principles of biopharmaceutical ethics in the regulatory documents of the Republic of Belarus. Laws of the Republic of Belarus «On Health Care», «On Circulation of Medicines». Status and purpose of the National Bioethics Committee in the Republic of Belarus.

State pharmaceutical supervision over compliance with the requirements of the legislation on the circulation of medicines. The concept of Good Pharmaceutical Practices in the field of drug circulation from the standpoint of bioethics.

Ethics of justice and definition of policy in the field of drug provision. Protection of the fundamental rights of citizens of the Republic of Belarus in the field of healthcare and drug provision. Responsibility for violation of the procedure for the circulation of medicines. Compensation for harm caused to human life and health due to the medical use of medicines.

Moral foundations of the pharmaceutical business. The priority of moral values over economic interests.

# 3.2. Bioethics of drug circulation. Ethical and legal aspects of drug development

Bioethics of drug circulation as a system of ethical and legal norms governing the development, preclinical (non-clinical) research, clinical research (tests), examination, inspection (pharmaceutical inspection), registration, pharmacovigilance, quality control, industrial production, pharmacy manufacturing, storage, transportation, import, export, sale, release, medical use, return to the manufacturer or supplier, destruction of drugs.

The main bioethical problems of drug development.

Bioethical aspects of using the achievements of biological, pharmaceutical and medical sciences to create drugs. Biotechnology, biosafety and genetic engineering in pharmaceuticals. The main directions of biosafety. Legal framework and international legal regime of biosafety. Convention on biological diversity. Cartagena Protocol on Biosafety. Activities and functions of the National Biosafety Coordination Centre.

Genetically modified products for pharmacy: achievements and ethical risks. Moral problems of embryonic stem cells use in pharmaceuticals. Experience of legal regulation of safety of genetic engineering activity in the Republic of Belarus. Law of the Republic of Belarus «On the safety of genetic engineering activities».

Bioethical aspects of the development of original and reproduced drugs (generics and biosimilars). The problem of protecting the rights of developers of new drugs, methods of their production, industrial designs and trademarks. High moral and ethical maturity of the staff is a condition for effective protection of intellectual

property of innovative medicines.

# 3.3. Ethical and legal bases of preclinical research and clinical trials of medicines

Bioethical substantiation of the purpose and necessity of preclinical studies and clinical trials of drugs.

Ethical aspects of preclinical drug research. Bioethics of the use of animals in medical-pharmaceutical research and humane education. The concept of «three R» and alternative methods of experimentation. Good Laboratory Practice (GLP - Good Laboratory Practice) as a set of rules for planning, implementing, monitoring, evaluating and documenting the results of preclinical research carried out in the development of new drugs.

Ethical and legal aspects of clinical trials of medicines. History of the development of ethical and legal principles of clinical research. Code of Practice for Human Experimentation (Nuremberg Code), Helsinki Declaration of the World Medical Association, Council of Europe Convention on Human Rights and Biomedicine, UNESCO Universal Declaration on Bioethics and Human Rights. Council of Europe Recommendations on Research Conducted on Biological Materials of Human Origin. Ethical and legal regulation of biomedical and biopharmaceutical research involving humans. Basic ethical principles and rules for clinical research of medicines. Autonomy and informed consent of the subject, the right to refuse participation in the study. Research conditions. Ethical problems of biomedical research on healthy volunteers, patients, embryos, children. Ethical aspects of biomedical research involving vulnerable groups of the population.

Legal regulation of biopharmaceutical research and clinical pharmacy in the Republic of Belarus. The Law of the Republic of Belarus «On Healthcare». Good Clinical Practice (GCP – Good Clinical Practice) as a set of rules for planning, implementing, monitoring, evaluating and documenting the results of clinical research of medicines.

The role of ethical committees in ensuring compliance with the rights of subjects during drug research.

# 3.4. Bioethics of registration and production of medicines

Ethical problems of drug registration. State registration of medicines as a procedure for recognizing the compliance of medicines with the requirements for safety, efficacy and quality imposed on it, carried out for the purpose of its admission to sale and medical use. Registration (registration confirmation) of drugs within the Eurasian Economic Union.

Bioethics of drug production. Quality assurance system (quality system) in the production of drugs. International Standard of Good Manufacturing Practice (GMP - Good Manufacturing Practice) as a set of rules for industrial production and quality control of drugs. Good Pharmacy Practice (GPP – Good Pharmacy Practice) as a set of rules for the pharmacy manufacture of medicines, quality control, shelf life, packaging and labeling, storage conditions, as well as the sale of medicines that ensure and guarantee their quality and availability. Destruction of pharmaceutical waste on the example of non-steroidal anti-inflammatory drugs using chemical methods. Destruction of calcium channel blockers (CCBs) and  $\beta_1$ -adrenergic receptor

blockers by chemical methods.

