

# National Training Requirements

**ROMANIA**

Specialty  
**Clinical Pharmacology**

Farmacologie Clinică

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On behalf of (organisation):	Romanian College of Physicians
Original language:	Romanian
NMA responsible for training:	Romanian Ministry of Health ( <i>Ministerul Sănătății</i> ); Romanian College of Physicians ( <i>Colegiul Medicilor din Romania</i> )
English translation:	UEMS Section of Pharmacology Executive Committee (TG)

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**MINISTRY OF HEALTH  
THE NATIONAL PERFECTION CENTER IN THE BUCHAREST SANITARY  
DOMAIN**

**CURRICULUM FOR PREPARATION  
IN THE SPECIALTY**

**CLINICAL PHARMACOLOGY**

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# **CURRICULUM FOR PREPARATION IN THE SPECIALTY CLINICAL PHARMACOLOGY**

**1.1. DEFINITION:** Clinical pharmacology is the medical specialty that studies the interactions between drugs and the human body, whether healthy or ill, for the purpose of evaluating, monitoring and rational use of drugs in the prophylaxis, diagnosis and treatment of diseases.

**1.2. DURATION:** 4 years

The curriculum provides a number of 200 teaching hours (courses, seminars, presentations) for the academic year, for the presented subject, outside of which there are also 40–50 hours of individual study.

Quantification of training in view of equivalence is done through credits (CFU).  
1 credit = 25 training hours

Of the training time, the teaching activity covers 20–30%, the rest of 70–80% being dedicated to practical activities and individual study.

At the end of each training module (at least once a year), an assessment takes place in the training unit by the trainee manager and mentor.

The evaluation is completed by granting CFU credits.

The whole training activity is monitored through the log book, which also includes the training assessments in credits, research activity, and participation.

## **1.3. STRUCTURE OF TRAINING**

**1.3.1.** Stage of employment, taking into account social administrative issues, presenting to the unit where he/she was assigned, choosing the mentor and setting up the work plan: ... 2 weeks

**1.3.2.** Basic pharmacology course: ... 12 months

**1.3.3.** Internship and organization: ... 3 months

**1.3.4.** Internal medicine internship: ... 6 months

**1.3.5.** Clinical toxicology training: ... 6 months

**1.3.6.** Internship in a medical specialty of choice, other than the above (in a clinical trials clinic): ... 3 months

**1.3.7.** Bioethics: ... ½ month

**1.3.8.** Clinical pharmacology training: ... 11 months and 2 weeks.

## **1.4. CONTENT OF TRAINING**

### **1.4.1. TRAINING IN FUNDAMENTAL PHARMACOLOGY**

#### **1.4.1.1. Content of lectures (200 hours)**

1. General pharmacodynamics.

2. General pharmacokinetics.
3. General pharmacotoxicology.
4. Principles of appreciation of the pharmacological bases of therapy.
5. Pharmacological influence on vegetative nerve transmission.
6. Pharmacological influence on cholinergic nerve transmission.
7. Pharmacological influence on adrenergic nerve transmission.
8. Neuro-humoral transmission in the central nervous system.
9. General anaesthetics.
10. Local anaesthetics.
11. Hypnotics and sedatives.
12. Medication of mental illness.
13. Drugs for extrapyramidal disorders.
14. Anticonvulsant medication.
15. Opioid analgesics and their antagonists.
16. Toxicomania and drug dependence.
17. Pharmacological influence on hormonal regulation.
18. Pharmacological influence on the pituitary gland and its functions.
19. Pharmacological influence on the thyroid gland and its functions.
20. Pharmacological influence on the cortico- and medullo-adrenal glands and their functions.
21. Insulin, oral antidiabetics and pharmacological influence of the pancreas.
22. Calcium, parathyroid hormone, calcitonin, vitamin D and other related substances.
23. Pharmacological influence on tissue regulation.
24. Histamine, bradykinin, serotonin and substances that act locally.
25. Prostaglandins, leukotrienes, platelet-activating factor and substances that locally.
26. Analgesics, anti-inflammatory, antipyretic, and antirheumatic drugs.
27. Medicines used in the treatment of rheumatoid arthritis and gout.
28. Antiasthmatics.
29. Renin-angiotensin-aldosterone system and its pharmacological management.
30. Medication for heart failure.
31. Antianginal drugs.
32. Medication of arrhythmias.
33. Antihypertensive drugs.
34. Medication for dyslipidaemia.
35. Antiulcer drugs.
36. Pharmacological influence on digestive motility and secretions.
37. Pharmacological influence on uterine motility.
38. Chemotherapy of bacterial diseases.
39. Chemotherapy of parasitic diseases.
40. Chemotherapy of viral diseases.
41. Anticancer chemotherapy
42. Pharmacological immunosuppression.

