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Approved

At the meeting of the Faculty Council Medicine Nr. 2 Minutes No. 25 ab 3, 2014 No. 4

Dean of the Faculty Medicine Nr. 2
PhD, associate prof \_\_\_\_\_\_\_\_M. B

Approved

At the meeting of the department of Pharmacology and Clinical Pharmacology Minutes No. 140f 10.03.12

Head of department PhD, professor V. Ghicavi

### SYLLABUS FOR STUDENTS OF THE

## **FACULTY MEDICINE NR. 2**

Name of the course: Clinical Pharmacology

Code of the course: F.10.O.098

**Medicine:** Total number of hours – 70 hours

lectures - 20 hours, seminars - 50 hours

Number of credits provided for the course units: 3

The teaching staff:

associate professor Vadim Gavriluta associate professor Lilia Podgurschi associate professor Lucia Turcan

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## I. Aim of the discipline

The main goal of clinical pharmacology is to develop students ability to apply gained knowledge of pharmacokinetics, pharmacodynamics, compliance and adverse reactions of drug substances, to achieve a rational and differential treatment for patients

## II. Objectives obtained in teaching the discipline

### a) at the level of knowledge and understanding:

- to know clinical pharmacology section and its importance; basic principles of pharmacokinetics, pharmacogenetics and clinical pharmacodynamics;
- to know fields of study of pharmacoeconomics, pharmacoepidemiology, pharmacovigilance; pharmacotoxicology, cronopharmacology and social pharmacology;
- to know principles of drugs classification (activity, duration of action, toxicity, clinical use, etc.);
- to know mechanisms of action at the molecular and systemic levels, pharmacological effects and appropriate clinical manifestations;
- to know indications, principles of selection and use of drugs groups;
- to know contraindications, side effects and precaution measures for medical drug groups and obligatory and essential drugs;
- to understand the etiotropic, pathogenetic and symptomatic actions of drugs in the pharmacotherapy of diseases and medical conditions;
- to establish individually the appropriate dosing regimen and ways of drug administration in accordance with the disease and pathological condition of the body;
- to take a patient's anamnesis (drug history), to know and implement systems of drug monitoring;
- to be able to identify essential medicines of vital importance;
- to understand OTC (Over The Counter)drugs and self-medication;
- to understand about designing principles and purposes of the national and institutional form of medical-economic standards of diagnosis and treatment, national and institutional clinical protocols;
- to understand principles of personalized medication;

### b) at the level of application:

- to select the drugs of choice (first line) for giving an optimized treatment;
- to present arguments to a patient for the regarding drug prescription, based on: pharmacokinetic, pharmacogenetic and pharmacodynamic proprieties of the drugs, and the individual characteristic of patient;
- to establish an optimal dosing regimen of drugs, with the selection of rational administration methods depending on both pharmacodynamics and pharmacokinetics parameters of the drug, the age, gender and the specific pathological state of a patient;
- to recommend the most effective and safe administration of medicinal substances combinations in the concrete clinical situation;
- to foresee the development and use methods of prevention or correction of adverse secondary drug effects;
- to implement the principles of selecting P-drugs and P-treatment in specific patients;
  - to determine the criteria of effectiveness and harmlessness of the groups of drugs;
  - -to select useful for the patient information about medication, to improve compliance and the fallowing of the offered drug administration system;
- to establish the criteria for monitoring the drugs effect;



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- to elucidate the possible drug interactions and their consequences.

### c) at the level of integration:

- to appreciate the importance and place of clinical pharmacology among clinical disciplines;
- to realize the necessity of clinical pharmacology with regards to establishing a rational and safe treatment;
- to analyze the results of pharmacokinetic and pharmacodynamic drug substances;
- to select the appropriate complex of methods of investigations to assess pharmacodynamic effects of medicinal remedies and interpretation of obtained results;
- to conduct analysis and synthesis of pharmacological and pharmacological information from literature according to evidence-based medicine;
- to formulate ethical principles and ethics in pharmacotherapy;
- to select the criteria of effectiveness and harmlessness of drugs for arguentation the proposed treatment;
- to carry out analysis of pharmacotherapy of various disorders and diseases based on uniform standards for diagnosis and treatment;
- to oversee the effectiveness and safety of drugs in the pharmacotherapy;
- to implement treatment monitoring criteria during the study of clinical disciplines;
- to develop scientific research projects in clinical pharmacology.