Negative trends towards unethical behavior in the pharmaceutical market of drug manufacturers. The problem of falsification of drugs as a result of ignoring ethical standards by manufacturers and distributors of drugs. The problem of uncontrolled distribution of functional nutrition products and biologically active food additives for the treatment of diseases as an alternative to medicines.

# 3.5. Ethical and legal aspects of the sale of medicines and the provision of pharmaceutical care

Characteristics of the modern drug market from the standpoint of bioethics and protection of consumer rights.

Bioethical, legal and organizational framework for regulation in the field of drug circulation in order to provide the population of the Republic of Belarus with safe, effective and high-quality drugs.

The principle of state regulation of the circulation of medicines in the Republic of Belarus and its implementation in the Law «On the circulation of medicines». Ethical aspects of unfair competition of drug manufacturers.

Ethical aspects of drug promotion from manufacturer to consumer. Ethics of distribution. Requirements of the Good Distribution Practice of the Eurasian Economic Union.

Activities of medical representatives of pharmaceutical companies: ethical and legal aspects. Ethical aspects of cooperation between medical professionals and pharmaceutical representatives in order to promote drugs.

Ethical criteria for advertising drugs. Ethical codes – documents containing norms of self-regulation in the field of drug advertising.

Availability of drugs as a necessary condition for providing the population with timely medical care. Bioethical principles of pharmaceutical care. Ethics of forming and protecting the rights of consumers of pharmaceutical care.

# 4. Deontological problems in the context of biopharmaceutical ethics

# 4.1. Modern pharmaceutical deontology

The importance of ethics for the pharmacist. Appearance and general culture of a pharmaceutical worker.

The essence, status and content of pharmaceutical ethics and deontology in biopharmaceutical ethics. Basic concepts of pharmaceutical deontology: professional duty and responsibility of a pharmacist. Honor and dignity as evaluative categories that fix the moral value of a person. The professional honor of a pharmacist and its social character. Deontology and specialization in pharmacy.

Paternalism and anti-paternalism in modern pharmacy. Modern pharmaceutical ethics and deontology as necessary and universally valid moral, ethical, psychological and legal norms and principles of the relationship between pharmaceutical workers and other participants in drug provision and provision of pharmaceutical care. Pharmacist – patient: ethical models of interaction. Deontology and patient rights. Bioethical principles defining the relationship between pharmaceutical personnel and society, doctors and pharmacists. Bioethics of relations between pharmacists and pharmacists and with other employees of pharmacy (pharmaceutical) organizations.

The moral climate of the team. The problems of corporatism, democracy and subordination. Partnership, personal responsibility, concern for professional authority, the image of the profession as a moral duty of a pharmacist. Professional solidarity and mentoring in pharmacy. Collegiality as a form of cooperation and interaction. The problem of competition among pharmaceutical employees. The responsibility of the pharmacist for the professional honor of colleagues.

Ethical professional codes in the field of pharmaceutical activity. International Code of Ethics for the Pharmacist (FIP). National codes of ethics for pharmacists. Rules of medical ethics and deontology (Decree of the Ministry of Health of the Republic of Belarus 07.08.2018 № 64).

# 4.2. The role of the pharmaceutical employee in the health care system

The role of a pharmaceutical employee in the healthcare and drug supply system. Rights, obligations and social protection of pharmaceutical employees.

Professional duty, honor and dignity of a pharmacist. Ethical requirements for pharmaceutical employees regarding the observance of medical secrecy. Confidentiality of pharmaceutical care in the context of computerization of modern pharmacy. Situations in which a pharmaceutical employee has the right to transfer information known to him to third parties.

The problem of corruption in pharmaceutical activities.

Biopharmaceutical ethics as the basis for the formation of the moral position of students in the study of specialized pharmaceutical disciplines and a necessary component of the professional culture of a pharmaceutical employee.

# II. The communications in pharmaceutical activity

# 5. The communication as a phenomenon of reality and a subject of study. The communication as a social practice

The communication as a basic need of people and the basis of social interaction. The communications as a product of the evolution of the process of developing relationships between people and the most important factor of socialization. The basic motives of cooperative communication: asking, informing, social exchange of emotions. The concept of «communicative action» (according to J. Habermas). The problem of understanding and individuals and various social groups. The communications. A systematic understanding of the main components of the science of effective communication.