43. Pharmacological influence on haematopoiesis.
44. Pharmacological influence on haemostasis.
45. Vitamins.

#### **1.4.1.2. Quantity of practical activities**

1. Designing, organizing and conducting pharmacodynamic experiments:  
... 3
2. Designing, organizing and conducting pharmacokinetic experiments: ... 1
3. Design, organization and conducting pharmacotoxicology experiments:  
... 3
4. Data processing and statistical analysis: ... 7
5. Writing and publishing of scientific articles: ... 2
6. Critical evaluation of experimental pharmacology data from the literature:  
... 7
7. Final seminar.

### **1.4.2. TRAINING IN LEGISLATION AND ORGANISATION**

#### **1.4.2.1. Content of lectures (50 hours)**

1. Basis of the legislation in Romania and the European Union in the area of medicines.
2. Basis of the legislation in Romania and the European Union in the area of biological products for human use.
3. Basis of the legislation in Romania and the European Union in the area of nutritional supplements and other similar products.
4. Basis of the Romanian and European Union legislation in the area of medical devices.
5. Basis of Romanian and European Union legislation in the area of cosmetics.
6. Political aspects of medicinal products.
7. Technical and scientific issues related to the authorization, supervision and control of medicinal products.
8. Authorization for placing on the market of medicinal products.
9. Evaluation of the pre-clinical pharmacological dossier of medicinal products for marketing authorization.
10. Evaluating the clinical efficacy of new medicinal products in order to authorise their marketing.
11. Evaluation of bioequivalence and interchangeability of medicinal products.
12. Preclinical safety assessment of medicinal products.
13. Evaluation of the clinical safety of medicinal products.
14. Evaluation of the quality of medicinal products.
15. Rules of Good Practice in the clinical studies.
16. Evaluation of clinical trial protocols to approve clinical trials.
17. GCP inspections.

18. Rules of Good Laboratory Practice.
19. GLP inspections.
20. Rules of good manufacturing practice.
21. GMP inspections.
22. Pharmacovigilance.
23. Ensuring the quality of medicinal products for human use.
24. Complaints about drugs.
25. Adverse drug reactions.
26. Non-conformities of drugs.
27. Regulations of the advertising of medicinal products.
28. Withdrawal and destruction of drugs.
29. Organization of the drug distribution network.
30. Good drug distribution practice and compliance inspections.
31. Good practice rules for storing medicinal products and inspections of compliance with them.
32. Good pharmacy practice rules and compliance inspections.
33. Import and export of medicines.
34. Pricing of medicines.
35. Legislation on the regime of toxic and narcotic substances and their medicinal products.
36. Surveillance of toxic and narcotic substances and medicinal products containing them.

#### **1.4.2.2. Quantity of practical activities**

1. Administrative evaluation of documentations of a proposed medicinal product for marketing authorization: ... 10
2. Evaluation of preclinical pharmacokinetic dossiers for authorization for marketing: ... 3
3. Evaluation of preclinical toxicological dossiers for authorization for placing on the market: ... 3
4. Evaluation of bioequivalence studies for marketing authorization: ... 3
5. Evaluation of clinical documentations for marketing authorization: ... 3
6. Participation in the evaluation of pharmaceutical dossiers for marketing authorization: ... 3
7. Evaluation of the clinical trial protocol for the approval of a clinical trial in Romania: ... 4
8. Evaluation of advertising materials: ... 5
9. Participation in GMP inspections: ... 2
10. Participation in GCP inspections: ... 4
11. Participation in distribution network inspections: ... 3

### **1.4.3. TRAINING IN INTERNAL MEDICINE**

#### **1.4.3.1. Content of lectures (100 hours)**

1. Chronic obstructive bronchopneumopathy.

2. Bronchial asthma.
3. Bronchopulmonal cancer.
4. Pleurisy.
5. Pulmonary tuberculosis.
6. Rhythm and conductance disorders.
7. Angina pectoris and myocardial infarction.
8. Cardiac insufficiency, pulmonary heart disease, acute pulmonary oedema.
9. Hypertension.
10. Vasculitis.
11. Vascular thrombotic disease.
12. Cardio-respiratory resuscitation.
13. Collagen diseases.
14. Gastric and duodenal ulcer.
15. Gastric and colon cancer.
16. Malabsorption syndrome.
17. Hepatitis, cirrhosis, liver cancer.
18. Portal encephalopathy.
19. Acute pancreatitis.
20. Diarrheal syndromes.
21. Acute and chronic nephritis.
22. Acute and chronic kidney failure.
23. Nephrotic syndrome.
24. Diabetes mellitus.

