

**The Ministry of Health of Ukraine  
Bogomolets National Medical University**

**METHODICAL RECOMMENDATIONS  
to practical classes**

Academic discipline	Pharmacovigilance in pharmaceutical practice
Field of knowledge	22 “Health care”
Specialty	226 “Pharmacy, Industrial pharmacy”
Specialization	226.01 “Pharmacy”
Form of education	Full-time study
Department	Pharmacology

Approved at the Department of Pharmacology meeting  
on August 26, 2024, protocol № 1

Head of the Department



prof. G.V. Zaychenko

Reviewed and approved by the CMC of specialty 226 “Pharmacy, Industrial Pharmacy” meeting on August 30, 2024, protocol № 1

2024-2025 a. y.

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## **Topic 1. Pharmacovigilance, the importance of its implementation for health care system/programs and registrants. Pharmacovigilance procedure in Ukraine.**

### **Competence:**

#### ***Integral Competence:***

- Ability to solve research and/or innovation problems in the field of pharmacy.

#### ***General Competencies (GC):***

- GC02. Knowledge and understanding of the subject area; Understanding of professional activities.
- GC03. Ability to communicate in the state language both orally and in writing.
- GC04. Ability to communicate in a foreign language.
- GC06. Ability to work in a team.
- GC09. Ability to use information and communication technologies.
- GC10. Ability to make decisions and act in compliance with the principle of inadmissibility of corruption and any other manifestations of dishonesty.

#### ***Special (professional, subject) competencies (PC):***

- PC01. Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts.
- PC02. Ability to collect, interpret and apply data necessary for professional activities, research and implementation of innovative projects in the field of pharmacy.
- PC03. Ability to solve pharmacy problems in new or unfamiliar environments with incomplete or limited information, taking into account aspects of social and ethical responsibility.
- PC04. Ability to clearly and unambiguously convey own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to students.
- PC06. Ability to consult on prescription and over-the-counter drugs and other products of the pharmacy assortment, pharmaceutical care during the selection and sale of drugs of natural and synthetic origin by assessing the risk/benefit ratio, compatibility, taking into account their biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical and chemical features, indications/contraindications for use, guided by data on the health status of a particular patient.
- PC08. Ability to monitor the efficacy and safety of the population's use of medicines according to the data on their clinical and pharmaceutical characteristics.

**Purpose:** acquisition of theoretical knowledge and practical skills on pharmacovigilance, its importance for the health care system/programs and registration holders and the procedure for pharmacovigilance in Ukraine.

**Equipment:** safety instructions, interactive multimedia system (if necessary), collection of medicines, reference books.

### Plan and organizational structure of the lesson

Stage Name	Stage description	Levels of assimilation	Time
<b>Preparatory</b>	Organizational issues (checking the presence of students)	Acquaintance	5 min.
	Checking the tasks that have been set for self-preparation for classes	Perception	5 min.
	Control and evaluation of the entrance level of training of students in pharmacology	Reproductive	15 min.
<b>Main</b>	Formation of professional skills and abilities (determination by students of the group affiliation of drugs, their mechanisms of action, main pharmacological effects, indications for prescription, possible side effects).	Comprehension Understanding	30 min.
	Development of professional competence: solving situational problems and their assessment	Putting it into practice Exploratory creative activity	10 min.
	Summarizing Knowledge	Fixing	5 min.
<b>Final</b>	Test control of the final level of training	Play	10 min.
	Overall assessment of the student's learning activities	Acquaintance	5 min.
	Informing students about the topic of the next lesson and tasks for independent work	Acquaintance	5 min.

### Recommended Reading.

#### Basic:

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2. Pharmacology : textbook / V. M. Bobyrov, O. M. Vazhnicha, T. O. Devyatkina, N. M. Devyatkina. - 5th ed., updat. - Vinnytsia : Nova Knyha, 2020. - 560 p.

#### Secondary:

1. Prasan R. Bhandari Textbook of Pharmacology / Prasan R. Bhandari. – Thieme, 2022. – 888 p.
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6. Color atlas of pharmacology, 5th edition, revised and expanded / Heinz Luellmann, Klaus Mohr, Lutz Hein, Detlef Bieger [et al.]; 174 color plates by Juergen Wirth. // New York; Thieme Stuttgart. – 2017. – 416 p.

### **Information Resources**

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3. National Library of Ukraine name after V.I. Vernadskyi <http://www.nbu.gov.ua/>
4. National Scientific Medical Library of Ukraine <https://library.gov.ua/>
5. British Medical Journal Publishing Group Ltd - [www.bmj.com](http://www.bmj.com)
6. The Lancet, Elsevier Limited [www.thelancet.com](http://www.thelancet.com)
7. Cochrane Library [www.cochrane.org](http://www.cochrane.org)
8. The Center for Polish Medical Literature of the National Medical Library of Ukraine "Zbigniew Religa Polish Medical Library." <https://polska.library.gov.ua/>
9. Nature [www.nature.com](http://www.nature.com)
10. Safety of medicines : a guide to detecting and reporting adverse drug reactions : why health professionals need to take action <https://iris.who.int/handle/10665/67378>
11. The importance of pharmacovigilance <https://iris.who.int/handle/10665/42493>
12. The safety of medicines in public health programs <https://www.who.int/publications/i/item/9241593911>
13. Pharmacovigilance system: questions and answers <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/pharmacovigilance-system-questions-answers>
14. Good pharmacovigilance practices <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/good-pharmacovigilance-practices-gvp>
15. Immunization safety surveillance: guidelines for immunization program managers on surveillance of adverse events following immunization. 3rd ed. <https://iris.who.int/handle/10665/208262>

### **Questions for the student's self-preparation for the practical lesson:**

1. The concept of pharmacovigilance (PV), its origins, goals and significance for the health care system. The place and role of the World Health Organization in the implementation of PV.

2. Structure, objects, tasks and goals of the PV system in Ukraine and the world. The concept of the structure of the country's PV system: the structure of the state PV system and the PV systems of registration holders.
3. Participants in the process of PV implementation in Ukraine. Normative legal acts regulating the implementation of PV in Ukraine. Sources of obtaining and exchanging information in the implementation of PV. Methods of collecting information on the efficacy and safety of medicinal products within the framework of PV implementation.
4. Tools and ways for pharmacists to provide reports on cases of adverse effects of drug use. Participants in the process of reporting on the adverse effects of drug use. Legislative requirements for reporting adverse reactions (AR) to drugs, adverse effects after immunization (AEFIs) and lack of effect (LE) of drugs. Reporting tools. Algorithm of actions of the Master of Pharmacy in the case when he became aware of a case of adverse effects of drug use. Spontaneous reports of adverse effects of drug use. Deadlines for reporting cases of serious and non-serious adverse reactions.
5. The role of the Master of Pharmacy in the prevention of ADRs. Pharmaceuticals as a tool to prevent the occurrence of ADRs.
6. Completion of the report card on adverse reaction / lack of efficacy of drugs and or adverse event after immunization / tuberculin diagnosis (AEFI).

