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: 6 th (as defined in the curriculum)			
Total number of classes per week: 4.5	lectures: 2	practical lessons: 2.5	seminars: -
Type of subject:compulsoryoptionalelective(PLEASE UNDERLINE AS APPLICABLE)			
Academic year: 2023/2024 2 nd semester			
Language of instruction, for optional or elective subjects:			
Course code: AOKFRM678_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@med.semmelweis-univ.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 multisemester 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
 - o Lecture: Anticoagulants, inhibitors of platelet aggregation
 - Practice: Fibrinolytics, drugs against bleeding, drugs acting on blood cell production.
- 2nd week
 - o 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.)
- 4^{th} 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. Autacoids, histamine, antihistamines.
- 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
 - o Lecture: Pharmacology of female sexual hormones.
 - Practice: Androgens, antiandrogens, anabolic steroids, drugs influencing sexual activity.
- 8^{th} 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. Retinoids.
- 11th week
 - Lecture: Small molecule cytostatic, signal transmission inhibitor anticancer drugs. Anticancer drugs with hormonal mechanisms
 - Practice: Toxicology I. 4th midterm
- 12th week
 - Lecture: Anticancer antibodies. Immunostimulant anticancer agents. Other drugs used in therapies of cancer
 - o Practice: Toxicology II. Drugs acting on smooth muscles
- 13th week
 - o Lecture: Pharmacodynamic and pharmacokinetic basics of drug interactions
 - o Practice: Contrast agents. Consultation
- 14th week
 - Lecture: Pharmacogenomics, personalized medicine, drugs for orphan disease. Special aspects of pharmacology in children and elderly
 - Practice: Drugs and pregnancy

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. Improvement attempt of the midterm tests (both) will be possible in week 13.

The course material for the third midterm test (study material from week 1 to 5): Pharmacology of the cardiovascular system. Drugs acting on lipid metabolism. Drug acting on blood glucose level. Fourth midterm test (study material 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.
- 2. If the student achieves at least 75% 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 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. Mechanisms of death due to poisoning, initial management of the poisoned patients
- 2. Management of the poisoned patient II. Decontamination
- 3. Management of the poisoned patient III. Enhancing of elimination of toxins
- 4. Pharmacology of chelators
- 5. Lead poisoning
- 6. Mercury poisoning
- 7. Arsenic poisoning
- 8. Carbon monoxide poisoning
- 9. Aliphatic hydrocarbons and aliphatic halogenated hydrocarbons
- 10. Aromatic hydrocarbons, glycols and aldehydes
- 11. Insecticides
- 12. Mushroom poisoning
- 13. Atropine poisoning
- 14. Cyanide poisoning
- 15. Methanol intoxication
- 16. Acid and base poisonings, oxalic acid
- 17. Poisons inducing methemoglobinemia
- 18. Botulism

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.)

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- 6. If the student achieves at least 75% 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.
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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.

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

- 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:

April 28, 2023