

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

**METHODICAL RECOMMENDATIONS  
to lectures**

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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## **Lecture № 1. Pharmacovigilance, the importance of its implementation for health care system/programs and registrants. Pharmacovigilance procedure in Ukraine.**

**Type of lecture:** traditional (informational).

### **Competence:**

- **Integral competence:** ability to solve research and/or innovation problems in the field of pharmacy.
- **General:**
  1. Knowledge and understanding of the subject area; Understanding of professional activities (GC02).
  2. Ability to communicate in the state language both orally and in writing (GC03).
  3. Ability to communicate in a foreign language (GC04).
  4. Ability to work in a team (GC06).
  5. Ability to use information and communication technologies (GC09).
  6. Ability to make decisions and act in compliance with the principle of inadmissibility of corruption and any other manifestations of dishonesty (GC10).
- **Special (professional, subject) competencies (PC):**
  1. Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts (PC01).
  2. Ability to collect, interpret and apply data necessary for professional activities, research and implementation of innovative projects in the field of pharmacy (PC02).
  3. Ability to solve pharmacy problems in new or unfamiliar environments with incomplete or limited information, taking into account aspects of social and ethical responsibility (PC03).
  4. Ability to clearly and unambiguously convey one's own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to students (PC04).
  5. Ability to consult on prescription and over-the-counter medicines and other pharmacy assortment, pharmaceutical care during the selection and sale of medicines 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 the health data of a particular patient (PC06).
  6. Ability to monitor the efficacy and safety of the population's use of medicines according to the data on their clinical and pharmaceutical characteristics (PC08).

### **Purpose:**

1) didactic goal – to form systematic knowledge about the importance of pharmacovigilance for the health care system/programs and registration holders and the procedure for pharmacovigilance in Ukraine;

- 2) educational goal – to promote the formation of a scientific worldview;
- 3) developmental goal – to develop intellectual abilities, thinking, independence.

**Lecture equipment:** multimedia system, appropriate software.

**Lecture tasks:**

1. To realize the importance of medicines for the health care system, maintaining the duration and quality of life of people.
2. To realize the role and importance of the discipline "Pharmacovigilance in pharmaceutical practice" for the formation of competencies of a modern pharmacist.
3. Visualize the process of quality assurance of medicinal products at their post-registration stage of life.
4. Understand the pharmacovigilance (PV) process.
5. To understand the goals and significance of the PV system for the health care system.
6. Substantiate the sources of obtaining and exchanging information in the implementation of PV.
7. Distinguish the elements that make up the PV system of Ukraine.
8. Know the participants in the process of PV implementation in Ukraine.
9. Know the regulations governing the implementation of PV in Ukraine.
10. Understand the place and role of WHO in the implementation of PV.

**Lecture plan:**

Lecture Stage Name	Content of the stages	Educational Objective of the stage	Time
Introductory Part	To present information on the importance of medicines for the health care system, the importance of the discipline "Pharmacovigilance in pharmaceutical practice" for the formation of competencies of a modern pharmacist.	Reveal the relevance of the topic of the lecture; acquaint students with the lecture plan.	5 minutes
Main part	<ol style="list-style-type: none"> <li>1. The concept of PV, its origins, goals and significance for the health care system.</li> <li>2. Sources of obtaining and exchanging information in the implementation of PV.</li> </ol>	<ul style="list-style-type: none"> <li>•Provide information on the Law of Ukraine "On Medicines"</li> <li>•Understand the functions, rights and obligations of the State Expert Center</li> </ul>	75 minutes

	<ol style="list-style-type: none"> <li>3. Elements that make up the system of the PV of Ukraine.</li> <li>4. Participants in the process of PV implementation in Ukraine.</li> <li>5. Normative legal acts regulating the implementation of PV in Ukraine.</li> <li>6. The place and role of the World Health Organization in the implementation of PV.</li> </ol>	<p>of the Ministry of Health of Ukraine</p> <ul style="list-style-type: none"> <li>• To provide knowledge of the concepts of "PV"</li> <li>• Understand the significance of PV in pharmacy.</li> <li>• To acquire knowledge about the process of quality assurance of medicines at their post-registration stage of life.</li> <li>• Understand the PV process.</li> <li>• To learn the goals and significance of the PV system for the health care system.</li> <li>• To assimilate the sources of obtaining and exchanging information in the implementation of PV.</li> <li>• Understand the elements that make up the PV system of Ukraine.</li> <li>• Distinguish between the participants in the process of PV implementation in Ukraine.</li> <li>• Know the regulations governing the implementation of PV in Ukraine.</li> <li>• Understand the place and role of WHO in the</li> </ul>	
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		implementation of PV.	
Results	Highlight the importance of PV for the health care system.	Summarize the material presented; emphasize the role and main Objective of studying the discipline.	5 minutes
Frequently Asked Questions	Active dialogue / discussion / discussion.	Explain the incomprehensible and most difficult points of the lecture.	5 minutes