### III. Provisional terms and conditions

Clinical pharmacology is a clinical and applicative discipline, which at the universitary stage enables future doctors to acquire pharmacokinetic, pharmacogenetic and pharmacodynamic principles of characterization of drug groups, in order to apply this knowledge in assessment of efficacy and safety, as well as rational selection of drugs. The course study allows students to argue the proper selection of drugs for a specific patient and to assess the accuracy of indications in accordance with standards and clinical protocols for diagnosis and treatment.

In order to acquire clinical pharmacology, deep knowledge of medical-biological disciplines (anatomy, physiology, histology, biochemistry, physiology, pathology, microbiology) and clinical disciplines (internal medicine, surgery, infectious diseases, pediatrics, endocrinology, neurology, obstetrics and gynecology, etc.) is needed.

## IV. Main theme of the course

### A. Lectures:

| Nr | Theme   | Medicine |
|----|---|----------|
|    |   | Nr.hours |
|    | Recent reforms in the drug domain. Clinical Pharmacology and its  | 1        |
|    | tasks. Selection and rational use of medicines.                   |          |
| 2. | Some aspects of associated drug use. Drug interactions. Drug      | 1        |
|    | interaction with food, alcohol and other beverages, herbal        |          |
|    | substances, tobacco smoke, bioactive nutrients, etc.              |          |
| 3. | Clinical pharmacokinetics and pharmacodynamics. Therapeutic drug  | 1        |
|    | monitoring: indications and interpretations.                      |          |
| 4. | Clinical pharmacology drugs used to treat pain (analgesics,       | 1        |
|    | anesthetics-local and general).                                   |          |
| 5. | Clinical pharmacology of antianginal and antiarrhythmic remedies. | 1        |



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|     | Total  | 20 |
|-----|--|----|
|     | drugs. Selection of personal drugs.                                |    |
| 15. | Clinical pharmacology of antibacterial, antiviral, and antifungal  | 2  |
|     | Drugs used with caution during lactation.                          |    |
|     | drugs with high risk of adverse actions on the fetus and newborn.  |    |
| 14. | Medication at extreme ages and some physiological states. OTC      | 2  |
|     | osteoporosis, obesity. Immunomodulatory drugs.                     |    |
| 13. | Clinical pharmacology of medication of chronic rheumatic diseases, | 2  |
|     | thyroid).  |    |
| 12. | Clinical pharmacology of hormonal drugs (glucocorticoid agents,    | 2  |
|     | plasma volume substitutes.   |    |
| 11. | Clinical pharmacology of antiagregants drugs, coagulant drugs and  | 2  |
|     | antiparkinsonian drugs, and central muscle relaxants.              |    |
| 10. | Clinical pharmacology of antiepileptic drugs, anticonvulsants,     | 1  |
| 9.  | Clinical pharmacology of psychotropic and hypnotic drugs.          | 1  |
| 8.  | Clinical pharmacology of antihypertensive drugs.                   | 1  |
| 7.  | Clinical pharmacology of antihypertensive drugs. Diuretics.        | 1  |
| 6.  | Clinical pharmacology of drugs used in heart failure.              | 1  |

B. Seminars (practical work)

| Nr. | Theme   | Medicine |
|-----|---|----------|
|     |   | Nr.hours |
| 1.  | Clinical pharmacokinetics and pharmacodynamics. Therapeutic drug monitoring: indications and interpretations.                                     | 2        |
| 2.  | Clinical pharmacology drugs used to treat pain (analgesics, anesthetics-local and general).   | 3        |
| 3.  | Clinical pharmacology of medication for respiratory diseases. Selection of personal drugs.  | 4        |
| 4.  | Clinical pharmacology of anti-allergic drugs. Selection of personal drugs.  | 1        |
| 5.  | Clinical pharmacology of TGI disease medication. Selection of personal drugs.   | 5        |
| 6.  | Clinical pharmacology of antianginal and antiarrhythmic medication. Selection of personal drugs.  | 3        |
| 7.  | Clinical pharmacology of medications used in heart failure.<br>Selection of personal drugs.   | 2        |
| 8.  | Clinical pharmacology of antihypertensive drugs. Diuretics. Selection of personal drugs.  | 3        |
| 9.  | Clinical pharmacology antihypotensive medication. Selection of personal drugs.  | 2        |
| 10. | Clinical pharmacology of CNS medications (psychotropic, hypnotics). Selection of personal drugs.  | 4        |
| 11  | Clinical pharmacology of antiepileptic drugs, anticonvulsants, antiparkinsonian drugs, and central muscle relaxants. Selection of personal drugs. | 1        |
| 12. | Clinical pharmacology of antiagregant drugs, coagulant drugs and  | 5        |