#### **1.4.3.2. Quantity of practical activities**

1. Phlebotomy: ... 1
2. Thoracocentesis: ... 2
3. Paracentesis: ... 2
4. Applying a naso-gastric probe: ... 2
5. Interpretation of ECG: ... 50
6. Interpretation of radiographs and computed tomographies: ... 20
7. Retrospective analysis of the cost/benefit ratio of a patient's medication:  
... 50 cases from observation sheets.
8. Report on adverse reactions encountered during the internship:  
... 1 presented at the final seminar.
9. Final seminar.

### **1.4.4. TRAINING IN INTENSIVE CARE MEDICINE**

#### **1.4.4.1. Content of lectures (100 hours)**

1. Medications used in general anaesthesia.
2. Medications for spinal anaesthesia.
3. Local anaesthetics.
4. Principles of haemorrhagic shock treatment.
5. Solutions used for electrolytic and acid–base rebalancing.

6. Hyperthermia.
7. Hypothermia.
8. Treatment of pain.
9. Obstruction of the upper airways (ensuring freedom of airways).
10. Cardio-respiratory-cerebral resuscitation.
11. Pharmacological therapy of cardiogenic shock.
12. The pharmacological phenomenon of septic shock.
13. Principles of treatment of anaphylactic shock.
14. Treatment of comatose states.
15. Therapy of acute cardio-circulatory insufficiency.
16. Therapy of pulmonary oedema.
17. Principles of therapy with blood and blood components.
18. Pharmacological therapy of pulmonary embolism.
19. Therapy of respiratory insufficiency.
20. Acute renal failure.
21. Acute pancreatitis.
22. Acute toxic drug-induced hepatitis.

#### **1.4.4.2. Quantity of practical activities**

1. Lumbar puncture: ... 2
2. Installing a venous catheter: ... 2
3. Install an infusion: ... 30
4. Tracheal intubation: ... 10
5. Cardiac resuscitation electroshock: ... 5
6. Monitoring a critical patient.
7. Retrospective analysis of the cost/benefit ratio of a patient's medication:  
... 50 cases from observation sheets.
8. Report on adverse reactions encountered during the internship:  
... 1 presented at the final seminar.
9. Final seminar.

### **1.4.5. TRAINING IN CLINICAL TOXICOLOGY**

#### **1.4.5.1. Content of lectures (100 hours)**

1. Epidemiology of acute intoxications.
2. Quantitative characteristics of acute toxicity.
3. Classification of toxic substances.
4. General toxicokinetics.
5. General toxicodynamics.
6. Data on medical conduct in acute intoxications.
7. Decontamination of intoxications.
8. Full evaluation of acute intoxication.
9. Use of antidotes in acute intoxications.
10. Therapeutic methods of increasing the elimination of toxins in the body.
11. Acute clinical intoxications with high incidence.



12. Acute drug intoxications.
13. Acute intoxications with drugs of abuse.
14. Principles of the treatment of addiction.

#### **1.4.5.2. Quantity of practical activities**

1. External decontamination of an intoxication: ... 5
2. Gastric lavage: ... 3
3. Assessment of an acute intoxication: ... 10
4. Filling in toxicological information sheets: ... 10
5. Implementation of algorithms for determination by laboratory analysis of an unknown toxicant that produced an intoxication: ... 5
6. Retrospective analysis of the cost/benefit ratio of a patient's medication: ... 50 cases from observation sheets.
7. Report on adverse reactions encountered during the internship: ... 1 presented at the final seminar.
8. Final seminar.

#### **1.4.6. MODULE OF BIOETHICS – 2 weeks**

##### **1.4.6.1. COURSE TOPICS (20 HOURS)**

###### **I. Introduction to Bioethics – 2 hours**

1. Morals, ethics, medical ethics – definition, delimitation of the subject.
2. The context of bioethics.
3. Definition of bioethics.
4. Delimitation of bioethics field of study.
5. Theories and methods in bioethics.

