National Training Requirements

POLAND

Specialty

Clinical Pharmacology

(Farmakologia kliniczna)

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MEDICAL CENTRE FOR POST-GRADUATE EDUCATION

Specialisation program

in the field of

CLINICAL PHARMACOLOGY

for doctors without second degree specialisation or the title of specialist
in the relevant field of medicine

Warszawa 2014

in accordance with Annex No. 5, point I "List of medical specialisations", item 24 of the Regulation of the Minister of Health of 2 January 2013 on the specialisation of doctors and dentists (Journal of Laws, issue 26)

The specialisation program has been developed by a team of experts composed of:

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2. Prof. dr hab. med. Dagmara Mirowska-Guzel – deputy of the domestic consultant;
3. Prof. dr hab. med. Marek Droździk – deputy of the domestic consultant;
4. Prof. dr hab. med. Przemysław Mrozikiewicz – representative of the Polish Society of Clinical Pharmacology and Therapy;
5. Dr med. Wojciech Matusewicz – representative of the Supreme Medical Council;
6. Prof. dr hab. med. Bogusław Okopień – representative of the Medical Center for Postgraduate Education.

I. AIMS OF SPECIALISATION TRAINING

1. Professional competences obtained

The purpose of the specialisation training is to obtain detailed qualifications in the field of clinical pharmacology that allow in accordance with modern medical knowledge:

1) rozwiązywanie problemów farmakoterapeutycznych związanych z leczeniem w różnych specjalnościach klinicznych;
1) solving pharmacotherapeutic problems related to treatment in various clinical specialties;
2) acting as an adviser to physicians practiticing in the field of pharmacotherapy;
3) critically evaluate the results of preclinical studies of a drug and design and conduct clinical trials in pharmacotherapy;
4) development of data from pharmacodynamic and pharmacokinetic studies of drug;
5) interpreting the results of analytical studies on the fate of the drug in the body;
6) critical evaluation of publications in the field of clinical pharmacology regarding the value of efficacy, safety and quality of medicines;
7) issue specialist opinions, certificates and applications for treated patients;
8) counseling physicians of other specialties;
9) conducting health promotion and prevention of diseases and injuries;
10) independent management of a clinical and hospital ward;
11) managing specialist training of other doctors in the field of clinical pharmacology;
12) managing a medical experiment in the field of clinical pharmacology..

2. Social competences obtained

During specialisation training, the doctor shapes and develops an ethical attitude and improves professional competence, in particular:

1) the guiding principle of the patient's wellbeing in his actions;
2) respect of the socially accepted system of values and deontological principles;
3) ability to make decisions and readiness to take responsibility for his/her own behaviour and the team entrusted to him/her;
4) ability to properly organise own work and harmonious cooperation in a team;
5) ability to establish relationships with the patient, the family and carer of the patient, respecting personal dignity and cultural, ethnic and social diversity;
6) knowledge of the psychological determinants of the doctor–patient relationship;
7) ability to provide information on health status, prognosis and diagnostic-therapeutic procedures.

II. REQUIRED KNOWLEDGE

The doctor is expected to show the following knowledge after completing the speciali Sation training in clinical pharmacology:

General topics:

1) mechanisms of drug action;
2) pharmacotherapy during pregnancy and during lactation;
3) pharmacotherapy of the developmental age;
4) geriatric pharmacotherapy;
5) pharmacotherapy in dysfunction of organs affecting pharmacokinetic processes;
6) adverse drug reactions;
7) drug interactions;
8) drug addiction;
9) therapy monitored by drug concentrations;
10) basics of toxicology;
11) basics of pharmacogenetics;
12) basics of chronopharmacotherapy;
13) basics of pharmacoeconomics;
14) basics of pharmacopoeiology;
15) innovative and generic drugs, biological and biosimilar drugs;
16) legal and administrative regulations regarding drug testing and registration in Poland and European Union countries;
17) post-registration supervision of medicines.

Specific topics:

1) chemotherapy of infections;
2) pharmacotherapy in intensive care;
3) pain therapy;
4) problems of pharmacotherapy in specific fields (anaesthesiology, endocrinology, metabolic diseases, allergology, gastroenterology, hepatology, cardiology, nephrology, pulmonology, neurology, psychiatry, rheumatology, obstetrics and gynecology, dermatology and venereology, haematology, oncology, ophthalmology, otolaryngology.

