REQUIREMENTS

Semmelweis University, Faculty of General Medicine – single, long-cycle medical training programme
Name of the host institution (and any contributing institutions):
Department of Pharmacology and Pharmacotherapy

Name of the subject: Pharmacology II.

in English: Pharmacology II.

in German: Pharmakologie II.

Credit value: 5

Semester: 6th
(as defined in the curriculum)

Total number of classes per week: 4.5	**lectures: 2**	**practical lessons: 2.5**	**seminars: -**

Type of subject: <u>compulsory</u> optional elective
(PLEASE UNDERLINE AS APPLICABLE)

Academic year: 2024/2025 2nd semester

Language of instruction, for optional or elective subjects:

Course code: AOKFRM1108_2A

Course director (tutor): Dr. Ferdinandy, Péter

Contact details: Department of Pharmacology and Pharmacotherapy, 1089 Budapest, Nagyvárad tér 4. Tel: +36-1-2104416, e-mail: ferdinandy.peter@semmelweis.hu

Position: Head of Department, full professor

Date of habilitation and reference number: June 2 2001., 26/2001 Hab.

Objectives of the course and its place in the medical curriculum:
Pharmacology is a synthesizing subject, building on what has been learned in the past, especially physiology, biochemistry, pathology, and translational medicine, and is essential for the later acquisition of clinical knowledge. The subject includes: general pharmacology, detailed pharmacology, toxicology and basics of prescription writing. General pharmacology (pharmacodynamics, pharmacokinetics) aims to acquire the basic concepts and knowledge needed for pharmacological thinking, while in detailed pharmacology the student learns the main principles of the mechanism of action, therapeutic effects, adverse effects, major interactions, and partly dosing of medicines. The basics of toxicology describe the mechanisms and targets of major intoxications and thus provide a theoretical background for oxyology education. All of these competencies form the grounds to study clinical pharmacology and prepare students for the skill-level application of pharmacotherapeutic knowledge essential to clinical subjects.

Place of instruction (address of lecture hall or seminar room etc.):

Nagyvárad téri Elméleti Tömb, 1089 Budapest, Nagyvárad tér 4.

Competencies acquired through the completion of the course:
Students understand the pharmacological terminology, learn the mechanism of action, therapeutic effects, adverse effects, important interactions of drugs and the basics of dosing. They understand the mechanisms and targets of the most important poisonings, as well as the knowledge of the basic rules of prescription writing.

Prerequisites for course registration and completion:

Pharmacology I, Medical Microbiology II, Pathology I

Conditions for concurrent course registration and permission thereof in the case of a multi-semester subject:
The Department of Pharmacology and Pharmacotherapy does not support concurrent course registration.

Student headcount conditions for starting the course (minimum, maximum) and method of student selection:
Through NEPTUN system.

Detailed course description:

- 1st week
  - Lecture: Anticoagulants, inhibitors of platelet aggregation
  - Practice: Fibrinolytics, drugs against bleeding, drugs acting on blood cell production.
- 2nd week
  - Lecture: Drugs influencing cardiac electrophysiology
  - Practice: Positive inotropic agents.
- 3rd week
  - Lecture: Diuretics, antidiuretics.
  - Practice: Drugs influencing blood pressure (sympatholytics, nitrates, Ca-channel blockers and other vasodilators. Pharmacology of RAAS.)
- 4th week
  - Lecture: Drugs acting on blood glucose control.
  - Practice: Drugs influencing the oxygen demand and oxygen supply of the heart. Drugs improving microcirculation.
- 5th week
  - Lecture: Drugs affecting lipid metabolism (1 study hour). Bronchodilators and drugs inhibiting the bronchial inflammatory processes (1 study hour).
  - Practice: Expectorants (secretomotorics, secretolytics, mucolytics), antitussive drugs. Histamine, antihistamines. Drugs acting on smooth muscles
- 6th week
  - Lecture: Corticosteroids and their antagonists. Drugs inhibiting steroid hormone synthesis
  - Practice: Pharmacology of pituitary hormones. Hypothalamic hormones, hormonanalogs and antagonists. Pharmacology of thyroid gland (thyroid hormones and antithyroid drugs). 3rd midterm
- 7th week
  - Lecture: Pharmacology of female sexual hormones. Contraceptive medications.
  - Practice: Androgens, antiandrogens, anabolic steroids, drugs influencing sexual activity.
- 8th week
  - Lecture: Basics of toxicology
  - Practice: Drugs affecting bone mineral homeostasis.
- 9th week
  - Lecture: Drugs influencing gastric acid secretion, drugs protecting gastric mucosa
  - Practice: Appetizers, drugs promoting digestion, antiemetics, prokinetic agents. Laxatives, drugs against diarrhea. Pharmacology of liver and bile.