**Methodical development compiled by: prof. Zaychenko G.V., assoc. prof. Savchenko N.V., assoc. prof. Hnatiuk V.V.**

## **Topic 2. Classifications and mechanisms of adverse drug reactions. The main ways to prevent adverse reactions to drugs.**

### **Competence:**

#### ***Integral Competence:***

- Ability to solve research and/or innovation problems in the field of pharmacy.

#### ***General Competencies (GC):***

- GC02. Knowledge and understanding of the subject area; Understanding of professional activities.
- GC03. Ability to communicate in the state language both orally and in writing.
- GC04. Ability to communicate in a foreign language.
- GC06. Ability to work in a team.
- GC09. Ability to use information and communication technologies.
- GC10. Ability to make decisions and act in compliance with the principle of inadmissibility of corruption and any other manifestations of dishonesty.

#### ***Special (professional, subject) competencies (PC):***

- PC01. Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts.
- PC02. Ability to collect, interpret and apply data necessary for professional activities, research and implementation of innovative projects in the field of pharmacy.
- PC03. Ability to solve pharmacy problems in new or unfamiliar environments with incomplete or limited information, taking into account aspects of social and ethical responsibility.
- PC04. Ability to clearly and unambiguously convey own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to students.
- PC06. Ability to consult on prescription and over-the-counter drugs and other products of the pharmacy assortment, pharmaceutical care during the selection and sale of drugs of natural and synthetic origin by assessing the risk/benefit ratio, compatibility, taking into account their biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical and chemical features, indications/contraindications for use, guided by data on the health status of a particular patient.
- PC08. Ability to monitor the efficacy and safety of the population's use of medicines according to the data on their clinical and pharmaceutical characteristics.

**Purpose:** to acquire theoretical knowledge and practical skills regarding the classifications and mechanisms of adverse reactions to drugs, the main ways to prevent adverse reactions to drugs.

**Equipment:** safety instructions, interactive multimedia system (if necessary), collection of medicines, reference books.

### Plan and organizational structure of the lesson

Stage Name	Stage description	Levels of assimilation	Time
<b>Preparatory</b>	Organizational issues (checking the presence of students)	Acquaintance	5 min.
	Checking the tasks that have been set for self-preparation for classes	Perception	5 min.
	Control and evaluation of the entrance level of training of students in pharmacology	Reproductive	15 min.
<b>Main</b>	Formation of professional skills and abilities (determination by students of the group affiliation of drugs, their mechanisms of action, main pharmacological effects, indications for prescription, possible side effects).	Comprehension Understanding	30 min.
	Development of professional competence: solving situational problems and their assessment	Putting it into practice Exploratory creative activity	10 min.
	Summarizing Knowledge	Fixing	5 min.
<b>Final</b>	Test control of the final level of training	Play	10 min.
	Overall assessment of the student's learning activities	Acquaintance	5 min.
	Informing students about the topic of the next lesson and tasks for independent work	Acquaintance	5 min.

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6. The Lancet, Elsevier Limited [www.thelancet.com](http://www.thelancet.com)
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<https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/pharmacovigilance-system-questions-answers>
14. Good pharmacovigilance practices <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/good-pharmacovigilance-practices-gvp>
15. Immunization safety surveillance: guidelines for immunization program managers on surveillance of adverse events following immunization. 3rd ed.  
<https://iris.who.int/handle/10665/208262>

### Questions for the student's self-preparation for the practical lesson:

1. The concept of ADR, foreseen and unforeseen ADR, serious and non-serious ADR.
2. Types of ADR according to the strength of action, time of development of manifestations, severity of the course, genesis, mechanism of development, association with damage to organs and systems.

3. Classification of ADR according to WHO.
4. Causes of ADR. Factors influencing the occurrence of AR on drugs (related to the patient, to the medical professional, to the medicinal product). The place and role of medical errors in the occurrence of ADR.
5. Dependence of AR manifestations on the chemical structure, physicochemical properties, dose and frequency of drug administration.
6. Dependence of AR manifestations on age, genotype, phenotype, sex, body weight, ethnic factor, biorhythms, climatic factors (seasonality, temperature), anthropogenic factors (pollution with toxic substances)
7. Dependence of AR manifestations on pathological conditions (kidney disease, liver disease, infections, cardiovascular pathology, metabolic and other disorders) and physiological characteristics of the body (pregnancy, lactation),
8. AR associated with the pharmacokinetic features of drugs.
9. ARs that occur with repeated use of drugs: tolerance or addiction (as a type of tachyphylaxis), dependence on the action of drugs (mental, physical).
10. The concept of withdrawal and recoil syndrome.
11. Medical and social aspects of combating drug addiction.
12. AR with combined use of drugs. Polyprasmazy.
13. The concept of pharmaceutical, pharmacokinetic and pharmacodynamic incompatibility of drugs (antagonism)
14. The concept of drug disease.
15. The concept of allergic reactions to drugs and polyvalent sensitization.
16. The concept of drug intolerance (idiosyncrasy).
17. The concept of mutagenicity and carcinogenicity of drugs.
18. The concept of embryotoxicity, teratogenicity, fetotoxicity of drugs.
19. Measures aimed at preventing the occurrence of hypersensitivity reactions.
20. Measures and tools that help minimize the risks of drugs.
21. Social factors of increasing the incidence of AR on drugs.
22. The role of the pharmacist in the prevention of ADR.

**Methodical development compiled by: prof. Zaychenko G.V., assoc. prof. Savchenko N.V., assoc. prof. Hnatiuk V.V.**

### **Topic 3. Adverse effects after immunization. Features of vaccine safety surveillance**

#### **Competence:**

##### ***Integral Competence:***

- Ability to solve research and/or innovation problems in the field of pharmacy.

##### ***General Competencies (GC):***

- GC02. Knowledge and understanding of the subject area; Understanding of professional activities.
- GC03. Ability to communicate in the state language both orally and in writing.
- GC04. Ability to communicate in a foreign language.
- GC06. Ability to work in a team.
- GC09. Ability to use information and communication technologies.
- GC10. Ability to make decisions and act in compliance with the principle of inadmissibility of corruption and any other manifestations of dishonesty.