## 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 lecture**

1. Medical and pharmaceutical terminology.
2. Stages of life of medicines.

### **Questions for preparation for the practical lesson, which are revealed by the lecture material**

1. The concept of pharmacovigilance, its origins, objectives and significance for the health care system.
2. Sources of obtaining and exchanging information in pharmacovigilance.
3. Elements that make up the pharmacovigilance system of Ukraine.
4. Participants in the pharmacovigilance process in Ukraine.
5. Regulations governing pharmacovigilance in Ukraine.
6. The place and role of the World Health Organization in pharmacovigilance.

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

## **Lecture № 2. Classifications and mechanisms of adverse drug reactions. The main ways to prevent adverse reactions to drugs.**

**Type of lecture:** traditional (informational).

### **Competence:**

- **Integral competence:** ability to solve research and/or innovation problems in the field of pharmacy.
- **General:**
  1. Knowledge and understanding of the subject area; Understanding professional activities (GC02).
  2. Ability to communicate in the state language both orally and in writing (GC03).
  3. Ability to communicate in a foreign language (GC04).
  4. Ability to work in a team (GC06).
  5. Ability to use information and communication technologies (GC09).
  6. Ability to make decisions and act in compliance with the principle of inadmissibility of corruption and any other manifestations of dishonesty (GC10).
- **Special (professional, subject) competencies (PC):**
  1. Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts (PC01).
  2. Ability to collect, interpret and apply data necessary for professional activities, research and implementation of innovative projects in the field of pharmacy (PC02).
  3. Ability to solve pharmacy problems in new or unfamiliar environments with incomplete or limited information, taking into account aspects of social and ethical responsibility (PC03).
  4. Ability to clearly and unambiguously convey one's own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to students (PC04).
  5. Ability to consult on prescription and over-the-counter medicines and other pharmacy assortment, pharmaceutical care during the selection and sale of medicines 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 the health data of a particular patient (PC06).
  6. Ability to monitor the efficacy and safety of the population's use of medicines according to the data on their clinical and pharmaceutical characteristics (PC08).

### **Purpose:**

1) didactic goal – to form systematic knowledge of classifications and mechanisms of adverse reactions to drugs, the main ways to prevent adverse reactions to drugs;



- 2) educational goal – to promote the formation of a scientific worldview;
- 3) developmental goal – to develop intellectual abilities, thinking, independence.

**Lecture equipment:** multimedia system, appropriate software.

**Lecture tasks:**

1. Understand the concept of AR drugs, foreseen and unforeseen AR drugs, serious and non-serious AR drugs.
2. Distinguish AR drugs by the strength of action, the time of development of manifestations, the severity of the course, the genesis, the mechanism of development, the relationship with damage to organs and systems.
3. Know the classifications of AR drugs according to the WHO.
4. To understand the causes of AR and the factors influencing the occurrence of AR on drugs (related to the patient, to the healthcare professional, to the medicinal product), the place and role of medical errors in the occurrence of AR drugs.
5. To realize AR with the combined use of drugs, polyprazmazion.
6. Understand the concept of a drug-induced disease.
7. Understand the concept of allergic reactions to drugs and polyvalent sensitization.
8. Justify measures aimed at preventing the occurrence of hypersensitivity reactions.
9. Substantiate measures and tools that contribute to minimizing the risks of drugs.
10. To understand the social factors of the increase in the incidence of AR drugs.
11. To realize the role of the pharmacist in the prevention of AR drugs.