# 6. Organizational communication links in pharmacy

The communication between a pharmaceutical organization and its environment. The role of regulations for communication in healthcare and pharmacy. Organizational structure and main participants of communication interaction in the pharmaceutical healthcare sector: Ministry of Health of the Republic of Belarus; Republican unitary enterprise «Management company of the holding «Belpharmprom»; Department of Licensing of Medical and Pharmaceutical Activities, Department of Organization of Drug Provision and Department of Pharmaceutical Inspection; State pharmaceutical supervision in the field of circulation of medicines «Gospharmnadzor»; Republican Unitary Enterprise «Center for Expertise and Testing in Healthcare»; the system of the republican unitary

enterprise «Pharmacy», pharmacies of the Main Departments of Health of the regional executive committees, pharmacy organizations that are outside the subordination of the Ministry of Health of the Republic of Belarus, pharmacy organizations of non-state form of ownership and etc. The communication between levels and departments. Horizontal and vertical communication links. Internal and external communications in pharmacy and pharmaceutical organizations.

# 7. Subject areas of communication in pharmacy

# 7.1. The information as the basis of the communication process in pharmacy

The category of «information»: interpretation and meaning. The information theory. The basic properties of the information. The information culture in pharmacy.

The organization of the communication process. The elements and stages of the communication process from the perspective of information flows. The coding and choice of communication channel. The information transfer and decoding. Feedback and interference.

The barriers to interpersonal communications (information barriers). The causes of messaging. The logical errors in communication. Alexithymia. Information and disinformation. The mythologization and stereotyping of public consciousness. The factors to improve the effectiveness of communication. The compressing information while maintaining its quality.

The right of a consumer of health care services to receive understandable and reliable information.

# 7.2. Professional communications in pharmacy: significance for the current stage and development prospects

Strengthening specialization as a factor in the formation of competencies in the field of professional communications. The role of professional communication in the activities of pharmaceutical organizations.

The relationship of professional communications in pharmacy and the principles of biopharmaceutical ethics.

The functions of communication in health care. The principles of effective communication in the field of pharmacy. The models of health communication. The features of interaction between patients and pharmaceutical employees in the service market. The value of communication for the categories «quality of life» and «life expectancy». The problem of understanding and misunderstanding, trust and distrust in the system of professional communications.

The target audience in the activities of pharmacy and pharmaceutical organizations. The levels of communication (according to the composition of communicants and the type of relationship between them; by the method of establishing and maintaining contact; by the degree of organization, etc.).

# 8. The business communication tools in pharmacy

# 8.1. The non-verbal tools of business communication in pharmacy

The non-verbal component of social communication in pharmacy. The ways to decode non-verbal communication. The emotional communication. «Understanding without words» is the basis of employee synergy. «Emotional intelligence» is one of

the key professional competencies in pharmacy. The emotional quotient (EQ). Empathy. The concept of «congruence».

The symbols as part of non-verbal systems. Tactical means of communication: control action, manipulation and ways to protect against it, modeling sustainable perception.

The non-verbal ways of transmitting information in pharmacy. The influence of non-verbal information on the interpretation of the message. nonverbal barriers.

# 8.2. The verbal tools of business communication in pharmacy

The traditional means of verbal communication in pharmacy. The culture of speech of a pharmaceutical employee.

The internal documents containing information for personnel on the processes of functioning and development of the organization, orders, instructions, memos, etc.

The business communication in pharmacy and professional ethics. The digital communication. E-mail and social networks as corporate communication tools. The business communication online using the channel of auditory and (or) visual communication. The business correspondence between participants of interaction in pharmacy. The business negotiations.

# 9. The applied aspects of communication in pharmacy

# 9.1. Communication with pharmacy visitors. Basic principles

The communicative competencies as an integral part of the professional culture of a pharmacist. Basic communication skills of the «pharmacist-pharmacy visitor» relationship: adequate physical environment, greeting pharmacy visitors, active listening, empathy, respect, interest, warmth and support, cooperation. The main types of visitors to pharmacies. The possible algorithms for effective interaction with pharmacy visitors. Ageism. The pharmaceutical consultation of the population. The role of communications in achieving an effective balance between commercial interests and ethical and deontological principles in pharmacy.

The conflict as a mechanism of social regulation. The methods of conflict management in the process of social communication. The modeling of communicative scenarios of reaction to various conflict situations. The reflection and introspection.

# 9.2. The communication with colleagues and management. The business ethics and effective means of professional communications in pharmacy

The rules of communication «horizontally» and «vertically». The corporate culture. The team building and effective team building. The personal characteristics in communication. The principles of politeness, honesty, justice. The correct communication approaches, if necessary, point out an error, requests for help, offers to help, etc. Conducting the discussion. Correct forms of objection (expression of disagreement). Prevention of conflicts in communication with colleagues and management.