##### ***Special (professional, subject) competencies (PC):***

- PC01. Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts.
- PC02. Ability to collect, interpret and apply data necessary for professional activities, research and implementation of innovative projects in the field of pharmacy.
- PC03. Ability to solve pharmacy problems in new or unfamiliar environments with incomplete or limited information, taking into account aspects of social and ethical responsibility.
- PC04. Ability to clearly and unambiguously convey own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to students.
- PC06. Ability to consult on prescription and over-the-counter drugs and other products of the pharmacy assortment, pharmaceutical care during the selection and sale of drugs of natural and synthetic origin by assessing the risk/benefit ratio, compatibility, taking into account their biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical and chemical features, indications/contraindications for use, guided by data on the health status of a particular patient.
- PC08. Ability to monitor the efficacy and safety of the population's use of medicines according to the data on their clinical and pharmaceutical characteristics.

**Purpose:** to acquire theoretical knowledge and practical skills regarding undesirable consequences after immunization, features of surveillance over the safety of vaccines.

**Equipment:** safety instructions, interactive multimedia system (if necessary), collection of medicines, reference books.

### Plan and organizational structure of the lesson

Stage Name	Stage description	Levels of assimilation	Time
<b>Preparatory</b>	Organizational issues (checking the presence of students)	Acquaintance	5 min.
	Checking the tasks that have been set for self-preparation for classes	Perception	5 min.
	Control and evaluation of the entrance level of training of students in pharmacology	Reproductive	15 min.
<b>Main</b>	Formation of professional skills and abilities (determination by students of the group affiliation of drugs, their mechanisms of action, main pharmacological effects, indications for prescription, possible side effects).	Comprehension Understanding	30 min.
	Development of professional competence: solving situational problems and their assessment	Putting it into practice Exploratory creative activity	10 min.
	Summarizing Knowledge	Fixing	5 min.
<b>Final</b>	Test control of the final level of training	Play	10 min.
	Overall assessment of the student's learning activities	Acquaintance	5 min.
	Informing students about the topic of the next lesson and tasks for independent work	Acquaintance	5 min.

### Recommended Reading.

#### Basic

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6. The Lancet, Elsevier Limited [www.thelancet.com](http://www.thelancet.com)
7. Cochrane Library [www.cochrane.org](http://www.cochrane.org)
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14. Good pharmacovigilance practices <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/good-pharmacovigilance-practices-gvp>
15. Immunization safety surveillance: guidelines for immunization program managers on surveillance of adverse events following immunization. 3rd ed. <https://iris.who.int/handle/10665/208262>

### Questions for the student's self-preparation for the practical lesson:

1. Concepts of vaccination (vaccination, active/passive immunization), adverse events after immunization/tuberculin diagnosis (AEFI), group AEFI; vaccine effectiveness; ineffectiveness of vaccination; seroconversion; seroprotection.
2. Types of AEFI: classification and characteristics. Classification of AEFIs depending on predictability, severity.
3. Terms of development of clinical manifestations of AEFI: significance and practical use.
4. Clinical manifestations of AEFI: classification, approaches to identification.
5. Causes of AEFI: classification and their characteristics.

6. Individual characteristics of the vaccinated person's body, which may be the causes of the development of AEFI.
7. AEFIs due to immunization procedural errors
8. AEFIs due to high immunization concerns
9. Individual, unpredictable post-vaccination reactions without an established cause.
10. Measures aimed at preventing the occurrence of AEFIs.
11. Measures and tools to help minimize the risks of AEFIs.
12. Social factors for the increase in the incidence of AEFIs.
13. The role of the pharmacist in the prevention of AEFIs.
14. Features of vaccine safety surveillance.

**Methodical development compiled by: prof. Zaychenko G.V., assoc. prof. Savchenko N.V., assoc. prof. Hnatiuk V.V.**

#### **Topic 4. Causal relationship between AR/AEFI and drugs.**

##### **Competence:**

##### ***Integral Competence:***

- Ability to solve research and/or innovation problems in the field of pharmacy.

##### ***General Competencies (GC):***

- GC02. Knowledge and understanding of the subject area; Understanding of professional activities.
- GC03. Ability to communicate in the state language both orally and in writing.
- GC04. Ability to communicate in a foreign language.
- GC06. Ability to work in a team.
- GC09. Ability to use information and communication technologies.
- GC10. Ability to make decisions and act in compliance with the principle of inadmissibility of corruption and any other manifestations of dishonesty.

##### ***Special (professional, subject) competencies (PC):***

- PC01. Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts.
- PC02. Ability to collect, interpret and apply data necessary for professional activities, research and implementation of innovative projects in the field of pharmacy.
- PC03. Ability to solve pharmacy problems in new or unfamiliar environments with incomplete or limited information, taking into account aspects of social and ethical responsibility.
- PC04. Ability to clearly and unambiguously convey own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to students.
- PC06. Ability to consult on prescription and over-the-counter drugs and other products of the pharmacy assortment, pharmaceutical care during the selection and sale of drugs of natural and synthetic origin by assessing the risk/benefit ratio, compatibility, taking into account their biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical and chemical features, indications/contraindications for use, guided by data on the health status of a particular patient.
- PC08. Ability to monitor the efficacy and safety of the population's use of medicines according to the data on their clinical and pharmaceutical characteristics.

**Purpose:** to acquire theoretical knowledge and practical skills in the cause-and-effect relationship between the AR/AEFI and medicines.

**Equipment:** safety instructions, interactive multimedia system (if necessary), collection of medicines, reference books.

### Plan and organizational structure of the lesson

Stage Name	Stage description	Levels of assimilation	Time
<b>Preparatory</b>	Organizational issues (checking the presence of students)	Acquaintance	5 min.
	Checking the tasks that have been set for self-preparation for classes	Perception	5 min.
	Control and evaluation of the entrance level of training of students in pharmacology	Reproductive	15 min.
<b>Main</b>	Formation of professional skills and abilities (determination by students of the group affiliation of drugs, their mechanisms of action, main pharmacological effects, indications for prescription, possible side effects).	Comprehension Understanding	30 min.
	Development of professional competence: solving situational problems and their assessment	Putting it into practice Exploratory creative activity	10 min.
	Summarizing Knowledge	Fixing	5 min.
<b>Final</b>	Test control of the final level of training	Play	10 min.
	Overall assessment of the student's learning activities	Acquaintance	5 min.
	Informing students about the topic of the next lesson and tasks for independent work	Acquaintance	5 min.