**Lecture plan:**

Lecture Stage Name	Content of the stages	Educational Objective of the stage	Time
Introductory Part	To provide information on the incidence of AR in Ukraine and the world.	Reveal the relevance of the topic of the lecture; acquaint students with the lecture plan.	5 minutes
Main part	<ol style="list-style-type: none"> <li>1. The concept of AR drugs, foreseen and unforeseen AR drugs, serious and non-serious AR drugs.</li> <li>2. Types of AR drugs 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.</li> </ol>	<ul style="list-style-type: none"> <li>• To provide knowledge about the concept of AR drugs, foreseen and unforeseen AR drugs, serious and non-serious AR drugs.</li> <li>• To distinguish AR drugs by the strength of action, time of development of manifestations, severity of the course, genesis,</li> </ul>	75 minutes

	<p>3. Classification of AR drugs according to WHO.</p> <p>4. Causes of AR drugs. Factors influencing the occurrence of AR on drugs (related to the patient, to the medical worker, to the drug). The place and role of medical errors in the occurrence of AR drugs.</p> <p>5. AR with combined use of drugs. Polyprasmazy.</p> <p>6. The concept of drug disease.</p> <p>7. The concept of allergic reactions to drugs and polyvalent sensitization.</p> <p>8. Measures aimed at preventing the occurrence of hypersensitivity reactions.</p> <p>9. Measures and tools that help minimize the risks of drugs.</p> <p>10. Social factors of increasing the incidence of AR drugs.</p> <p>11. The role of the pharmacist in the prevention of AR drugs</p>	<p>mechanism of development, association with damage to organs and systems.</p> <ul style="list-style-type: none"> <li>• To learn the classifications of AR drugs according to the WHO.</li> <li>• Understand the causes of AR and the factors influencing the occurrence of AR on drugs (related to the patient, to the medical worker, to the drug), the place and role of medical errors in the occurrence of AR drugs.</li> <li>• Assimilate AR with the combined use of drugs, polyprazmazium.</li> <li>• Learn the concept of drug disease.</li> <li>• Know the concept of allergic reactions to drugs and polyvalent sensitization.</li> <li>• Substantiate measures aimed at preventing the occurrence of hypersensitivity reactions.</li> <li>• Substantiate measures and tools that contribute to minimizing the risks of drugs.</li> <li>• Understand the social factors behind the increase in the</li> </ul>	
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		incidence of AR drugs. • Understand the role of the pro-visor in the prevention of AR drugs.	
Results	To highlight the importance of preventing AR drugs for the preservation of public health.	Summarize the material presented; to emphasize the role of the pharmacist in the prevention of AR drugs.	5 minutes
Frequently Asked Questions	Active dialogue / discussion / discussion.	Explain the incomprehensible and most difficult points of the lecture.	5 minutes

## 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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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."  
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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 lecture**

1. Pharmacokinetics and pharmacodynamics of medicinal products.

### **Questions for preparation for the practical lesson, which are revealed by the lecture material**

1. The concept of AR drugs, foreseen and unforeseen AR drugs, serious and non-serious AR drugs.
2. Types of AR drugs 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 AR drugs according to WHO.
4. Causes of AR drugs. 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 AR drugs.
5. AR with combined use of drugs. Polyprasmazy.
6. The concept of drug disease.
7. The concept of allergic reactions to drugs and polyvalent sensitization.
8. Measures aimed at preventing the occurrence of hypersensitivity reactions.
9. Measures and tools that help minimize the risks of drugs.
10. Social factors of increasing the incidence of AR on drugs.
11. The role of the pharmacist in the prevention of AR drugs.

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

## Lecture № 3. Adverse effects after immunization. Features of vaccine safety surveillance.

**Type of lecture:** traditional (informational).

### Competence:

- **Integral competence:** ability to solve research and/or innovation problems in the field of pharmacy.
- **General:**
  1. Knowledge and understanding of the subject area; Understanding professional activities (GC02).
  2. Ability to communicate in the state language both orally and in writing (GC03).
  3. Ability to communicate in a foreign language (GC04).
  4. Ability to work in a team (GC06).
  5. Ability to use information and communication technologies (GC09).
  6. Ability to make decisions and act in compliance with the principle of inadmissibility of corruption and any other manifestations of dishonesty (GC10).
- **Special (professional, subject) competencies (PC):**
  1. Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts (PC01).
  2. Ability to collect, interpret and apply data necessary for professional activities, research and implementation of innovative projects in the field of pharmacy (PC02).
  3. Ability to solve pharmacy problems in new or unfamiliar environments with incomplete or limited information, taking into account aspects of social and ethical responsibility (PC03).
  4. Ability to clearly and unambiguously convey one's own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to students (PC04).
  5. Ability to consult on prescription and over-the-counter medicines and other pharmacy assortment, pharmaceutical care during the selection and sale of medicines 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 the health data of a particular patient (PC06).
  6. Ability to monitor the efficacy and safety of the population's use of medicines according to the data on their clinical and pharmaceutical characteristics (PC08).