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|     | plasma volume substitutes. Selection of personal drugs.            |    |
|-----|--|----|
| 13. | Clinical pharmacology of antibacterial, antiviral, and antifungal  | 5  |
|     | drugs. Selection of personal drugs.                                |    |
| 14. | Clinical pharmacology of hormonal drugs (glucocorticoid, agents,   | 5  |
|     | thyroid). Selection of personal drugs.                             |    |
| 15. | Clinical pharmacology of medication of chronic rheumatic diseases, | 5  |
|     | osteoporosis, obesity. Immunomodulatory drugs. Selection of        |    |
|     | personal drugs.  |    |
|     | Total  | 50 |

### V. Recommended literature:

- A. compulsory:
- 1. Clinical Pharmacology (edited by Professor. Ghicavîi V.). Chisinau, 2009.
- 2. Pharmacology (edited by Professor. Ghicavîi V.). Chisinau, 2010.
- 3. Clinical Pharmacology (self-assessment tests). Chisinau, 2000.
- 4. Ghicavîi V., Bacinschi N., Gu uila Gh. Pharmacology. Chisinau, 2010.
- 5. Cristea A.N. Treaty of Pharmacology, ed I. Bucharest, 2005.
- 6. Ghicavîi V. Some aspects of rational use of medicines. Chisinau, 2002.
- 7. V. Ghicavîi. Drugs and their rational use. Chisinau, 2004.
- 8. Stroescu V. "Pharmacological Basis of medical practice." Bucharest, 2000.
- 9. V. Ghicavîi etc., Dental disorders Pharmacotherapy, 2002.
- 10. Kukes VG. Clinical pharmacology. GEOTAR M. Medicine, 2004.
- 11. Mikhailov IB. Clinical pharmacology. St. Petersburg, 2005.
- 12. Gikavy VI. Pharmacotherapy and other major dental diseases, Chisinau, 2006.
- 13. Ghicavîi V., Bacinschi N., Gonciar V., Bumacov L., Gu uil Gh., Podgurschi L. Methodical indications (syllabus) for clinical pharmacology practical works. Chi in u, 2012,

### - B. additional:

- 1. V. Ghicavîi etc. "Antibiotics in otorhinolaryngology", Chisinau, 2001.
- 2. Pharmacotherapeutic Guide, Chisinau, 2006, 2010.
- 3. Gonciar V., N. Bacinschi, drugs used in diseases of the digestive tract, Chisinau, 1997.
- 4. Muhina E., Ghicavîi V. Gonciar V., N. Bacinschi brain and peripheral circulation disturbances, medications, Chisinau, 1998.
- 5. Antibiotic therapy M. Angelescu, Bucharest, 1998.
- 6. Cristea A.N. General Framacologia, Bucharest, 1999, 2003.
- 7. C. Framacologie cub, 1994, vol I, II, III.
- 8. Medico-economic standards. Chisinau, 2010
- 9. Belousov YB et al. Clinical pharmacology and pharmacotherapy. M. Science, 2003.
- 10. Bertman G. Kattsung. Basic and clinical pharmacology, 2007
- 11. Bochkarev MV, Mukhin, EA, Gikavy VI Reference precinct therapist pharmacotherapy. Chisinau. "Map Moldovenyaske. 1986.
- 12. G. Goodman and Gilman G. Clinical pharmacology. X-ed, MA: 2006.
- 13. Karkishchenko NN Pharmacological basis of therapy, 1996.
- 14. Mikhailov IB Fundamentals of rational pharmacotherapy. St. Petersburg, 1999.
- 15. Kharkevich DA Pharmacology. GEOTAR M. Medicine, 2006.
- 16. Markova IV et al. Pediatric pharmacology. M. Medicine, 1987, 1991.