- 10th week
  - Lecture: Immunopharmacology (cytotoxic agents, inhibitors of intracellular signaling, cytokine and cytokine receptor inhibitors)
  - Practice: Cytotoxic anticancer drugs.
- 11th week
  - Lecture: Small molecule signal transmission inhibitor anticancer drugs. Anticancer drugs with hormonal mechanisms
  - Practice: Toxicology I. 4th midterm
- 12th week
  - Lecture: Anticancer antibodies. Immunostimulant anticancer agents.
  - Practice: Toxicology II.
- 13th week
  - Lecture: Pharmacodynamic and pharmacokinetic basics of drug interactions
  - Practice: Drugs and pregnancy. Toxicology exam.
- 14th week
  - Lecture: Pharmacogenomics, personalized medicine, drugs for orphan disease. Special aspects of pharmacology in children and elderly
  - Practice: Contrast agents. Consultation

Related subjects due to interdisciplinary fields (both compulsory and elective) and potential overlaps between subjects:
Physiology, biochemistry, molecular biology, pathology, translational medicine, internal medicine, cardiology, pulmonology, neurology, psychiatry, clinical pharmacology

Attendance requirements; conditions under which students can make up for absences and the method of absence justification:
Maximum number of absences is 25 percent of the number of practices in the semester. In the case of absence, the student can attend another class the same week.

Form of assessment in the study period:
(including the number, topics and scheduling of oral and written tests, their share in the overall evaluation, make-up tests and improvement tests)

During the semester, we organise two compulsory midterm tests in weeks 6 and 11. These can be made up in weeks 7 and 12. Making up or improving the midterm (or both midterms) will be possible in week 13. The correction may only be a verbal demonstration. The first semester midterms cannot be improved in the second semester.
The course material for the third midterm test (study material from week 1 to 4 and the half of the 5th week lecture.): Pharmacology of the cardiovascular system. Drugs acting on lipid metabolism. Drug acting on blood glucose level.
Fourth midterm test (study material: seminar topics of the 5th week, half of the 5th week lecture and from week 6 to 10): Endocrine pharmacology. Pharmacology of the respiratory system. Pharmacology of the gastrointestinal system. Histamine and antihistamines. Drugs acting on smooth muscles. Immunopharmacology.

The midterm tests will count towards the final exam results:

1. If the student scores better than 60% in all four midterm tests during the whole year, the drug recognition question will be waived and in case of a doubtful grade, the better one will be awarded. There is no exemption from the Core Concept topics.
2. If the student achieves at least 80% score of all four midterm tests one final exam topic will be waived as well as the drug recognition question. The waived topic will be chosen by the examiner.
3. At the competition at the end of the year, the student who has at least one midterm of 80% and none of his/her demonstrations is worse than 33%, depending on the result of the competition, will be rewarded: between scores 90-100% the students will choose one of the three topics, between 80-89% the students will choose which one he/she will drop, between 70-79% the

examiner will choose one topic to be dropped. The drug recognition question will be waived.
4. If the student fails both midterm tests of the second semester (even at the time of a retake), or fails to achieve 33% in either midterm test with a correction, the student will receive a grade penalty on the first attempt of the final exam.
5. In the case of a repeated exam after a failure, the negative and, in the case of an improvement exam, both the positive and the negative modifications are cancelled. The first semester midterms, if their results were worse than 30%, will not be counted for the final exam.

Number and type of assignments for individual work and the deadline for submission:
-

Requirements to obtain the teacher's signature:
The number of absences must not be more than 25 percent of the number of practices in the semester.

Type of assessment *(comprehensive examination, end-term examination, term-grade, term-grade on a three-grade rating scale, no examination)***:**
oral comprehensive examination

Examination requirements:
(*list of examination topics, subject areas of tests / examinations, lists of mandatory parameters, figures, concepts and calculations, practical skills)*
To apply for the oral examination, the student must pass the toxicology exam before the examination period starts. The grade in the toxicology exam counts towards the final grade. In the oral final exam, at first 5 active substances selected from the compulsory list of active substances must be identified the and their mechanism of action explained. If the student does not recognize at least 3 of the active substances, he/she will not be allowed to continue and will receive a fail mark. After successful completion of one core-concept question and three topics of three lists of topics (one from each), an acceptable level of knowledge of pharmacology must be demonstrated.