### Purpose:

- 1) didactic goal – to form systematic knowledge about undesirable effects after immunization (AEFI) and the specifics of vaccine safety surveillance;
- 2) educational goal – to promote the formation of a scientific worldview;

3) developmental goal – to develop intellectual abilities, thinking, independence.

**Lecture equipment:** multimedia system, appropriate software.

**Lecture tasks:**

1. Understand the concept of adverse events after immunization/tuberculin diagnosis (AEFI), group AEFI; vaccine effectiveness; ineffectiveness of vaccination; seroconversion; seroprotection.
2. Know the classification and characteristics of the AEFI,
3. Distinguish between types of NNPEs depending on predictability and severity.
4. Know the timing of the development of clinical manifestations of AEFI: meaning and practical use.
5. Know the clinical manifestations of AEFI: classification, approaches to identification.
6. Know the causes of the development of AEFIs: classification and their characteristics.
7. Understand the individual characteristics of the vaccinated person's body, which may be the reasons for the development of AEFI:.
8. Distinguish between AEFIs due to immunization procedural errors
9. Distinguish between AEFIs due to great immunization conCERNs
10. Distinguish between individual, unpredictable post-vaccination reactions without an established cause.
11. Substantiate measures aimed at preventing the occurrence of AEFIs.
12. Substantiate measures and tools that contribute to minimizing the risks of AEFIs.
13. Understand the social factors behind the increase in the incidence of AEFIs.
14. Understand the role of the pharmacist in the prevention of AEFIs.
15. Understand the specifics of vaccine safety surveillance.

**Lecture plan:**

Lecture Stage Name	Content of the stages	Educational Objective of the stage	Time
Introductory Part	To provide information on the incidence of AEFI in Ukraine and the world.	Reveal the relevance of the topic of the lecture; acquaint students with the lecture plan.	5 minutes
Main part	1. The concept of adverse events after immunization/tuberculinide agnostic (AEFI), group NNPI; vaccine effectiveness; ineffectiveness of vaccination; Seroco-nversion; seroprotection..	<ul style="list-style-type: none"> <li>• To provide knowledge on the concept of adverse events after immunization/tuberculin diagnostics (AEFI), group NIPI; vaccine effectiveness; non-efficiency of the vaccination; seroconversion; seroprotection..</li> </ul>	75 minutes

	<ol style="list-style-type: none"> <li>2. Types of NNPI: classification and characteristics. Classification of NNPIs depending on foreseeability, seriousness.</li> <li>3. Terms of development of clinical manifestations of NNPI: significance and practical use.</li> <li>4. Clinical manifestations of NNPI: classification, approaches to identification.</li> <li>5. Causes of AEFI: classification and their characteristics.</li> <li>6. Individual characteristics of the vaccinated organism, which may be the causes of the development of AEFI.</li> <li>7. AEFIs due to immunization procedural errors</li> <li>8. AEFIs due to high immunization conCERns</li> <li>9. Individual, unforeseen post-consciential reactions without an established cause.</li> <li>10. Measures aimed at preventing the occurrence of AEFIs.</li> <li>11. Measures and tools to help minimize the risks of AEFIs.</li> <li>12. Social factors of increasing the incidence of AEFIs.</li> <li>13. The role of the pharmacist in the prevention of AEFIs.</li> <li>14. Features of vaccine safety surveillance.</li> </ol>	<ul style="list-style-type: none"> <li>• To provide knowledge on the classification and characteristics of NNPIs,</li> <li>• Distinguish between types of NNPIs depending on their predictability and severity.</li> <li>• To learn the terms of development of clinical manifestations of NNPI: knowledge and practical use.</li> <li>• To learn the clinical manifestations of NNPI: classification, approaches to identification.</li> <li>• Learn the causes of AEFIs: classification and their characteristics.</li> <li>• Understand the individual characteristics of the vaccinated person's body, which may be the reasons for the development of AEFIs:.</li> <li>• Distinguish between AEFIs due to immunization procedures</li> <li>• Distinguish between AEFIs due to high immunization conCERns</li> <li>• Distinguish between individual, unpredictable post-vaccination reactions without an established cause.</li> <li>• Justify measures aimed at preventing the occurrence of AEFIs.</li> </ul>	
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		<ul style="list-style-type: none"> <li>• Substantiate measures and tools that contribute to minimizing the risks of AEFIs.</li> <li>• Understand the social factors behind the increase in the incidence of AEFIs.</li> <li>• Understand the role of the pharmacist in the prevention of AEFIs.</li> <li>• Understand the importance of vaccine safety surveillance</li> </ul>	
Results	To highlight the importance of AEFI prevention for the preservation of public health.	Summarize the material presented; to emphasize the role of the pharmacist in the prevention of AEFIs.	5 minutes
Frequently Asked Questions	Active dialogue / discussion / discussion.	Explain the incomprehensible and most difficult points of the lecture.	5 minutes