### Recommended Reading.

#### Basic

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2. DSpace of Bogomolets National Medical University <http://ir.librarynmu.com/handle/123456789/410>
3. National Library of Ukraine name after V.I. Vernadskyi <http://www.nbu.gov.ua/>
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9. Nature [www.nature.com](http://www.nature.com)
10. Safety of medicines : a guide to detecting and reporting adverse drug reactions : why health professionals need to take action <https://iris.who.int/handle/10665/67378>
11. The importance of pharmacovigilance <https://iris.who.int/handle/10665/42493>
12. The safety of medicines in public health programs <https://www.who.int/publications/i/item/9241593911>
13. Pharmacovigilance system: questions and answers <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/pharmacovigilance-system-questions-answers>
14. Good pharmacovigilance practices <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/good-pharmacovigilance-practices-gvp>
15. Immunization safety surveillance: guidelines for immunization program managers on surveillance of adverse events following immunization. 3rd ed. <https://iris.who.int/handle/10665/208262>

### Questions for the student's self-preparation for the practical lesson:

1. Definition of “cause-and-effect relationship” (CER).
2. Criteria for determining CER.
3. Methods for determining CER, their advantages and disadvantages.
4. Categories of CER.
5. Features of the determination of CER in vaccines: stages, structures.

**Methodical development compiled by: prof. Zaychenko G.V., assoc. prof. Savchenko N.V., assoc. prof. Hnatiuk V.V.**

## **Topic 5. Pharmacotoxic adverse drug reactions.**

### **Competence:**

#### ***Integral Competence:***

- Ability to solve research and/or innovation problems in the field of pharmacy.

#### ***General Competencies (GC):***

- GC02. Knowledge and understanding of the subject area; Understanding of professional activities.
- GC03. Ability to communicate in the state language both orally and in writing.
- GC04. Ability to communicate in a foreign language.
- GC06. Ability to work in a team.
- GC09. Ability to use information and communication technologies.
- GC10. Ability to make decisions and act in compliance with the principle of inadmissibility of corruption and any other manifestations of dishonesty.

#### ***Special (professional, subject) competencies (PC):***

- PC01. Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts.
- PC02. Ability to collect, interpret and apply data necessary for professional activities, research and implementation of innovative projects in the field of pharmacy.
- PC03. Ability to solve pharmacy problems in new or unfamiliar environments with incomplete or limited information, taking into account aspects of social and ethical responsibility.
- PC04. Ability to clearly and unambiguously convey own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to students.
- PC06. Ability to consult on prescription and over-the-counter drugs and other products of the pharmacy assortment, pharmaceutical care during the selection and sale of drugs of natural and synthetic origin by assessing the risk/benefit ratio, compatibility, taking into account their biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical and chemical features, indications/contraindications for use, guided by data on the health status of a particular patient.
- PC08. Ability to monitor the efficacy and safety of the population's use of medicines according to the data on their clinical and pharmaceutical characteristics.

**Purpose:** to acquire theoretical knowledge and practical skills regarding pharmacotoxic adverse drug reactions.

**Equipment:** safety instructions, interactive multimedia system (if necessary), collection of medicines, reference books.

### Plan and organizational structure of the lesson

Stage Name	Stage description	Levels of assimilation	Time
<b>Preparatory</b>	Organizational issues (checking the presence of students)	Acquaintance	5 min.
	Checking the tasks that have been set for self-preparation for classes	Perception	5 min.
	Control and evaluation of the entrance level of training of students in pharmacology	Reproductive	15 min.
<b>Main</b>	Formation of professional skills and abilities (determination by students of the group affiliation of drugs, their mechanisms of action, main pharmacological effects, indications for prescription, possible side effects).	Comprehension Understanding	30 min.
	Development of professional competence: solving situational problems and their assessment	Putting it into practice Exploratory creative activity	10 min.
	Summarizing Knowledge	Fixing	5 min.
<b>Final</b>	Test control of the final level of training	Play	10 min.
	Overall assessment of the student's learning activities	Acquaintance	5 min.
	Informing students about the topic of the next lesson and tasks for independent work	Acquaintance	5 min.

### Recommended Reading.

#### Basic

1. Rang and Dale's Pharmacology / [H. P. Rang, J. M. Ritter, R. J. Flower et al.]. – [9th ed.]. – Elsevier Ltd., 2019. – 808 p.
2. Pharmacology : textbook / V. M. Bobyrov, O. M. Vazhnicha, T. O. Devyatkina, N. M. Devyatkina. - 5th ed., updat. - Vinnytsia : Nova Knyha, 2020. - 560 p.

#### Secondary

1. Prasan R. Bhandari Textbook of Pharmacology / Prasan R. Bhandari. – Thieme, 2022. – 888 p.
2. Patient Assessment in Clinical Pharmacy : A Comprehensive Guide / by editor Sherif Hanafy Mahmoud. – Springer Nature Switzerland, 2019. – 439 p.
3. Pharmacology / [M. A. Clark, R. Finkel, J. A. Rey et al.]. – [7th ed.]. – Baltimore: Lippincott Williams & Wilkins, 2018. – 638 p.
4. Katzung B. G. Basic and clinical pharmacology / B. G. Katzung, S. B. Masters, A. J. Trevor. – [14th ed.]. – The McGraw-Hill Companies, Inc., 2018. – 1250 p.

5. Whalen Karren Lippincott Illustrated Reviews: Pharmacology / K. Whalen. – Wolters Kluwer Health, 2018. – 576 p.
6. Color atlas of pharmacology, 5th edition, revised and expanded / Heinz Luellmann, Klaus Mohr, Lutz Hein, Detlef Bieger [et al.]; 174 color plates by Juergen Wirth. // New York; Thieme Stuttgart. – 2017. – 416 p.

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15. Immunization safety surveillance: guidelines for immunization program managers on surveillance of adverse events following immunization. 3rd ed. <https://iris.who.int/handle/10665/208262>

### **Questions for the student's self-preparation for the practical lesson:**

1. Drug overdose: absolute and relative (toxic effects).
2. Causes of acute poisoning.
3. Symptoms of acute poisoning with drugs of various pharmacological groups.
4. Basic principles of pharmacotherapy of acute drug poisoning.
5. Active detoxification methods.
6. Types of antidote therapy.
7. Principles of symptomatic therapy of acute poisoning.

**Methodical development compiled by: prof. Zaychenko G.V., assoc. prof. Savchenko N.V., assoc. prof. Hnatiuk V.V.**

## **Topic 6. ADR that affect the nervous system.**

### **Competence:**

#### ***Integral Competence:***

- Ability to solve research and/or innovation problems in the field of pharmacy.

#### ***General Competencies (GC):***

- GC02. Knowledge and understanding of the subject area; Understanding of professional activities.
- GC03. Ability to communicate in the state language both orally and in writing.
- GC04. Ability to communicate in a foreign language.
- GC06. Ability to work in a team.
- GC09. Ability to use information and communication technologies.
- GC10. Ability to make decisions and act in compliance with the principle of inadmissibility of corruption and any other manifestations of dishonesty.