Toxicology topics
1. Management of the poisoned patient I. antidotes
2. Management of the poisoned patient II. Emergency care. Decontamination. Enhancing of elimination of toxins. supportive treatment.
3. Pharmacology of chelators
4. Acid and base poisonings
5. Mercury poisoning
6. Lead poisoning
7. Arsenic poisoning
8. Cadmium poisoning
9. Poisons inducing methemoglobinemia
10. Aliphatic hydrocarbons and aliphatic halogenated hydrocarbons
11. Aromatic hydrocarbons,
12. Nitrobenzene and aniline poisonings
13. DNP, DNOC poisonongs
14. Methanol and glycol poisonings
15. Poisonings caused by aliphatic aldehydes.
16. Carbon monoxide poisoning
17. Poisonings caused by insecticides and herbicides
18. Mushroom poisoning
19. Cyanide poisoning
20. Snake and bee bites
21. Poisonous plants

Core concept topic list
1. Stages of drug development in brief.
2. Types of clinical trials.
3. History of the Hungarian pharmaceutical industry.
4. Molecular targets of drugs
5. Receptor theory - agonist, partial agonist, antagonist, inverse agonist

6. Efficacy, potency
7. Dose-effect relationships at population level
8. Adverse drug reactions
9. Therapeutic index
10. Tolerance, tachyphylaxis, dependence
11. Absorption of drugs
12. Membrane transport mechanisms.
13. Distribution of drugs
14. Bioavailability
15. Volume of distribution
16. Phases of drug biotransformation
17. Excretion of drugs
18. Linear and non-linear pharmacokinetics
19. Clearance
20. Half-life
21. Saturating and maintenance dose
22. Drug accumulation and cumulation
23. Enzyme inducers
24. Enzyme inhibitors
25. Pharmacodynamic interactions - synergism
26. Pharmacodynamic interactions - antagonism
27. Pharmacokinetic drug interactions - at the level of absorption
28. Pharmacokinetic drug interactions - at the level of distribution
29. Pharmacokinetic drug interactions - at the level of metabolism
30. Pharmacokinetic drug interactions - at the level of elimination
31. Special groups - drug interactions: pregnancy
32. Special groups - drug interactions: childhood
33. Special groups - drug interactions: ageing
34. Characterisation of biological medicinal products
35. Orphan drugs
36. Advanced therapy medicinal products
37. Nutritional supplements
38. Traditional herbal active substances
39. Medical device
40. Principles of antimicrobial treatment - selective toxicity
41. Principles of antimicrobial treatment - empirical, targeted and prophylactic therapy
42. Principles of antimicrobial treatment - principles of bactericidal, bacteriostatic antibiotic and antibiotic combinations
43. Principles of antimicrobial treatment - time-, concentration- and exposure-dependent antibiotics
44. Narrow and broad spectrum antibiotics
45. Antibiotic selection considerations - pregnancy, childhood
46. Antibiotic selection considerations - infections affecting specific compartments
47. Considerations for antibiotic choice - comorbidities
48. Antidote - definition and examples
49. Pharmacogenetics, pharmacogenomics - definition, examples
50. Classification of drugs according to chemical structure and complexity
51. Drug-induced adverse reaction: sulfonamide allergy and its characterization
52. Drug-induced adverse reaction: serotonin syndrome
53. Drug-induced adverse reaction: neuroleptic malignant syndrome
54. Drug-induced adverse reaction: Stevens-Johnson sy.
55. Drug-induced adverse reaction: pseudomembranous colitis
56. Drug-induced adverse reaction: cheese reaction
57. Drug-induced adverse reaction: orthostatic hypotension
58. Drug-induced adverse reaction: hemorrhage
59. Drug-induced adverse reaction: thrombosis
60. Drug-induced adverse reaction: bone marrow damage
61. Drug-induced adverse reaction: nephrotoxicity
62. Drug-induced adverse reaction: ototoxicity