## 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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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.
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### Information Resources

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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 lecture**

1. The concept of vaccination (vaccination, active/passive immunization).

### **Questions for preparation for the practical lesson, which are revealed by the lecture material**

1. Concept of 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.**

## Lecture № 4. Causal relationship between AR/AEFI and drugs.

**Type of lecture:** traditional (informational).

### **Competence:**

- **Integral competence:** ability to solve research and/or innovation problems in the field of pharmacy.
- **General:**
  1. Knowledge and understanding of the subject area; Understanding of professional activities (GC02).
  2. Ability to communicate in the state language both orally and in writing (GC03).
  3. Ability to communicate in a foreign language (GC04).
  4. Ability to work in a team (GC06).
  5. Ability to use information and communication technologies (GC09).
  6. Ability to make decisions and act in compliance with the principle of inadmissibility of corruption and any other manifestations of dishonesty (GC10).
- **Special (professional, subject) competencies (PC):**
  1. Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts (PC01).
  2. Ability to collect, interpret and apply data necessary for professional activities, research and implementation of innovative projects in the field of pharmacy (PC02).
  3. Ability to solve pharmacy problems in new or unfamiliar environments with incomplete or limited information, taking into account aspects of social and ethical responsibility (PC03).
  4. Ability to clearly and unambiguously convey one's own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to students (PC04).
  5. Ability to consult on prescription and over-the-counter medicines and other pharmacy assortment, pharmaceutical care during the selection and sale of medicines 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 the health data of a particular patient (PC06).
  6. Ability to monitor the efficacy and safety of the population's use of medicines according to the data on their clinical and pharmaceutical characteristics (PC08).

### **Purpose:**

- 1) didactic goal – to form systematic knowledge about the cause-and-effect relationships between AR/AEFI and drugs;
- 2) educational goal – to promote the formation of a scientific worldview;
- 3) developmental goal – to develop intellectual abilities, thinking, independence.

**Lecture equipment:** multimedia system, appropriate software.

**Lecture tasks:**

1. Understand the definition of "Cause-and-effect relationship" (CER).
2. Distinguish between the criteria for determining the CER.
3. To substantiate the methods for determining the CER, their advantages and disadvantages.
4. Know the categories of CER.
5. Understand the specifics of the determination of CER in vaccines: stages, structures.

**Lecture plan:**

Lecture Stage Name	Content of the stages	Educational Objective of the stage	Time
Introductory part	Investigation of AR drugs and AEFIs: determination of CER between the adverse reaction and the suspected drug.	Reveal the relevance of the topic of the lecture; acquaint students with the lecture plan.	5 minutes
Main part	<ol style="list-style-type: none"> <li>1. Definition of the concept of CER.</li> <li>2. Criteria for determining CER.</li> <li>3. Methods for determining CER, their advantages and disadvantages.</li> <li>4. Categories of CER.</li> <li>5. Features of the determination of CER in vaccines: stages, structures.</li> </ol>	<ul style="list-style-type: none"> <li>• To provide knowledge about the definition of the concept of CER.</li> <li>• Distinguish between the criteria for determining the CER.</li> <li>• To substantiate the methods for determining the CER, their advantages and disadvantages.</li> <li>• Know the categories of CER.</li> <li>• Understand the specifics of the definition of CER in vaccines: stages, structures.</li> </ul>	75 minutes
Results	To highlight the importance of AEFI prevention for the preservation of public health.	Summarize the material presented; to emphasize the role of the pharmacist in the prevention of AEFIs.	5 minutes