#### ***Special (professional, subject) competencies (PC):***

- PC01. Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts.
- PC02. Ability to collect, interpret and apply data necessary for professional activities, research and implementation of innovative projects in the field of pharmacy.
- PC03. Ability to solve pharmacy problems in new or unfamiliar environments with incomplete or limited information, taking into account aspects of social and ethical responsibility.
- PC04. Ability to clearly and unambiguously convey own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to students.
- PC06. Ability to consult on prescription and over-the-counter drugs and other products of the pharmacy assortment, pharmaceutical care during the selection and sale of drugs of natural and synthetic origin by assessing the risk/benefit ratio, compatibility, taking into account their biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical and chemical features, indications/contraindications for use, guided by data on the health status of a particular patient.
- PC08. Ability to monitor the efficacy and safety of the population's use of medicines according to the data on their clinical and pharmaceutical characteristics.

**Purpose:** to acquire theoretical knowledge and practical skills regarding adverse reactions to drugs that affect the nervous system.

**Equipment:** safety instructions, interactive multimedia system (if necessary), collection of medicines, reference books.

### Plan and organizational structure of the lesson

Stage Name	Stage description	Levels of assimilation	Time
<b>Preparatory</b>	Organizational issues (checking the presence of students)	Acquaintance	5 min.
	Checking the tasks that have been set for self-preparation for classes	Perception	5 min.
	Control and evaluation of the entrance level of training of students in pharmacology	Reproductive	15 min.
<b>Main</b>	Formation of professional skills and abilities (determination by students of the group affiliation of drugs, their mechanisms of action, main pharmacological effects, indications for prescription, possible side effects).	Comprehension Understanding	30 min.
	Development of professional competence: solving situational problems and their assessment	Putting it into practice Exploratory creative activity	10 min.
	Summarizing Knowledge	Fixing	5 min.
<b>Final</b>	Test control of the final level of training	Play	10 min.
	Overall assessment of the student's learning activities	Acquaintance	5 min.
	Informing students about the topic of the next lesson and tasks for independent work	Acquaintance	5 min.

### Recommended Reading.

#### Basic

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15. Immunization safety surveillance: guidelines for immunization program managers on surveillance of adverse events following immunization. 3rd ed. <https://iris.who.int/handle/10665/208262>

### Questions for the student's self-preparation for the practical lesson:

1. The main manifestations and mechanisms of occurrence of typical AR on drugs that affect the function of cholinergic nerves. Clinical symptoms, preventive measures and assistance in case of adverse reactions.

2. The main manifestations and mechanisms of occurrence of typical AR on drugs that affect adrenergic innervation. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
3. The main manifestations and mechanisms of occurrence of typical ADR for local anesthesia, astringent drugs, adsorbent agents, and drugs that irritate the endings of sensory nerves. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
4. The main manifestations and mechanisms of occurrence of typical ADR for anesthesia. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
5. The main manifestations and mechanisms of occurrence of typical AR for analgesic drugs: opiate and non-opiate analgesic drugs. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
6. The main manifestations and mechanisms of occurrence of typical AR on psychotropic drugs: neuroleptics, tranquilizers, hypnotics, sedatives, lithium preparations. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
7. The main manifestations and mechanisms of occurrence of typical AR are antiepileptic and antiparkinsonian drugs, drugs for the treatment of muscular disease, drugs that can be used in Alzheimer's disease, multiple sclerosis and amyotrophic lateral sclerosis. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
8. The main manifestations and mechanisms of occurrence of typical AR on antidepressants, adaptogens of plant and animal origin, psychostimulants, analeptics. Clinical symptoms, preventive measures and assistance in case of adverse reactions.

**Methodical development compiled by: prof. Zaychenko G.V., assoc. prof. Savchenko N.V., assoc. prof. Hnatiuk V.V.**



## **Topic 7. ADR that affect metabolism.**

### **Competence:**

#### ***Integral Competence:***

- Ability to solve research and/or innovation problems in the field of pharmacy.

#### ***General Competencies (GC):***

- GC02. Knowledge and understanding of the subject area; Understanding of professional activities.
- GC03. Ability to communicate in the state language both orally and in writing.
- GC04. Ability to communicate in a foreign language.
- GC06. Ability to work in a team.
- GC09. Ability to use information and communication technologies.
- GC10. Ability to make decisions and act in compliance with the principle of inadmissibility of corruption and any other manifestations of dishonesty.

#### ***Special (professional, subject) competencies (PC):***

- PC01. Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts.
- PC02. Ability to collect, interpret and apply data necessary for professional activities, research and implementation of innovative projects in the field of pharmacy.
- PC03. Ability to solve pharmacy problems in new or unfamiliar environments with incomplete or limited information, taking into account aspects of social and ethical responsibility.
- PC04. Ability to clearly and unambiguously convey own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to students.
- PC06. Ability to consult on prescription and over-the-counter drugs and other products of the pharmacy assortment, pharmaceutical care during the selection and sale of drugs of natural and synthetic origin by assessing the risk/benefit ratio, compatibility, taking into account their biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical and chemical features, indications/contraindications for use, guided by data on the health status of a particular patient.
- PC08. Ability to monitor the efficacy and safety of the population's use of medicines according to the data on their clinical and pharmaceutical characteristics.

**Purpose:** to acquire theoretical knowledge and practical skills regarding adverse reactions to drugs that affect metabolism.

**Equipment:** safety instructions, interactive multimedia system (if necessary), collection of medicines, reference books.

### Plan and organizational structure of the lesson

Stage Name	Stage description	Levels of assimilation	Time
<b>Preparatory</b>	Organizational issues (checking the presence of students)	Acquaintance	5 min.
	Checking the tasks that have been set for self-preparation for classes	Perception	5 min.
	Control and evaluation of the entrance level of training of students in pharmacology	Reproductive	15 min.
<b>Main</b>	Formation of professional skills and abilities (determination by students of the group affiliation of drugs, their mechanisms of action, main pharmacological effects, indications for prescription, possible side effects).	Comprehension Understanding	30 min.
	Development of professional competence: solving situational problems and their assessment	Putting it into practice Exploratory creative activity	10 min.
	Summarizing Knowledge	Fixing	5 min.
<b>Final</b>	Test control of the final level of training	Play	10 min.
	Overall assessment of the student's learning activities	Acquaintance	5 min.
	Informing students about the topic of the next lesson and tasks for independent work	Acquaintance	5 min.