###### **II. The concepts of health, illness, suffering from the perspective of bioethics – 2 hours**

1. Definition of concepts of health, illness, suffering.
2. The concepts of health, illness and suffering in the context of the evolution of medicine and the life sciences.
3. The role of personal or group beliefs and values in shaping the concepts of health, illness and suffering (particular perceptions of religion, ethnicity, etc.)

###### **III. Doctor–patient relationship I – 2 hours**

1. Values of physician-patient relationship.
2. Paternalism versus autonomy.
3. Models of doctor-patient relationship.
4. Justice, equity and patient access to health care.

###### **IV. Doctor–patient relationship II – 2 hours**

1. Informed consent.
2. Confidentiality in the physician–patient relationship.
3. The doctor–minor-patient relationship.
4. Normative acts governing the doctor–patient relationship.

**V. Mistakes and errors in medical practice – 2 hours**

1. Defining the concepts of mistake and error.
2. Medical malpractice – definition, forms, legal and deontological implications.
3. Managing mistakes and medical errors in medical practice.

**VI. Ethical issues at the beginning of life – 2 hours**

1. Freedom of procreation.
2. Ethical dilemmas in abortion.
3. Ethics of medically assisted human reproduction.
4. Ethical issues in reproductive cloning.

**VII. Ethical issues at the end of life – 2 hours**

1. Defining death in the age of new technologies in medicine.
2. Ethical issues in terminal states.
3. Unnecessary treatments in medical practice.
4. Euthanasia and assisted suicide.
5. Palliative care.

**VIII. Ethical issues in transplantation of human tissues and organs – 2 hours**

1. Organ donation from a dead body.
2. Organ donation from a living person.
3. Ethics of resource allocation in transplantation.

**IX. Ethical issues in genetics and genomics – 2 hours**

1. Eugenics and discrimination based on genetics.
2. The human genome project – ethical issues, redefinition of the notion of disease through the knowledge of the human genome.
3. Ethics and prenatal, neonatal and postnatal genetic testing.
4. Moral status of the human embryo; embryo research.
5. Gene therapy.
6. The possibility of improving the human race through genetic interventions.

**X. Ethics of research on humans – 2 hours**

1. Ethical principles in research on humans.
2. Protecting participants in biomedical research – discussing the main codes of ethics and international conventions in research, the legislative framework in which research is conducted on humans.

3. Vulnerable populations in the context of research on human subjects.
4. Ethical aspects in multicentre, multinational researches.
5. Ethics committees of research.
6. Inappropriate scientific behaviour, conflict of interest in scientific research.

#### **1.4.6.2. SEMINAR TOPICS**

- I. Illustration of particular cases of theories and principles in bioethics – 2 hours**
- II. Regulating medical practice by codes of ethics – 2 hours**
  1. Oath of Hippocrates – commenting on the initial form of the Hippocratic Oath and evaluating the degree of applicability of its perceptions under the conditions of current medicine.
  2. Alternatives to the Hippocratic Oath.
  3. Other codes of ethics and medical deontology currently in use.
- III. Illustration of ethical values of doctor–patient relationship through practical cases – 2 hours**
  1. Value and limits of informed consent in current medical practice.
  2. Value and limits of confidentiality in current medical practice.
  3. The role of communication in the doctor–patient relationship.
- IV. Illustration of ethical values of doctor–patient relationship through practical cases – 2 hours**
  1. Access to health care – discussion of cases.
  2. Rights of patients – legislative regulation.
  3. The role of ethics committees in hospitals.
- V. Exemplifying the notions of mistakes and error in medicine through concrete cases – 2 hours**
  1. The delimitation of the notion of malpractice.
  2. Medical mistakes from the perspective of malpractice.
  3. The deontological perspective on medical mistakes.
- VI. Discussing ethical issues at the beginning of life based on concrete cases – 2 hours**
- VII. Discussing ethical issues at the end of life based on concrete cases – 2 hours**
- VIII. Discussion of ethical issues in tissue and organ transplantation based on concrete cases – 2 hours**