63. Drug-induced adverse reaction: hepatotoxicity
64. Drug-induced adverse reaction: QT prolongation
65. Drug-induced adverse reaction: bradycardia / AV block
66. Drug-induced adverse reaction: constipation, diarrhea, vomiting
67. Drug-induced adverse reaction: mucosal damage
68. Drug-induced adverse reaction: weight gain/loss
69. Drug-induced adverse reaction: sedation
70. Drug-induced adverse reaction: epileptiform seizures MI
71. Drug-induced adverse reaction: sexual dysfunction
72. Drug-induced adverse reaction: dental and oral cavity adverse reactions
73. The Summary of Product Characteristics

Topic list "A"

1. Cholinergic and adrenergic transmission and its presynaptic modification.
2. Cholinomimetics
3. Muscarinic receptor blocking drugs
4. Catecholamines
5. Indirect sympathomimetics. Selective α_1 agonists
6. α_2-agonists and drugs acting on the imidazoline receptors
7. α-receptor antagonists
8. β-receptor antagonists
9. Centrally and peripherally acting skeletal muscle relaxants
10. Local anesthetics
11. Opioids
12. NSAIDs.
13. Drugs used for treatment of gout. Drugs for headache syndromes
14. Inhalational anesthetics
15. Intravenous anesthetics. Perioperative medication
16. Benzodiazepines
17. Non benzodiazepine anxiolytics and non-benzodiazepine hypnotics.
18. Antipsychotics
19. Monoamine reuptake inhibitors.
20. Non-reuptake-inhibitor antidepressants. Agents used for treatment of manic phase of bipolar disorders.
21. Antiepileptics. Adjuvant analgesics.
22. Drugs of neurodegenerative diseases. (Drugs acting in the extrapyramidal motoric system. Nootropic drugs)

Topic list "B"

1. Drugs influencing blood coagulation I: Antiplatelet agents. Fibrinolytic drugs. Drugs inhibiting bleeding
2. Drugs influencing blood coagulation II: Anticoagulant drugs
3. Agents used in anemias
4. Positiv inotropic drugs
5. Drugs influencing cardiac electrophysiology.
6. Drugs acting on the renin-angiotensin-aldosterone-system (RAAS)
7. Ca^{++}-channel blockers and other vasodilators
8. Drugs influencing the oxygen demand and oxygen supply of the heart. Drugs improving microcirculation.
9. Drugs affecting lipid metabolism.
10. Potassium excreting (wasting) diuretics
11. Potassium sparing diuretics, ADH antagonists, osmotic diuretics
12. Glucocorticoids for oral and parenteral use
13. Mineralocorticoids. Topically applied glucocorticoids. Adrenocortical antagonists, inhibitors of corticosteroid synthesis.
14. Androgens, anabolic steroids, antiandrogens. Agents affecting the sexual activity
15. Estrogens and antiestrogens

16. Progestins and antiprogestins. Contraceptives
17. Thyroid and antithyroid drugs. Pituitary hormones. Hypothalamic hormones, hormonanalogs and antagonists.
18. Pancreatic hormones and parenterally applied antidiabetic drugs.
19. Oral antidiabetics.
20. Agents affecting bone mineral homeostasis (calcium, vitamin D, parathyroid hormone, calcitonin, etc.).
21. Selective β_2-stimulants and other bronchodilators.
22. Antiinflammatory agents inhibiting bronchial inflammatory processes. Antitussive agents and expectorants
23. Drugs influencing gastric acid secretion, protective drugs of gastric mucosa
24. Antiemetic drugs. Prokinetic agents.
25. Drugs used in constipation (laxatives) and diarrhea. Drugs promoting digestion. Pharmacology of liver and biliary tract
26. Histamine and antihistamines
27. Drugs acting on smooth muscles. Drugs influencing uterus contractions.
28. Immunopharmacology I. (cytotoxic agents).
29. Immunopharmacology II. (Inhibitors of cytokine gene expression, 5-ASA derivatives)
30. Immunopharmacology III. (Antibodies and fusion proteins)
31. Drugs used in cancer treatment I (antimetabolites)
32. Drugs used in cancer treatment II (cytotoxic agents targeting DNA)
33. Drugs used in cancer treatment III (Topisomerase inhibitors. Inhibitors of mitotic spindle)
34. Drugs used in cancer treatment IV. (Hormonal agents)
35. Drugs used in cancer treatment V. (Small molecule signal transduction inhibitors. Retinoids)
36. Drugs used in cancer treatment VI. (Large molecule signal transduction inhibitors. Immunostimulant anticancer drugs.)