# 9.3. The search, preparation and interpretation of information messages in the activities of pharmaceutical organizations

The criteria for the reliability of the source of information. The filters for deliberately false, unreliable, unverified and outdated information. The causal

thinking. The stablishment of causal relationships. Using methods of abduction, analogy, etc.

The public speaking in the system of social communication. The self-organization of public speaking. public speech. The features of public speaking. The presence of feedback. The use of various means of communication.

The preparation of information messages (reports, presentations) for colleagues, business partners, investors and consumers. The formation of skills for drawing up a speech plan and preparing for a speech. The communicative methods of interaction with the audience. The basic presentation rules. The storytelling in pharmacy.

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# CURRICULAR CHART OF THE ACADEMIC DISCIPLINE « BIOPHARMACEUTICAL ETHICS AND COMMUNICATIONS » OF THE COMMUNICATION MODULE

	Form of control					Interviews, situational tasks (case-method), tests or electronic tests
	Self-studies		49	4	ı	7
emic	practical		51	9	ı	$\kappa$
r of acade hours	supervised student independent		က	1	1	1
lectures  the state of a control of a contro			10	2	2	1
	Section (topic) name	2 semester	- Biopharmaceutical ethics	Bioethics and biopharmaceutical ethics: status, essence and basic principles	Bioethics and biopharmaceutical ethics: status, essence and basic principles. The phenomenon of life and death from the standpoint of bioethics. The main ethical problems in the development of transplantation and genetics	
	Section, topic #		<b>i</b>	1.	1-2	<b></b>

1.2	Biopharmaceutical ethics: theoretical foundations and principles  The originality of the subject biopharmaceutical ethics, content, structure and functions.					Interviews, tests or electromic tests
	Actualization and relationship of problems of biomedical and biopharmaceutical ethics.		ı	8	7	
	Conceptual model of biopharmaceutical ethics. Universal principles of bioethics					
2.	The phenomenon of life and death from the standpoint of	***************************************		Ä	, Y	
•••••			ı	3	3	
	Life as the highest value					Interviews, situational tasks
•••••••••••	Bioethics of family planning and reproductive technologies.					(case-method), tests or
	Abortion as an ethical issue.	1	ı	3	8	electronic tests, reports
	Ethical and legal components in matters of reproductive technologies,					
	contraception					
	Death as an ethical-philosophical and biomedical problem					Interviews, situational tasks
•••••••••••	The problem of death criteria.					(case-method), tests or
	Clinical and blological death.			Ç	C	electromic tests, reports
	Brain death: medical and moral problems.	ı		<b>n</b>	<b>O</b>	
	Ethics of resuscitation.					
	Eufhanasia as a bioethical problem					
	Main ethica! issues of organ and tissue transplantation.					Interviews, situational tasks
••••••	Legal and bloethical foundations of legislation on transplantation of	1	3	3	$\sim$	(case-method), tests or
	hurnan organs and tissues					electronic tests, reports
	The specificity of moral problems of geneties. Moral problems of					Interviews, situational tasks
••••••	obtaining and using genetic information. Ethical problems of the	1	3	3	m	(case-method), tests or
	international project «Human genome»					electronic tests reports
	Final lesson «Bioethics and biopharmaceutical ethics: status, essence					Control quiz, situational tasks
	and basic principles. The main ethical problems in the development	1	3	3	т	(case-method), tests or
	of transplantation and genetics»	10				electronic tests colloquium
	Problems of biopharmacentical ethics	9	1,5	21	21	
3.1-	Bioethics and foundations of state policy in the field of health care					