### Recommended Reading.

#### Basic

1. Rang and Dale's Pharmacology / [H. P. Rang, J. M. Ritter, R. J. Flower et al.]. – [9th ed.]. – Elsevier Ltd., 2019. – 808 p.
2. Pharmacology : textbook / V. M. Bobyrov, O. M. Vazhnicha, T. O. Devyatkina, N. M. Devyatkina. - 5th ed., updat. - Vinnytsia : Nova Knyha, 2020. - 560 p.

#### Secondary

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15. Immunization safety surveillance: guidelines for immunization program managers on surveillance of adverse events following immunization. 3rd ed. <https://iris.who.int/handle/10665/208262>

### Questions for the student's self-preparation for the practical lesson:

1. The main manifestations and mechanisms of occurrence of typical AR on hormonal drugs. Clinical symptoms, preventive measures and assistance in case of adverse reactions.

2. The main manifestations and mechanisms of occurrence of typical AR on anti-inflammatory drugs. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
3. The main manifestations and mechanisms of occurrence of typical AR for antiallergic drugs. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
4. The main manifestations and mechanisms of occurrence of typical AR on drugs that affect immune processes. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
5. The main manifestations and mechanisms of occurrence of typical AR for vitamin drugs. Clinical symptoms, preventive measures and assistance in case of adverse reactions.

**Methodical development compiled by: prof. Zaychenko G.V., assoc. prof. Savchenko N.V., assoc. prof. Hnatiuk V.V.**

## **Topic 8. ADR that affect the respiratory system, gastrointestinal tract, kidney function and reproductive processes.**

### **Competence:**

#### ***Integral Competence:***

- Ability to solve research and/or innovation problems in the field of pharmacy.

#### ***General Competencies (GC):***

- GC02. Knowledge and understanding of the subject area; Understanding of professional activities.
- GC03. Ability to communicate in the state language both orally and in writing.
- GC04. Ability to communicate in a foreign language.
- GC06. Ability to work in a team.
- GC09. Ability to use information and communication technologies.
- GC10. Ability to make decisions and act in compliance with the principle of inadmissibility of corruption and any other manifestations of dishonesty.

#### ***Special (professional, subject) competencies (PC):***

- PC01. Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts.
- PC02. Ability to collect, interpret and apply data necessary for professional activities, research and implementation of innovative projects in the field of pharmacy.
- PC03. Ability to solve pharmacy problems in new or unfamiliar environments with incomplete or limited information, taking into account aspects of social and ethical responsibility.
- PC04. Ability to clearly and unambiguously convey own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to students.
- PC06. Ability to consult on prescription and over-the-counter drugs and other products of the pharmacy assortment, pharmaceutical care during the selection and sale of drugs of natural and synthetic origin by assessing the risk/benefit ratio, compatibility, taking into account their biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical and chemical features, indications/contraindications for use, guided by data on the health status of a particular patient.
- PC08. Ability to monitor the efficacy and safety of the population's use of medicines according to the data on their clinical and pharmaceutical characteristics.

**Purpose:** to acquire theoretical knowledge and practical skills regarding adverse reactions to drugs that affect the respiratory system, gastrointestinal tract, kidney function and reproductive processes.

**Equipment:** safety instructions, interactive multimedia system (if necessary), collection of medicines, reference books.

### Plan and organizational structure of the lesson

Stage Name	Stage description	Levels of assimilation	Time
<b>Preparatory</b>	Organizational issues (checking the presence of students)	Acquaintance	5 min.
	Checking the tasks that have been set for self-preparation for classes	Perception	5 min.
	Control and evaluation of the entrance level of training of students in pharmacology	Reproductive	15 min.
<b>Main</b>	Formation of professional skills and abilities (determination by students of the group affiliation of drugs, their mechanisms of action, main pharmacological effects, indications for prescription, possible side effects).	Comprehension Understanding	30 min.
	Development of professional competence: solving situational problems and their assessment	Putting it into practice Exploratory creative activity	10 min.
	Summarizing Knowledge	Fixing	5 min.
<b>Final</b>	Test control of the final level of training	Play	10 min.
	Overall assessment of the student's learning activities	Acquaintance	5 min.
	Informing students about the topic of the next lesson and tasks for independent work	Acquaintance	5 min.

### Recommended Reading.

#### Basic

1. Rang and Dale's Pharmacology / [H. P. Rang, J. M. Ritter, R. J. Flower et al.]. – [9th ed.]. – Elsevier Ltd., 2019. – 808 p.
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#### Secondary

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8. The Center for Polish Medical Literature of the National Medical Library of Ukraine "Zbigniew Religa Polish Medical Library." <https://polska.library.gov.ua/>
9. Nature [www.nature.com](http://www.nature.com)
10. Safety of medicines : a guide to detecting and reporting adverse drug reactions : why health professionals need to take action <https://iris.who.int/handle/10665/67378>
11. The importance of pharmacovigilance <https://iris.who.int/handle/10665/42493>
12. The safety of medicines in public health programs <https://www.who.int/publications/i/item/9241593911>
13. Pharmacovigilance system: questions and answers <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/pharmacovigilance-system-questions-answers>
14. Good pharmacovigilance practices <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/good-pharmacovigilance-practices-gvp>
15. Immunization safety surveillance: guidelines for immunization program managers on surveillance of adverse events following immunization. 3rd ed. <https://iris.who.int/handle/10665/208262>

### Questions for the student's self-preparation for the practical lesson:

1. The main manifestations and mechanisms of occurrence of typical AR on drugs that affect the respiratory system. Clinical symptoms, preventive measures and assistance in case of adverse reactions.

2. The main manifestations and mechanisms of occurrence of typical AR on drugs affecting the gastrointestinal tract. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
3. The main manifestations and mechanisms of occurrence of typical AR on drugs that affect renal function. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
4. The main manifestations and mechanisms of occurrence of typical AR on drugs that affect the myometrium. Clinical symptoms, preventive measures and assistance in case of side effects.
5. The main manifestations and mechanisms of occurrence of typical AR on drugs that affect hematopoiesis and hemostasis. Clinical symptoms, preventive measures and assistance in case of adverse reactions.

**Methodical development compiled by: prof. Zaychenko G.V., assoc. prof. Savchenko N.V., assoc. prof. Hnatiuk V.V.**



## **Topic 9. ADR that affect the functions of the blood and cardiovascular system.**

### **Competence:**

#### ***Integral Competence:***

- Ability to solve research and/or innovation problems in the field of pharmacy.

#### ***General Competencies (GC):***

- GC02. Knowledge and understanding of the subject area; Understanding of professional activities.
- GC03. Ability to communicate in the state language both orally and in writing.
- GC04. Ability to communicate in a foreign language.
- GC06. Ability to work in a team.
- GC09. Ability to use information and communication technologies.
- GC10. Ability to make decisions and act in compliance with the principle of inadmissibility of corruption and any other manifestations of dishonesty.

