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: Clinical Pharmacology

in English: Clinical Pharmacology in German: Klinische Pharmakologie

Credit value: 3

Semester: 7th and 8th

(as defined in the curriculum)

Total number of classes	lectures:	practical lessons: 3	seminars:
per week:		P	

Type of subject: <u>compulsory</u> optional elective

(PLEASE UNDERLINE AS APPLICABLE)

Academic year: 2023/2024

Language of instruction, for optional or elective subjects:

Course code: AOKFRM1117 1A

(In the case of a new subject, this cell is filled in by the Dean's Office, following approval)

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:

Clinical Pharmacology is based on the knowledge of the subject Pharmacology taught in the 3rd year. In the teaching of clinical pharmacology, we assign drugs to the given disorders and present clinical cases. Based on students' active teamwork and problem-oriented thinking, we teach therapeutic strategies for priority diseases of public health importance according to current guidelines, as well as practical skills in clinical trials and pharmacovigilance. We cover the development of drugs and medical devices used in clinical practice, including clinical trials, and the continuous evaluation of their efficacy and safety during their use (pharmacovigilance - reporting of side effects). Furthermore, during the practical teaching of the prescription writing, students will master the practical application and legal background of prescribing medicines. Part of the subject is clinical toxicology, which describes the symptomatology and therapy of major drug toxicities and drug overdoses.

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

Nagyvárad téri Elméleti Tömb, 1089 Budapest, Nagyvárad tér 4. laboratory L-3, or L-4 or L-5

Competencies acquired through the completion of the course:

Students will learn:

- a pharmacotherapeutic strategy for diseases of public health importance according to current guidelines
- the practical application and legal background of prescription writing in connection with disorders
- therapy for major drug toxicities and drug overdoses
- the most common drug interactions
- the process of drug development, especially in clinical trials
- and be able to use the side effect reporting method
- the basics of personalized pharmacotherapy and the digital therapy systems that support it.

Prerequisites for course registration and completion:

Pharmacology II (AOKFRM678_2A)

Conditions for concurrent course registration and permission thereof in the case of a multisemester subject:

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

According to NEPTUN system

Detailed course description:

In a block system of 5 days, divided into two weeks, 7 contact hours of practice per day and altogether 7 hours of individual student's work:

All relevant topics are developed with the involvement of clinical experts. The clinical cases prepared in this way (3-5 cases per topic) are presented and processed in an interactive way on a problem-oriented basis. Related to the above is a description of current therapeutic recommendations.

Day 1:

<u>Infectious Diseases Treatment Strategy</u> - Dr. Kornél Király, Ph.D., associate professor; Dr. Zsófia Gulyás-Onódi PhD., assistant professor; Dr. Erzsébet Kató, Ph.D., assistant professor <u>Treatment strategy for respiratory and gastrointestinal diseases</u> - Dr. Klára Gyires, Ph.D., D.Sc., Professor Emerita, clinical pharmacologist, Dr. Zoltán Zádori, Ph.D., associate professor

Day 2:

<u>Endocrine Disease Treatment Strategy</u> - Dr. Bence Ágg, Ph.D., associate professor, Dr. Júlia Timár, Ph.D., retired associate professor

<u>Treatment strategy for cardiovascular diseases and metabolic syndrome</u> - Dr. Péter Ferdinandy, Ph.D., D.Sc., MBA, professor, clinical pharmacologist, Dr. Anikó Görbe, Ph.D., associate professor, specialist in clinical laboratory tests, specialist in psychotherapy, Dr. Zoltán Varga, Ph.D., Associate Professor

Day 3:

<u>Strategy for the treatment of psychiatric and neurological diseases</u> - Dr. István Gyertyán, Ph.D., Research associate, Dr. László Hársing, Ph.D., D.Sc., retired professor, Dr. Ildikó Miklya, Ph.D., retired associate professor,

<u>Clinical Toxicology, Emergency Medicine</u> - Dr. Erzsébet Kató, Ph.D., assistant professor, Dr. Júlia Timár, Ph.D., retired associate professor