III. REQUIRED PRACTICAL SKILLS

It is expected that the doctor, after completing the specialisation training in the field of clinical pharmacology, will demonstrate the ability to:

1) using methods to assess the pharmacological action of the basic drug groups taking into account the toxicity assessment (acute, subacute, cumulative and chronic), side effects, mechanisms and site of action (within one department, the full range of modern assessment methods should be mastered);
2) evaluation of preclinical studies of a drug;
3) using methods of testing drugs in the system, and especially pharmacokinetic methods;
4) planning pharmacokinetic studies and interpretation of their results;
5) determination of pharmacokinetic parameters;
6) using methods of medical statistics;

7) definition and determination, after obtaining the necessary data, of constant elimination rate, half-life, volume of distribution and drug clearance in a one-compartment and two-compartment model;
8) determine the rules of drug dosing in conditions of renal and hepatic failure as well as in chronic circulatory insufficiency;
9) establishing rules and determining the purposefulness of monitoring blood levels of drugs;
10) planning of clinical studies (controlled clinical trials) taking into account the principles of good clinical practice – ICH GCP);
11) solving pharmacotherapeutic problems in selected patients;
12) assessment of potential drug interactions and appropriately modifying pharmacotherapy;
13) use of pharmacogenetic data in the selection of pharmacotherapy;
14) oversee the system for collecting and reporting data on adverse drug reactions.

IV. FORMS AND METHODS OF TRAINING

A – Specialisation courses

Note: The physician will only get credit for the courses that have been entered into the list of courses kept by the CMKP[1], published annually on the CMKP website: www.cmkp.edu.pl. The duration of the courses is determined in days and didactic hours, wherein 1 teaching hour = 45 minutes. The total duration of individual classes during one day of the course can not exceed 8 didactic hours.
Selected courses can be implemented via an e-learning platform.

1. Introductory course: "Introduction to the specialisation in clinical pharmacology – the basics of pharmacokinetics"

Scope of knowledge:
The aim of the course is to familiarise the participants with the following topics:
1) basics of pharmacokinetics;
2) pharmacokinetics of a drug in humans,
3) pharmacokinetic parameters – determination and interpretation;
4) differences of pharmacokinetics in the developmental age;
5) differences in pharmacokinetics in the elderly;
6) differences in gender-related pharmacokinetics;
7) pharmacokinetics of a drug during pregnancy and lactation;
8) elements of pharmacogenetics;
9) elements of chronopharmacology;
10) the influence of pathological conditions on pharmacokinetic processes;
11) modification of drug dosage in pathological conditions;
12) drug interactions at the pharmacokinetic level;
13) therapy monitored by drug concentrations;
14) elements of toxicology.

Duration of the course: 5 days (40 teaching hours).

Assessment of the course: confirmation of participation in the course and a test of the knowledge covering the course program conducted by the course manager.

[1] Medical Centre for Postgraduate Education.

2. Course: "Correct conduct of clinical trials (ICH GCP)"

Scope of knowledge:
The aim of the course is to learn the principles of conducting clinical trials according to the requirements of Pharmaceutical Law and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals (ICH GCP):

1) basic assumptions regarding conducting research;
2) Helsinki Declaration as the basis of ICH GCP;
3) tasks of independent ethics committees;
4) protection of patients;
5) placebo role in clinical trials;
6) the researcher's qualifications and responsibilities;
7) the role of the sponsor in the preparation and conduct of research;
8) monitoring and control of tests;
9) protocol of clinical examination and amendments to the protocol;
10) research brochure;
11) basic documentation necessary to conduct a clinical trial;
12) legal provisions regarding clinical trials and drug registration;
13) rules for the publication of results;
14) financing and insurance.

Duration of the course: 5 days (40 teaching hours).

Assessment of the course: confirmation of participation in the course and a test of the knowledge covering the course program conducted by the course manager.

3. Course: "Basics of pharmacoeconomics"

Scope of knowledge:
The aim of the course is to familiarise the participants with the following topics:

1) definitions and basic concepts in pharmacoeconomics;
2) elements of pharmacoeconomic evaluation;
3) types of pharmacoeconomic analysis;
4) research stages;
5) research ethics;
6) cost analysis;
7) cost-effectiveness analysis;
8) cost-utility analysis;
9) cost-benefit analysis;
10) cost-consequences analysis;
11) decision analysis.

Duration of the course: 3 days (24 teaching hours).

Assessment of the course: confirmation of participation in the course and a test of the knowledge covering the course program conducted by the course manager.