Frequently Asked Questions	Active dialogue / discussion / discussion.	Explain the incomprehensible and most difficult points of the lecture.	5 minutes
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## 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.library.nmu.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 lecture**

1. The concept of ADR and AEFIs.

### **Questions for preparation for the practical lesson, which are revealed by the lecture material**

1. Definition of the concept of 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.**

## Lecture № 5. Pharmacotoxic ADR.

**Type of lecture:** traditional (informational).

### **Competence:**

- **Integral competence:** ability to solve research and/or innovation problems in the field of pharmacy.
- **General:**
  1. Knowledge and understanding of the subject area; Understanding professional activities (GC02).
  2. Ability to communicate in the state language both orally and in writing (GC03).
  3. Ability to communicate in a foreign language (GC04).
  4. Ability to work in a team (GC06).
  5. Ability to use information and communication technologies (GC09).
  6. Ability to make decisions and act in compliance with the principle of inadmissibility of corruption and any other manifestations of dishonesty (GC10).
- **Special (professional, subject) competencies (PC):**
  1. Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts (PC01).
  2. Ability to collect, interpret and apply data necessary for professional activities, research and implementation of innovative projects in the field of pharmacy (PC02).
  3. Ability to solve pharmacy problems in new or unfamiliar environments with incomplete or limited information, taking into account aspects of social and ethical responsibility (PC03).
  4. Ability to clearly and unambiguously convey one's own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to students (PC04).
  5. Ability to consult on prescription and over-the-counter medicines and other pharmacy assortment, pharmaceutical care during the selection and sale of medicines 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 the health data of a particular patient (PC06).
  6. Ability to monitor the efficacy and safety of the population's use of medicines according to the data on their clinical and pharmaceutical characteristics (PC08).

### **Purpose:**

- 1) didactic goal – to form systematic knowledge about pharmacotoxic adverse reactions to medicinal products;
- 2) educational goal – to promote the formation of a scientific worldview;
- 3) developmental goal – to develop intellectual abilities, thinking, independence.

**Lecture equipment:** multimedia system, appropriate software.

**Lecture tasks:**

1. Distinguish between drug overdose: absolute and relative (toxic effects).
2. Understand the causes of acute poisoning.
3. Know the symptoms of acute poisoning with drugs of different pharmacological groups.
4. Substantiate the basic principles of pharmacotherapy of acute drug poisoning.
5. Know the methods of active detoxification.
6. Distinguish between types of antidote therapy.
7. Substantiate the principles of symptomatic therapy of acute poisoning.

**Lecture plan:**

Lecture Stage Name	Content of the stages	Educational Objective of the stage	Time
Introductory part	To provide information on the incidence of pharmacotoxic ADRs in Ukraine and the world.	Reveal the relevance of the topic of the lecture; introduce students to the lecture plan.	5 minutes
Main part	<ol style="list-style-type: none"> <li>1. Drug overdose: absolute and relative (toxic effects).</li> <li>2. Causes of acute poisoning.</li> <li>3. Symptoms of acute drug poisoning of various pharmacological groups.</li> <li>4. Basic principles of pharmacotherapy of acute drug poisoning.</li> <li>5. Active detoxification methods.</li> <li>6. Types of antidote therapy.</li> <li>7. Principles of symptomatic therapy of acute poisoning.</li> </ol>	<ul style="list-style-type: none"> <li>• Distinguish between drug overdose: absolute and relative (toxic effects).</li> <li>• Understand the causes of acute poisoning.</li> <li>• To provide knowledge about the symptoms of acute drug poisoning of different pharmacological groups.</li> <li>• Substantiate the basic principles of pharmacotherapy of state drug poisoning.</li> <li>• Provide knowledge on active detoxification techniques.</li> <li>• Distinguish between types of antidote therapy.</li> </ul>	75 minutes



		<ul style="list-style-type: none"> <li>• Substantiate the principles of symptomatic therapy of acute poisoning</li> </ul>	
Results	To highlight the importance of prevention of pharmacotoxic AR drugs for the preservation of public health.	Summarize the material presented; to emphasize the role of the pharmacist in the prevention of pharmacotoxic AR drugs.	5 minutes
Frequently Asked Questions	Active dialogue / discussion / discussion.	Explain the incomprehensible and most difficult points of the lecture.	5 minutes

## 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)
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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 lecture**

1. Pharmacokinetics and pharmacodynamics of drugs.

### **Questions for preparation for the practical lesson, which are revealed by the lecture material**

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.**