	aspects of drug development					
3.1	Bioethics and foundations of state policy in the field of health					Interviews, situational tasks
	care and drug provision					(case-method), tests or
	The main directions of state policy in the field of circulation of					electronic tests
	medicines.			'n	7	
	Laws of the Republic of Belarus «On Health Care», «On Circulation	ı	ı	n	<u> </u>	
	of Medicines».					
	State pharmaceutical supervision over compliance with the					
	requirements of the legislation on the circulation of medicines					
3.2	Bioethics of drug circulation. Ethical and legal aspects of drug					Interviews, situational tasks
						(case-inethod), tests or
••••••	Biotechnology, biosafety and genetic engineering in pharmaceuticals.					electronic tests
••••••		ı	ı	$\kappa$	3	
•••••						
	The problem of protecting the rights of developers of new drugs,					
	methods of their production, industrial designs and trademarks					
3.3	Ethical and legal bases of preclinical research and clinical trials of	(				
•••••		7	0,5	ı	ı	
3.3	Ethical and legal bases of preclinical drug research					Interviews, situational tasks
	Bioethics of the use of animals in medical-pharmaceutical research			r	~	(case-method), tests or
•••••	and humane education. The concept of «three R».	ı		n	<u> </u>	electronic tests, reports
	Alternative methods of experimentation. Good Laboratory Practice					
3.3	Ethical and legal aspects of clinical trials of medicines					Interviews, situational tasks
	Ethical problems of biomedical research on healthy volunteers,					(case-method), tests or
	patients, embryos, children.			r	~	electronic tests, reports
	Ethical aspects of biomedical research involving vulnerable groups of	ı		n	<u> </u>	
	the population.					
••••••	Good Clinical Practice					
3.4-	Bioethics of production of medicines. Ethical and legal aspects of the	C	3.0			
3.5	sale of medicines and the provision of pharmaceutical care.	1	۰,5	•	1	
3.4	Bioethics of registration and production of medicines					Interviews, situational tasks
	State registration of medicines as a procedure for recognizing the	ı	1	n	3	(case-method), tests or
	compliance of medicines with the requirements for safety efficacy					oloctronic toote monte

	Interviews, situational tasks	electronic tests, reports		Control quiz, situational tasks (case-method), tests or electronic tests colloquium			Interviews, situational tasks (case-method), tests or electronic tests, reports
		<b>C</b>		8	6	ı	ν.
		R		æ	6	ı	<b>C</b>
		ı			5,0	5,0	r d
		1		ı	2	2	
<b>○</b> \ i	The problem of uncontrolled distribution of functional nutrition products and biologically active food additives  3.5 Ethical and legal aspects of the sale of medicines and the	provision of pharmaceutical care  Bioethical, legal and organizational framework for regulation in the field of drug circulation.  Ethical aspects of unfair competition of drug manufacturers.  Ethics of distribution.	Activities of medical representatives of pharmaceutical companies: ethical and legal aspects.  Ethical criteria for advertising drugs	Final lesson «Problems of biopharmaceutical ethics»	4 Deontological problems in the context of biopharmaceutical ethics	4.1- Deontological problems in the context of biopharmaceutical ethics 4.2	<ul> <li>Appearance and general culture of a pharmaceutical worker.</li> <li>The essence, status and content of pharmaceutical ethics and deontology in biopharmaceutical ethics.</li> <li>Basic concepts of pharmaceutical deontology: professional duty and responsibility of a pharmacist.</li> <li>Paternalism and anti-paternalism in modern pharmacy.</li> <li>Pharmacist – patient: ethical models of interaction.</li> <li>Ethical professional codes in the field of pharmaceutical activity</li> </ul>

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4.2	The role of the pharmaceutical employee in the health care					Interviews, situational tasks (case-method) tests or
	Rights, obligations and social protection of pharmaceutical employees					electronic tests, reports,
	Ethical requirements for pharmaceutical employees regarding the observance of medical secrecy	ı	ı	ω	3	control quiz
	Confidentiality of pharmaceutical care in the context of computerization					
	of modern pharmacy					
	The problem of corruption in pharmaceutical activities		1.			
4.2	Final lesson «Bioethics and biopharmaceutical ethics: status, essence					Situational tasks (case-
	and basic principles. Ethical problems of life, death, transplantology			~	~	method), tests or electronic
	and genetics. Problems of biopharmaceutical ethics, Deontological	ı	ı	<b>n</b>	<b>n</b>	tests, control quiz, credit
	problems in the context of biopharmaceutical ethics»					
	3 semester					
H	The communications in pharmacentical activity	10	3	38	42	
S	The communication as a phenomenon of reality and a subject of					Interviews, situational tasks
	study. The communication as a social practice					(case-method), tests or
	The communication as the basis of social interaction.			******************************		electronic tests
	The basic motives of cooperative communication: asking, informing,	(	<b>Y</b>	•	~	
	social exchange of emotions.	4	3	1	<b>)</b>	
	The concept of «communicative action».					
	The problem of understanding and mutual understanding between					
	individuals and various social groups					
9	Organizational communication links in pharmacy					Interviews, situational tasks
	The communication between a pharmaceutical organization and its					(case-method), tests or
	environment.					electronic tests
	Organizational structure and main participants of communication	•	4	~	,	
	interaction in the pharmaceutical healthcare sector.	4		7	מ	
	Horizontal and vertical communication links.					
	Internal and external communications in pharmacy and					
	pharmaceutical organizations					
_	Subject areas of communication in pharmacy	2	5,0	9	9	
7.1-	Communication as a social practice.	7	0,5	ı	ı	