#### ***Special (professional, subject) competencies (PC):***

- PC01. Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts.
- PC02. Ability to collect, interpret and apply data necessary for professional activities, research and implementation of innovative projects in the field of pharmacy.
- PC03. Ability to solve pharmacy problems in new or unfamiliar environments with incomplete or limited information, taking into account aspects of social and ethical responsibility.
- PC04. Ability to clearly and unambiguously convey own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to students.
- PC06. Ability to consult on prescription and over-the-counter drugs and other products of the pharmacy assortment, pharmaceutical care during the selection and sale of drugs of natural and synthetic origin by assessing the risk/benefit ratio, compatibility, taking into account their biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical and chemical features, indications/contraindications for use, guided by data on the health status of a particular patient.
- PC08. Ability to monitor the efficacy and safety of the population's use of medicines according to the data on their clinical and pharmaceutical characteristics.

**Purpose:** to acquire theoretical knowledge and practical skills regarding adverse reactions to drugs that affect the functions of the blood and cardiovascular system.

**Equipment:** safety instructions, interactive multimedia system (if necessary), collection of medicines, reference books.

### Plan and organizational structure of the lesson

Stage Name	Stage description	Levels of assimilation	Time
<b>Preparatory</b>	Organizational issues (checking the presence of students)	Acquaintance	5 min.
	Checking the tasks that have been set for self-preparation for classes	Perception	5 min.
	Control and evaluation of the entrance level of training of students in pharmacology	Reproductive	15 min.
<b>Main</b>	Formation of professional skills and abilities (determination by students of the group affiliation of drugs, their mechanisms of action, main pharmacological effects, indications for prescription, possible side effects).	Comprehension Understanding	30 min.
	Development of professional competence: solving situational problems and their assessment	Putting it into practice Exploratory creative activity	10 min.
	Summarizing Knowledge	Fixing	5 min.
<b>Final</b>	Test control of the final level of training	Play	10 min.
	Overall assessment of the student's learning activities	Acquaintance	5 min.
	Informing students about the topic of the next lesson and tasks for independent work	Acquaintance	5 min.

### Recommended Reading.

#### Basic

1. Rang and Dale's Pharmacology / [H. P. Rang, J. M. Ritter, R. J. Flower et al.]. – [9th ed.]. – Elsevier Ltd., 2019. – 808 p.
2. Pharmacology : textbook / V. M. Bobyrov, O. M. Vazhnicha, T. O. Devyatkina, N. M. Devyatkina. - 5th ed., updat. - Vinnytsia : Nova Knyha, 2020. - 560 p.

#### Secondary

1. Prasan R. Bhandari Textbook of Pharmacology / Prasan R. Bhandari. – Thieme, 2022. – 888 p.
2. Patient Assessment in Clinical Pharmacy : A Comprehensive Guide / by editor Sherif Hanafy Mahmoud. – Springer Nature Switzerland, 2019. – 439 p.
3. Pharmacology / [M. A. Clark, R. Finkel, J. A. Rey et al.]. – [7th ed.]. – Baltimore: Lippincott Williams & Wilkins, 2018. – 638 p.

4. Katzung B. G. Basic and clinical pharmacology / B. G. Katzung, S. B. Masters, A. J. Trevor. – [14th ed.]. – The McGraw-Hill Companies, Inc., 2018. – 1250 p.
5. Whalen Karren Lippincott Illustrated Reviews: Pharmacology / K. Whalen. – Wolters Kluwer Health, 2018. – 576 p.
6. Color atlas of pharmacology, 5th edition, revised and expanded / Heinz Luellmann, Klaus Mohr, Lutz Hein, Detlef Bieger [et al.]; 174 color plates by Juergen Wirth. // New York; Thieme Stuttgart. – 2017. – 416 p.

### Information Resources

1. State expert center of Ministry of Health of Ukraine <https://www.dec.gov.ua/>
2. DSpace of Bogomolets National Medical University <http://ir.librarynmu.com/handle/123456789/410>
3. National Library of Ukraine name after V.I. Vernadskyi <http://www.nbu.gov.ua/>
4. National Scientific Medical Library of Ukraine <https://library.gov.ua/>
5. British Medical Journal Publishing Group Ltd - [www.bmj.com](http://www.bmj.com)
6. The Lancet, Elsevier Limited [www.thelancet.com](http://www.thelancet.com)
7. Cochrane Library [www.cochrane.org](http://www.cochrane.org)
8. The Center for Polish Medical Literature of the National Medical Library of Ukraine "Zbigniew Religa Polish Medical Library." <https://polska.library.gov.ua/>
9. Nature [www.nature.com](http://www.nature.com)
10. Safety of medicines : a guide to detecting and reporting adverse drug reactions : why health professionals need to take action <https://iris.who.int/handle/10665/67378>
11. The importance of pharmacovigilance <https://iris.who.int/handle/10665/42493>
12. The safety of medicines in public health programs <https://www.who.int/publications/i/item/9241593911>
13. Pharmacovigilance system: questions and answers <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/pharmacovigilance-system-questions-answers>
14. Good pharmacovigilance practices <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/good-pharmacovigilance-practices-gvp>
15. Immunization safety surveillance: guidelines for immunization program managers on surveillance of adverse events following immunization. 3rd ed. <https://iris.who.int/handle/10665/208262>

### Questions for the student's self-preparation for the practical lesson:

1. The main manifestations and mechanisms of occurrence of typical AR on drugs that affect hematopoiesis and hemostasis. Clinical symptoms, preventive measures and assistance in case of adverse reactions.

2. The main manifestations and mechanisms of occurrence of typical AR for antihypertensive drugs. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
3. The main manifestations and mechanisms of occurrence of typical AR on antianginal drugs. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
4. The main manifestations and mechanisms of occurrence of typical AR on anti-atherosclerotic drugs. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
5. Main manifestations and mechanisms of occurrence of typical AR on antiarrhythmic drugs. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
6. The main manifestations and mechanisms of occurrence of typical AR on cardiotonic drugs. Clinical symptoms, preventive measures and assistance in case of adverse reactions.

**Methodical development compiled by: prof. Zaychenko G.V., assoc. prof. Savchenko N.V., assoc. prof. Hnatiuk V.V.**

## **Topic 10. AR of chemotherapeutic drugs.**

### **Competence:**

#### ***Integral Competence:***

- Ability to solve research and/or innovation problems in the field of pharmacy.