Topic list "C"

1. Disinfectants and antiseptics
2. Antimycobacterial drugs
3. Antiprotozoal and antihelminthic drugs.
4. Antifungal agents
5. Agents to treat Herpes simplex (HSV), varicella-zoster (VZV) virus, cytomegalovirus (CMV). Anti-influenza agents Drugs against Corona- and other viruses
6. Antiretroviral agents.
7. Agents against hepatitis viruses
8. Penicillins
9. Cephalosporins
10. Carbapenems. Monobactams. Beta-lactamase inhibitors.
11. Chloramphenicol. Polymyxins. Antifolate drugs
12. Tetracyclines and glycylcyclines
13. Aminoglycosides
14. Quinolones and fluoroquinolones
15. Macrolides. Pleuromutilins
16. Clindamycin. Streptogramins. Oxazolidinones. Fusidans.
17. Glycopeptides. Lipopeptides. Bacitracin. Mupirocin.
18. Metronidazole. Fidaxomycine. Rifaximin. Nitrofurantoin. Phosphomycine.

Method and type of grading:

(*Share of theoretical and practical examinations in the overall evaluation. Inclusion of the results of the end-of-term assessment. Possibilities of and conditions for offered grades.)*

To apply for the final examination, the student must have passed the toxicology exam (on week 13). The student may improve the result of the toxicology exam orally with his/her teacher. The grade of the toxicology exam will be counted towards the result of the final exam.

The midterm tests will count towards the semester final exam results:

1. If the student scores better than 60% in all four midterm tests during the whole year, the drug

recognition question will be waived and in case of a doubtful grade, the better one will be awarded.

2. If the student achieves at least 80% score of all four midterm tests one final exam topic will be waived as well as the drug recognition question. The waived topic will be chosen by the examiner.
3. At the competition at the end of the year, the student who has at least one midterm of 80% and none of his/her demonstrations is worse than 33%, depending on the result of the competition, will be rewarded: between scores 90-100% the students will choose one of the three topics, between 80-89% the students will choose which one he/she will drop, between 70-79% the examiner will choose one topic to be dropped. The drug recognition question will be waived.
4. If the student fails both midterm tests of the second semester (even at the time of a retake), or fails to achieve 33% in either midterm test with a correction, the student will receive a grade penalty on the first attempt of the final exam.
5. In the case of a repeated exam after a failure, the negative and, in the case of an improvement exam, both the positive and the negative modifications are cancelled. The first semester midterms, if their results were worse than 30%, will not be counted for the final exam.

In the oral final exam, at first 5 active substances selected from the compulsory list of active substances must be identified the and their mechanism of action explained (unless the student achieves better than 60% in each of the four midterms of the academic year). If the student does not recognize at least 3 of the active substances, he/she will not be allowed to continue and will receive a fail mark. After successful completion of one core-concept question and three topics of three lists of topics (one from each), an acceptable level of knowledge of pharmacology must be demonstrated.

Detailed information on the compulsory and the full lists of active substances. If the candidate:

1. knows all the active substances to be studied in full detail, or knows all the active substances with some minor lacks and can mention names of active substances from the full drug list,– mark 5
2. knows all the active substances to be studied and the information to a varying degree and can mention the names of active substances from the full drug list to a varying degree - 2,3,4
3. knows all the active substances to be learned, but only the name and nothing else – unsatisfactory (failure)
4. does not know any active substance names – unsatisfactory (failure)
5. does not know all the active substances from the mandatory list, but knows the active substances from the full list of active substances in the given topic, then points 1,2 or 3 above are taken into consideration, the mark is awarded according to these points

Type of grade: five-mark scale (1=unsatisfactory, 2=satisfactory, 3=average, 4=good, 5=excellent)

List of course books, textbooks, study aids and literature facilitating the acquisition of knowledge to complete the course and included in the assessment, precisely indicating which requirement each item is related to (e.g., topic by topic) as well as a list of important technical and other applicable study aids:

Basic and Clinical Pharmacology (Ed. B. G. Katzung), 15th edition, McGraw-Hill Education, 2021. ISBN 978-1 260 45231 0

Materials discussed during lectures and seminars: Moodle (https://itc.semmelweis.hu)

Signature of habilitated instructor (course coordinator) announcing the course:

Péter Ferdinandy, MD, DSc, MBA
Head of Department

Signature of the director of the host institution:

Péter Ferdinandy, MD, DSc, MBA
Head of Department

Date of submission:

May 27, 2024