**IX. Discussion of ethical issues in genetics and genomics based on concrete cases – 2 hours**

**X. Discussion of ethical issues in research on humans through concrete cases – 2 hours**

### **1.4.7. MODULE OF CLINICAL PHARMACOLOGY**

#### **1.4.7.1. Content of lectures (200 hours)**

##### **General Clinical Pharmacology (150 hours)**

1. The definition of Clinical Pharmacology, the importance of the problem, the place of Clinical Pharmacology among other sciences and subjects.
2. Importance of the specialty. The place and importance of the clinical pharmacologist in the complex nursing team.
3. The place and importance of drug therapy among other types of therapies.
4. The importance of allopathic therapy vs. other types of therapy (homeopathy, phytotherapy, magnetotherapy, acupuncture, etc.).
5. Iatrogenicity and consequences of inadequate prescription of drugs.
6. Clinical pharmacokinetics in the normal subject (basic notions). Clinical pharmacokinetics in various diseases. Drug interactions of the pharmacokinetic type.
7. Pharmacodynamics. Drug interactions of the pharmacodynamic type.
8. Fundamentals of pharmacogenetics, teratogenesis, oncogenetics.
9. Kinetic and dynamic particularities in certain physiological situations (children, old age, pregnancy, lactation, race, etc.).
10. Kinetic and dynamic particularities in certain pathological situations (renal failure, hepatic failure, heart failure, consumptive diseases / malnutrition / dehydration, alcoholism and drug addiction, etc.).
11. Rational drug prescribing – general presentation. Essential medicines.
12. The concept of medication P. Criteria of choice (effectiveness, toxicity, suitability of the proposed goal, cost) and their importance. The weight of the criteria according to the type of drug policy.
13. Choosing a drug group P. Choosing a P-drug from that group.
14. Defining the patient's problem.
15. Declaration of the therapeutic objective.
16. Checking the suitability of a medicine for a specific case.
17. Writing prescriptions.
18. What information and warnings about the prescribed treatment the patient and the caregivers require.
19. Monitoring (stopping) treatment.
20. Complex therapeutic regimens. Establishing doses in these particular situations. Compliance with complex schemes. Drug interactions.
21. Pharmacological diagnosis – a valuable feed-back for checking the

- diagnosis / therapeutic scheme.
22. Polypharmacy. Self-medication.
  23. Fundamentals of pharmacoepidemiology.
  24. Fundamentals of pharmacoconomics. Cost/effect ratio.
  25. Selection of sources of objective information on medicines.
  26. Information "from industry" and their critical processing.
  27. Assessment of clinical trials and large trials, objectivity criteria.
  28. Orientation in the classification of tricyclic antidepressants.
  29. Construction and completion of a clinical study of a drug.
  30. Phase I, II, III, IV studies.
  31. Bioequivalence.
  32. GMP, GLP norms.
  33. Interpretation of statistical data.
  34. Fundamentals of drug legislation.
  35. Decision-making bodies (Medicines Agency, Transparency Commission, MS Pharmaceutical Division, Hospital Pharmaceutical Commission).
  36. Clinical pharmacologist decision to use and purchase the medicine.
  37. Pharmacovigilance.

### **Special Clinical Pharmacology (50 hours)**

38. Evidence of the clinical efficacy of drugs affecting:
  - the central nervous system
  - the peripheral nervous system
  - the cardiovascular apparatus
  - the respiratory apparatus
  - the digestive system
  - the urogenital apparatus
  - the endocrine system
  - blood and infectious diseases, neoplasms, allergic diseases
39. Nutritional aspects of clinical pharmacology.
40. The impact of molecular and genomic biology on the development of clinical pharmacology.
41. Ethical issues in the treatment of new, expensive medicines.
42. Orphan drugs.

#### **1.4.7.2. Quantity of practical activities**

1. Participation in pharmacokinetic or bioequivalence studies: ... 1
2. Participation in Phase II or III studies: ... 1
3. Carrying out pharmaco-economic studies: ... 1
4. Final Seminar.

# CLINICAL PHARMACOLOGY

## 4 YEARS

### PRACTICAL TRAINING and COURSES-CONFERENCE

- MODULE OF FUNDAMENTAL PHARMACOLOGY (I.1) 12 MONTHS
- MODULE OF LEGISLATION AND ORGANISATION (I.2) 3 MONTHS
- MODULE OF INTERNAL MEDICINE (I.3) 6 MONTHS
- MODULE OF INTENSIVE CARE  
and EMERGENCY MEDICINE (I.4) 6 MONTHS
- MODULE OF CLINICAL TOXICOLOGY (I.5) 6 MONTHS
- MODULE OF A MEDICAL SPECIALTY OF CHOICE  
OTHER THAN THOSE (I.6) 3 MONTHS
- BIOETHICS (I.7) ½ MONTH
- MODULE OF CLINICAL PHARMACOLOGY (I.8) 11 MONTHS and 2 WEEKS

	YEAR I	YEAR II			YEAR III			YEAR IV
MODULE	I.1	I.2	I.3	I.4	I.5	I.6	I.7	I.8