#### ***General Competencies (GC):***

- GC02. Knowledge and understanding of the subject area; Understanding of professional activities.
- GC03. Ability to communicate in the state language both orally and in writing.
- GC04. Ability to communicate in a foreign language.
- GC06. Ability to work in a team.
- GC09. Ability to use information and communication technologies.
- GC10. Ability to make decisions and act in compliance with the principle of inadmissibility of corruption and any other manifestations of dishonesty.

#### ***Special (professional, subject) competencies (PC):***

- PC01. Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts.
- PC02. Ability to collect, interpret and apply data necessary for professional activities, research and implementation of innovative projects in the field of pharmacy.
- PC03. Ability to solve pharmacy problems in new or unfamiliar environments with incomplete or limited information, taking into account aspects of social and ethical responsibility.
- PC04. Ability to clearly and unambiguously convey own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to students.
- PC06. Ability to consult on prescription and over-the-counter drugs and other products of the pharmacy assortment, pharmaceutical care during the selection and sale of drugs of natural and synthetic origin by assessing the risk/benefit ratio, compatibility, taking into account their biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical and chemical features, indications/contraindications for use, guided by data on the health status of a particular patient.
- PC08. Ability to monitor the efficacy and safety of the population's use of medicines according to the data on their clinical and pharmaceutical characteristics.

**Purpose:** to acquire theoretical knowledge and practical skills regarding adverse reactions to chemotherapeutic drugs.

**Equipment:** safety instructions, interactive multimedia system (if necessary), collection of medicines, reference books.

### Plan and organizational structure of the lesson

Stage Name	Stage description	Levels of assimilation	Time
<b>Preparatory</b>	Organizational issues (checking the presence of students)	Acquaintance	5 min.
	Checking the tasks that have been set for self-preparation for classes	Perception	5 min.
	Control and evaluation of the entrance level of training of students in pharmacology	Reproductive	15 min.
<b>Main</b>	Formation of professional skills and abilities (determination by students of the group affiliation of drugs, their mechanisms of action, main pharmacological effects, indications for prescription, possible side effects).	Comprehension Understanding	30 min.
	Development of professional competence: solving situational problems and their assessment	Putting it into practice Exploratory creative activity	10 min.
	Summarizing Knowledge	Fixing	5 min.
<b>Final</b>	Test control of the final level of training	Play	10 min.
	Overall assessment of the student's learning activities	Acquaintance	5 min.
	Informing students about the topic of the next lesson and tasks for independent work	Acquaintance	5 min.

### Recommended Reading.

#### Basic

1. Rang and Dale's Pharmacology / [H. P. Rang, J. M. Ritter, R. J. Flower et al.]. – [9th ed.]. – Elsevier Ltd., 2019. – 808 p.
2. Pharmacology : textbook / V. M. Bobyrov, O. M. Vazhnicha, T. O. Devyatkina, N. M. Devyatkina. - 5th ed., updat. - Vinnytsia : Nova Knyha, 2020. - 560 p.

#### Secondary

1. Prasan R. Bhandari Textbook of Pharmacology / Prasan R. Bhandari. – Thieme, 2022. – 888 p.
2. Patient Assessment in Clinical Pharmacy : A Comprehensive Guide / by editor Sherif Hanafy Mahmoud. – Springer Nature Switzerland, 2019. – 439 p.
3. Pharmacology / [M. A. Clark, R. Finkel, J. A. Rey et al.]. – [7th ed.]. – Baltimore: Lippincott Williams & Wilkins, 2018. – 638 p.

4. Katzung B. G. Basic and clinical pharmacology / B. G. Katzung, S. B. Masters, A. J. Trevor. – [14th ed.]. – The McGraw-Hill Companies, Inc., 2018. – 1250 p.
5. Whalen Karren Lippincott Illustrated Reviews: Pharmacology / K. Whalen. – Wolters Kluwer Health, 2018. – 576 p.
6. Color atlas of pharmacology, 5th edition, revised and expanded / Heinz Luellmann, Klaus Mohr, Lutz Hein, Detlef Bieger [et al.]; 174 color plates by Juergen Wirth. // New York; Thieme Stuttgart. – 2017. – 416 p.

### Information Resources

1. State expert center of Ministry of Health of Ukraine <https://www.dec.gov.ua/>
2. DSpace of Bogomolets National Medical University <http://ir.librarynmu.com/handle/123456789/410>
3. National Library of Ukraine name after V.I. Vernadskyi <http://www.nbu.gov.ua/>
4. National Scientific Medical Library of Ukraine <https://library.gov.ua/>
5. British Medical Journal Publishing Group Ltd - [www.bmj.com](http://www.bmj.com)
6. The Lancet, Elsevier Limited [www.thelancet.com](http://www.thelancet.com)
7. Cochrane Library [www.cochrane.org](http://www.cochrane.org)
8. The Center for Polish Medical Literature of the National Medical Library of Ukraine "Zbigniew Religa Polish Medical Library." <https://polska.library.gov.ua/>
9. Nature [www.nature.com](http://www.nature.com)
10. Safety of medicines : a guide to detecting and reporting adverse drug reactions : why health professionals need to take action <https://iris.who.int/handle/10665/67378>
11. The importance of pharmacovigilance <https://iris.who.int/handle/10665/42493>
12. The safety of medicines in public health programs <https://www.who.int/publications/i/item/9241593911>
13. Pharmacovigilance system: questions and answers <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/pharmacovigilance-system-questions-answers>
14. Good pharmacovigilance practices <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/good-pharmacovigilance-practices-gvp>
15. Immunization safety surveillance: guidelines for immunization program managers on surveillance of adverse events following immunization. 3rd ed. <https://iris.who.int/handle/10665/208262>

### Questions for the student's self-preparation for the practical lesson:

1. The main manifestations and mechanisms of occurrence of typical AR for antiseptic and disinfectant drugs. Clinical symptoms, preventive measures and assistance in case of adverse reactions.

2. Main manifestations and mechanisms of occurrence of typical AR for synthetic antimicrobial drugs. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
3. The main manifestations and mechanisms of occurrence of typical antibiotic antibiotic disorders. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
4. Main manifestations and mechanisms of occurrence of typical AR for antimycosis drugs. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
5. The main manifestations and occurrence of typical ARs for drugs used for the treatment of tuberculosis. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
6. The main manifestations and mechanisms of occurrence of typical antiviral drugs. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
7. The main manifestations and mechanisms of occurrence of typical ARs for antimalarial, antiprotozoal and anthelmintic drugs. Clinical symptoms, preventive measures and assistance in case of adverse reactions.
8. Main manifestations and mechanisms of occurrence of typical AR on antitumor drugs. Clinical symptoms, preventive measures and assistance in case of adverse reactions.

**Methodical development compiled by: prof. Zaychenko G.V., assoc. prof. Savchenko N.V., assoc. prof. Hnatiuk V.V.**