	nhormoon.					
	pharmacy					(case-method), tests or
	The category of «information»: interpretation and meaning.					electronic tests
	The information theory. The basic properties of the information.  The organization of the communication process. The information	,	ı	ĸ	~	
				)	)	
	The barriers to interpersonal communications.					
	The right of a consumer of health care services to receive		,			
	understandable and reliable information					
7.2	Professional communications in pharmacy: significance for the					Interviews, situational tasks
	current stage and development prospects					(case-method), tests or
	The target audience in the activities of pharmacy and pharmaceutical	i	ı	3	n	electronic tests
	organizations. The levels of communication					
9	The business communication tools in phermoon					
0	The Dusiness communication tools in pnarmacy	7	0,5	6	6	
8.1-	Business communication tools in pharmacy	C	9.0			
8.2		1	۲,0	I	•	
8.1	The non-verbal component of social communication in pharmacy					Interviews, situational tasks
	The ways to decode non-verbal communication.					(case-method), tests or
	The emotional communication.	,	1	,,	~	electronic tests
	The symbols as part of non-verbal systems.			)	)	
	Tactical means of communication: control action, mampulation and					
	ways to protect against it, modeling sustainable perception					
8.2	The verbal tools of business communication in pharmacy					Interviews, situational tasks
	The traditional means of verbal communication in pharmacy.					(case-method), tests or
	The culture of speech of a pharmaceutical employee.	1	ı	3	Μ	electronic tests
	The internal documents containing information for personnel.					
	The business communication in pharmacy and professional ethics					
	Final lesson «The communications in pharmaceutical activity»					Control quiz, situational tasks
			*************			(case-method), tests or
		,	ı	3	m	electronic tests colloquium

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6	The applied aspects of communication in pharmacy	7	0,5	18	18	
9.1-	Business ethics and effective means of professional communications					
9.3	in pharmacy. Communication with pharmacy visitors. Basic	7	0,5		ı	
0.1	principles The communication with colleagues and management					1.42
9.1	itors. Basic principles					Interviews, situational tasks
	The communicative competencies as an integral part of the					(case-method), tests or
	professional culture of a pharmacist.					electronic tests
	Basic communication skills of the «pharmacist-pharmacy visitor»		ı	3	m	
	relationship.					
	The main types of visitors to pharmacies.					
	The pharmaceutical consultation of the population	••••••••				
9.1	Conflict management in pharmacy and pharmacentical					Interviews, situational tasks
						(case-method), tests or
	The conflict as a mechanism of social regulation.					electronic tests
	The methods of conflict management in the process of social			r	c	
		ı		<b>1</b>	<b>n</b>	
	The modeling of communicative scenarios of reaction to various					
	conflict situations.					
	The reflection and introspection.					
9.2	The business ethics. The communication with colleagues.					Interviews, situational tasks
	The rules of communication «horizontally».					(case-method), tests or
	The corporate culture.					electronic tests
	The team building and effective team building.	ı	1	3	$\mathcal{C}$	
	The personal characteristics in communication.					
	Prevention of conflicts in communication with colleagues and					
	management.					
9.2	The business ethics. The communication with managers.					Interviews, situational tasks
	The rules of communication (vertically».					(case-method), tests or
	The corporate culture.					electronic tests
	The team building and effective team building.	ı	ı	3	4	
	Prevention of conflicts in communication with colleagues and					
	management					

Interviews, situational tasks	(case-method), tests or	3   4   electronic tests	-			Situational tasks, tests or	3   4   electronic tests, control quiz.	Exam	89   91
					***************************************			***************************************	
							'		9
***************************************		٠					•		20
9.3 Information messages in the activities of pharmaceutical	organizations	The criteria for the reliability of the source of information.	The public speaking in the system of social communication.	The preparation of information messages (reports, presentations) for	colleagues, business partners, investors and consumers.	9.3 Final lesson «The applied aspects of communication in pharmacy»			Total hours

## INFORMATION AND INSTRUCTIONAL UNIT

#### LITERATURE

## Basic (relevant):

1. Biomedical ethics and communications in health service: study guide/V. S. Clushanko, C. P. Kulik, A. A. Gerberg., A. M. Myasoedov, E. V. Mihnevich, L. I. Orehova, A. L. Tserkovskiy – Vitebsk: VSMU, 2018. – 233 p.

#### Additional:

2. Bobyrov, V.M. Bases of bioethics and biosafety: study guide for stud. of institutions of higher education of Ministry of Helth of Ukraine. – Vinnytsia: Nova Knyha, 2019. – 248 p.