<u>Clinical Addictology</u>- Dr. Erzsébet Kató, Ph.D., Assistant Professor, Dr. Júlia Timár, Ph.D., Retired Associate Professor

Day 4:

<u>Clinical trials and drug registration</u> - Dr. Zoltán Giricz, Ph.D., senior research fellow, pharmacist, Dr. Pál Riba, Ph.D., associate professor

<u>Basics of Drug Development</u> - Dr. Péter Ferdinandy, Ph.D., D.Sc., MBA, clinical pharmacologist, Dr. Zoltán Giricz, Ph.D., senior research Ffellow, pharmacist

<u>Pharmacovigilance</u>, recognition of adverse drug reactions in clinical practice. - Dr. Péter Ferdinandy, Ph.D., D.Sc., MBA, professor, specialist in clinical pharmacology, Dr. Anikó Görbe, Ph.D., associate professor, specialist in clinical laboratory tests, specialist in psychotherapy

<u>Pain Relief</u> - Dr. Al-Khrasani Mahmoud, Ph.D., associate professor, pharmacist in drug supply and organization, Dr. Kornél Király, Ph.D., associate professor

Day 5:

<u>Treatment strategy of autoimmune diseases</u> - Dr. Klára Gyires, Ph.D., D.Sc., professor emeritus, specialist in clinical pharmacology, Dr. Zoltán Zádori, Ph.D., associate professor <u>Pharmaceutical Formulations and Prescriptions</u> - Dr. Al-Khrasani Mahmoud, Ph.D., associate professor, specialist pharmacist in drug supply and pharmaceutical organization, Dr. Viktória Tóth, Ph.D., research associate

<u>Individualized pharmacotherapy, special patient populations</u> - Dr. Zsófia Gulyás-Onódi PhD., assistant professor, Dr. Ildikó Miklya, Ph.D., retired associate professor,

Independent student work (7 hours):

- 1. Drug development and regulation: independent processing of video material, completion of a control test
- 2. Pharmacovigilance: independent study of video material, completion of a control test, online exercises related to the topic
- 3. Personalised pharmacotherapy: independent processing of video material, completion of a control test, online exercises related to the topic

Related subjects due to interdisciplinary fields (both compulsory and elective) and potential overlaps between subjects:

Internal medicine, cardiology, pulmonology, neurology, psychiatry, pediatrics, infectology, immunology, oncology

Attendance requirements; conditions under which students can make up for absences and the method of absence justification:

Maximum number of absences is 10 percent of the number of practices in the semester. In the case of absence the student can attend another block class later during the semester.v

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)

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

Watch instructional videos on drug development, pharmacovigilance, personalised pharmacotherapy, solve exercises, complete tests at home by the morning of the day of the given topic. Solving the independent tasks is a condition for being admitted to the examination.

Requirements to obtain the teacher's signature:

The number of absences must not be more than 10 percent of the number of practices in the semester. Solving independent tasks is a prerequisite for the signature.

Type of assessment (comprehensive examination, end-term examination, term-grade, term-grade on

a three-grade rating scale, no examination):

semifinal exam

written multiple choice test, evaluation with the five mark scale (excellent=5, good=4, average=3, satisfactory=2, unsatifactory=1)

Examination requirements:

(list of examination topics, subject areas of tests / examinations, lists of mandatory parameters, figures, concepts and calculations, practical skills)

A home-solved test of drug development prior to the exam. At the exam: answering problem-oriented competence tasks with test questions compiled from the topics listed above.

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.)

The result of the independent student assignment completed at home counts for 30% of the final grade and the written exam for 70%. For the homework 50% of the maximum 30 points and at least 40% of the 70 points for the written exam must be achieved to pass.

Formulation of the grade:

88 to 100 points: excellent (5) 76-87,5 points: good (4)

63-75 points: average (3) 50-62 points: satisfactory (2)

Less than 50 points: unsatisfactory (1)

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), 15^{th} edition, McGraw-Hill Education, 2021. ISBN 978-1 260 45231 0

Materials discussed during practices: 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