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- 17. Mashkovsky MD drugs that and , Kharkiv, "Torsing, 2004, 2006.
- 18. Snowstorm VI Guide to Clinical Pharmacology of cardiovascular drugs. St. Petersburg, 2005.
- 19. Fundamentals of clinical pharmacology and rational pharmacotherapy. M.2002.
- 20. Parijskij T.V, Orlova NV, Gikavy VI Directory of GP in pediatrics. Chisinau, 2001.
- 21. Parijskij TV Pediatrics urgent condition in children. Moscow, St. Petersburg, 2006
- 22. Pastushenkov LV Pharmacotherapy and others with the basics of herbal medicine ch. and , St. Petersburg, 1995.
- 23. Rational antimicrobial pharmacotherapy. M.2003.
- 24. Rational pharmacotherapy of digestive diseases. M.2003.
- 25. Rational pharmacotherapy of rheumatic diseases. M.2003.
- 26. Rational pharmacotherapy in ophthalmology. M.2004.
- 27. Rational pharmacotherapy for cardiovascular disease. M.2005.
- 28. Rational pharmacotherapy of skin diseases and sexually transmitted infections. M.2005
- 29. Rational pharmacotherapy in obstetrics and gynecology. M.2005.
- 30. Rational pharmacotherapy in urology. M. 2005.
- 31. Rational pharmacotherapy of respiratory diseases. M.2006.
- 32. Rational pharmacotherapy of the endocrine system and metabolism vuschustv. M., 2006
- 33. Rational pharmacotherapy in dentistry. M., 2006.
- 34. Rational pharmacotherapy in nephrology. M., 2006.
- 35. Rational pharmacotherapy in urology. M., 2006
- 36. Rational pharmacotherapy of allergic diseases. M., 2007.
- 37. Rational pharmacotherapy for children's diseases. V.1-2. M., 2007
- 38. Reference Vidal. M. 2000 2006.
- 39. Stratchounski LS, Belousov YB, Kozlov SN Antibacterial therapy. Moscow, 2003
- 40. Stratchounski LS, Belausov JB, Kozlov SN Guidelines for rational antibiotic therapy. Moscow, 2007.
- 41. Clinical pharmacology. National leadership. Moscow, 2009.

## VI. Teaching and learning methods

Clinical pharmacology is taught by classical principles of university studies. At lectures, the theoretical material selected from the specialized literature that is not available in the regular literature is taught. During seminars, students are asked to deepen their theoretical knowledge and demonstrate their skills in drug prescriptions; prepare adequate treatment protocols; provide good arguments on the prescribed drugs; elucidate pharmacological effects of the prescribed drugs; monitor the dynamic evolution of the patient's clinical condition; select each patient's personal drug (P-drug) on the bases of the criteria of effectiveness, harmlessness, acceptability and cost; determine patterns of drug administration (P-treatment); learn new skills to supplement the information sheet about side effects the drugs can have.

# VII. Suggestions for individual activity

The study of clinical pharmacology provides an essential individual work. With this purpose, different forms of self-learning are used by students. In the process of preparation for seminars, students make a comparative analysis of characteristics of food groups and selected and prescribed drugs in ways that are appropriate for the treatment of patients.

At seminars, students are granted with possibilities for the application of theoretical knowledge in solving clinical trials and cases. Students also have the chance to analyze the treatment prescribed to patients in those wards, which they manage throughout the course.



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Taking into consideration the treatment protocol, student choose drug prescriptions based on strong arguments, depending on pharmacological properties the drugs have and the clinical condition of a patient.

The students need to prove these skills during the patient's presentation, commenting on the evolution of the patient's clinical condition due to the change of laboratory indices, clinical and preclinical data.

In the analysis, students select P-treatment product according to the criteria of effectiveness, harmlessness, acceptability and cost, and assess compliance with the treatment standards and clinical protocols concerning diagnosis and treatment.

## VIII. Methods of assessment

#### **Current assessment:**

- Test of primary knowledge of the course;
- Test of ultimate knowledge of the course;
- Interactive discussion:
- Preparation of the treatment protocol;
- Solving clinical cases;

**Final assessment**: attestation, practical habits, final examination.

The final paper includes correlation-type tests and problem situations that require the application of knowledge obtained in self-instruction and interactive discussions. The clinical protocol (research paper) grants the analysis of drug therapy prescribed to patients based on the student's knowledge gained in self-learning, interactive discussions, and solving of clinical cases.

The final examination includes theoretical questions, exercises tests and medical prescription exercises (simple and multiple).

### Methods of mark rounding

| The average of current and final marks | Final mark |
|--|------------|
| 5                                      | 5          |
| 5,1-5,5                                | 5,5        |
| 5,6-6,0                                | 6          |
| 6,1-6,5                                | 6,5        |
| 6,6-7,0                                | 7          |
| 7,1-7,5                                | 7,5        |
| 7,6-8,0                                | 8          |
| 8,1-8,5                                | 8,5        |
| 8,6-9,0                                | 9          |
| 9,1-9,5                                | 9,5        |
| 9,6-10                                 | 10         |

Absence on examination without good reason is recorded as "absent" and is equivalent to 0 (zero). The student has the right to re-take the exam twice.

# IX. Language of study

Romanian, Russian, English, French.