# Laws and regulations:

- 3. WMA Declaration of Geneva 1947 (adopted in 1948, amended in 2006) The physician's pledge.
- 4. WMA International Code of Medical Ethics 1948 (adopted in 1949, amended in 2006).
- 5. WMA Declaration of Helsinki 1964 (amended in 2013) Ethical Principles for Medical Research Involving Human Subjects.
- 6. WMA Declaration of Sydney on the Determination of Death and the Recovery of Organs, 1968 (amended in 2016).
  - 7. UN Declaration on the Rights of Mentally Retarded Persons, 1971.
  - 8. WPA Declaration of Hawaii, 1983.
  - 9. WMA Declaration of Venice on Terminal Illness, 1983 (amended in 2006).
- 10. UN Principles for the protection of persons with mental illness and the improvement of mental health care, 1991.
  - 11. WMA Declaration of Lisbon on the Rights of the Patient, 1991.
- 12. The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, 1997 (Oviedo Convention).
  - 13. Additional Protocol on the Prohibition of Cloning Human Beings.
- 14. Additional Protocol on Transplantation of Organs and Tissues of Human Origin.
  - 15. Additional Protocol on Biomedical Research.
  - 16. Additional Protocol on Genetic Testing for Health Purposes.
- 17. Recommendation CM/Rec(2016)6 of the Committee of Ministers to member Stateson research on biological materials of human origin.
- 18. The Universal Declaration on Bioethics and Human Rights, 2005 (UNESCO).
- 19. WHO Cuiding Principles on Human Cell, Organ and Tissue Transplantation, 2010.
- 20. WPA Madrid Declaration on Ethical Standards for Psychiatric Practice, 1996 (amended in 2011).
  - 21. Convention on Biological diversity 1992 (signed in Rio de Janeiro).

- 22. The Cartagena Protocol on Biosafety to the Convention on Biological Diversity 2000.
  - 23. WMA Declaration on End-of-Life Medical Care, 2011.
- 24. WMA Declaration on Euthanasia and Physician-Assisted Suicide, 2019 (Tbilisi).

# METHODOLOGICAL RECOMMENDATIONS FOR THE ORGANIZATION AND PERFORMANCE OF INDEPENDENT WORK OF STUDENTS IN ACADEMIC DISCIPLINE

The time allotted for independent work can be used by students to:

preparation for lectures and practical exercises;

preparation for the final lessons, credits and exam in the academic discipline; solution of situational tasks;

test solving;

preparation of thematic reports, abstracts, presentations;

implementation of practical tasks;

note-taking of educational literature;

design of information and demonstration materials (stands, posters, graphics, tables, newspapers, etc.).

# METHODOLOGICAL RECOMMENDATIONS FOR THE ORGANIZATION AND PERFORMANCE OF SUPERVISED STUDENT INDEPENDENT WORK IN THE ACADEMIC DISCIPLINE

The main forms of organizing managed independent work:

writing and presentation of an report;

giving a report;

studying topics and problems that are not covered in lectures;

taking notes from primary sources (sections of anthologies, collections of documents, monographs, textbooks);

computer testing;

compiling tests for students to organize mutual control;

production of didactic materials;

preparation and participation in active forms of learning.

Control of controlled independent work is carried out in the form of:

test work;

final lesson, colloquium in the form of an oral interview, written work, testing;

discussions of reports;

protection of educational assignments;

evaluation of an oral answer to a question, message, report or solution to a problem;

individual conversation.

## LIST OF AVAILABLE DIAGNOSTIC TOOLS

The following forms are used for competences assessment:

## Oral form:

interviews:

situational tasks.

#### Written form:

tests;

reports;

control quiz.

# Oral-written form:

credit;

exam.

## Technical form:

electronic tests.

## LIST OF AVAILABLE TEACHING METHODS

Traditional method (lecture, laboratory practicals);

Active (interactive) methods:

Problem-Based Learning (PBL);

Team-Based Learning (TBL).

## LIST OF PRACTICAL SKILLS

List of practical skills in the academic discipline	Control form of practical skills			
1. Application of the basic ethical and deontological	Solving situational tasks,			
rules of pharmaceutical consultation of the population and medical workers.	including using the case- method with grading.			
2. Using the basic principles and methods of	Colloquium. Exam.			
organizing communication in the field of				
pharmaceutical activity.				
3. Analysis and substantiation of methods for				
forecasting, planning and developing communication				
campaigns aimed at solving the problems of modern				
healthcare in the field of maintaining health and				
providing medicines to the population.				
4. Reasoned presentation of a personal position on				
topical issues of biopharmaceutical ethics and				
communication in pharmacy.				

## LIST OF LECTURES

#### 2 semester

- 1. Bioethics and biopharmaceutical ethics: status, essence and basic principles. The phenomenon of life and death.
- 2. Bioethics and foundations of state policy in the field of health care and drug provision. Bioethics of drug circulation. Ethical and legal aspects of drug development.
- 3. Ethical and legal bases of preclinical research and clinical trials of medicines.
- 4. Bioethics of production of medicines. Ethical and legal aspects of the sale of medicines and the provision of pharmaceutical care.
  - 5. Deontological problems in the context of biopharmaceutical ethics.

#### 3 semester

- 1. Communication as a phenomenon of reality and a subject of study. The communication as a social practice.
  - 2. Organizational communication links in pharmacy.
  - 3. Subject areas of communication in pharmacy.
  - 4. Business communication tools in pharmacy.
- 5. Business ethics and effective means of professional communications in pharmacy. Communication with pharmacy visitors. Basic principles The communication with colleagues and management.

## LIST OF PRACTICAL STUDIES

#### 2 semester

- 1. Moral guidelines of pharmaceutical knowledge and activity.
- 2. Biopharmaceutical ethics: theoretical foundations and principles.
- 3. Life as the highest value.
- 4. Death as an ethical-philosophical and biomedical problem.
- 5. Main ethical issues of organ and tissue transplantation.
- 6. The specificity of moral problems of genetics. Moral problems of obtaining and using genetic information. Ethical problems of the international project «Human genome».
- 7. Final lesson « Bioethics and biopharmaceutical ethics: status, essence and basic principles. The main ethical problems in the development of transplantation and genetics».
- 8. Bioethics and foundations of state policy in the field of health care and drug provision.
- 9. Ethical and legal aspects of drug development. Bioethical aspects of the development of original and reproduced drugs.
  - 10. Ethical aspects of preclinical drug research.
  - 11. Ethical and legal aspects of clinical trials of medicines.
  - 12. Bioethics of registration and production of medicines
- 13. Ethical and legal aspects of the sale of medicines and the provision of pharmaceutical care.
  - 14. Final lesson «Problems of biopharmaceutical ethics».

- 15. Modern pharmaceutical deontology. Appearance and general culture of a pharmaceutical worker.
  - 16. The role of the pharmaceutical employee in the health care system.
- 17. Final lesson «Bioethics and biopharmaceutical ethics: status, essence and basic principles. Ethical problems of life, death, transplantology and genetics. Problems of biopharmaceutical ethics, Deontological problems in the context of biopharmaceutical ethics».

#### 3 semester

- 1. The communication as a phenomenon of reality and a subject of study.
- 2. The communications in pharmaceutical activity.
- 3. The information as the basis of the communication process in pharmacy.
- 4. Professional communications in pharmacy: significance for the current stage and development prospects.
  - 5. The non-verbal component of social communication in pharmacy.
  - 6. The verbal tools of business communication in pharmacy.
  - 7. Final lesson «The communications in pharmaceutical activity».
  - 8. Communication with pharmacy visitors. Basic principles.
  - 9. Conflict management in pharmacy and pharmaceutical organizations.
  - 10. The business ethics. The communication with managers.
  - 11. The business ethics. The communication with colleagues.
  - 12. Information messages in the activities of pharmaceutical organizations.
  - 13. Final lesson «The applied aspects of communication in pharmacy».

# PROTOCOL OF THE CURRICULUM APPROVAL BY OTHER DEPARTMENTS

Decision of the department, which designed the curriculum	(date, protocol #)	protocol # 5 of 01.11.2023);		protocol # 5 of 01.11.2023);		protocol # 5 of 01.11.2023);	
Amendments to the curriculum in the	academic discipline	ou		ou		ou	
Department		Department of Organization	and Economics of Pharmacy	Department of Organization	and Economics of Pharmacy	Department of Organization	and Economics of Pharmacy
Title of the discipline requiring approval		1. Management in pharmacy		2. History of pharmacy		3.Pharmaceutical Care	

### **COMPILERS/AUTHORS:**

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G.G.Voronov

E.Yu.Kasyanyuk

Meuf K.Y.Shalova

Curriculum content, composition and the accompanying documents comply with the established requirements.

Dean of the Medical Faculty for International Students of the educational institution «Belarusian State Medical University»

13.11. 2023

Methodologist of the educational institution «Belarusian State Medical University»

13.11. 2023

O.S.Ishutin

S.V.Zaturanova