4. Course: "Progress in pharmacotherapy in selected fields"

Scope of knowledge:
The aim of the course is to learn current treatment methods of disease entities in selected

areas:

1) progress of pharmacotherapy in allergology;
2) progress of pharmacotherapy in anaesthesiology and intensive c<are and pain therapy;
3) progress of pharmacotherapy in chemotherapy of infections;
4) progress of pharmacotherapy in endocrinology and metabolic diseases;
5) progress of pharmacotherapy in gastroenterology;
6) progress of pharmacotherapy in cardiology;
7) progress of pharmacotherapy in nephrology;
8) advances in pharmacotherapy in neurology;
9) progress of pharmacotherapy in psychiatry;
10) progress of pharmacotherapy in oncology;
11) progress of pharmacotherapy in pulmonology;
12) progress of pharmacotherapy in rheumatology;
13) advances in drug technology;
14) place of herbal medicines in pharmacotherapy.

Duration of the course: 5 days (40 teaching hours).

Assessment of the course: confirmation of participation in the course and a test of the knowledge covering the course program conducted by the course manager.

5. Course: "Emergency medicine"

Aim of the course:
It is expected that the physician after completing the course will demonstrate knowledge of advanced techniques of cardiopulmonary resuscitation and emergency treatment of injuries.

Scope of knowledge:
Day I. Introduction to emergency medicine, mechanisms of pain formation and methods of chronic pain control:

1) history of the development of emergency medicine;
2) organisational assumptions and tasks of emergency medicine in contemporary health care systems. Legal bases in Poland;
3) structure, organisation and functioning of the hospital emergency department;
4) epidemiology of sudden threats to health and life;
5) monitoring vital functions and clinical evaluation of the patient in the hospital emergency department;
6) in-hospital medical segregation – intrahospital triage, medical documentation, patients' movement in emergency medical services;
7) definition and pathomechanism of chronic pain;
8) pain classification;
9) clinical evaluation of a patient with pain;
10) assessment of pain intensity (quantitative assessment) – pain scales;
11) pain characteristics (qualitative assessment) – questionnaires and other tools for qualitative assessment;
12) assessment of the effectiveness of treatment of chronic pain;
13) clinical evaluation of a patient with chronic pain;
14) pharmacotherapy of pain;
15) non-pharmacological methods of pain control;

16) effects of improper pain control.

Day II. Advanced cardiopulmonary resuscitation:

1) epidemiology, clinic and diagnostics of sudden cardiac arrest;
2) basics of advanced respiratory resuscitation in adults: emergency airway patency, replacement breathing techniques, monitoring the quality and effectiveness of replacement ventilation;
3) the basics of advanced cardiopulmonary resuscitation in adults: techniques of unmanned circulatory support, substitute circulation technologies, monitoring of the quality and efficiency of substitute circulation;
4) electrotherapy in sudden cardiac arrest and in conditions of danger of cardiac arrest;
5) emergency intravascular access;
6) pharmacotherapy of sudden cardiac arrest.

Day III. Advanced cardiopulmonary resuscitation (cont.):

1) epidemiology and clinic of sudden cardiac arrests in children, anatomical-physiological differences of childhood;
2) the specificity of advanced cardiopulmonary resuscitation of newborns, infants and children: patency of the airways, replacement ventilation, circulatory support, pharmaco- and fluid therapy;
3) modern recommendations and algorithms for cardiopulmonary resuscitation: resuscitation team – its tasks and performance monitoring;
4) cardiopulmonary resuscitation in special situations: anaphylactic shock, cardiogenic shock, septic shock, resuscitation of pregnant women, submersion, hypothermia, electric shock / lightning, acute coronary syndrome, cerebral stroke;
5) ethical and legal aspects of cardiopulmonary resuscitation, do not resuscitate (DNR), death statement, brain death;
6) introduction to intensive post-resuscitation therapy: replacement ventilation, central nervous system protection, therapeutic hypothermia, renal replacement therapy, hyperbaric oxygen therapy.

Day IV. Emergency treatment of injuries:

1) epidemiology of traumatic, multiple severe injuries;
2) tasks of emergency medical services and emergency medicine in trauma-related proceedings: trauma centers in Poland – legislation, financing;
3) initial assessment of the victims and rescue procedures in multiple injuries periarticular in the prehospital period: assessment of injury kinetics, pre-hospital report, telemedical transmission, patient transport with trauma injuries;
4) secondary assessment of a patient with multiple injuries in a hospital emergency department: perinatal resuscitation, intra-hospital *triage*[*], bedside diagnostics, scales severity of injuries;
5) *Trauma team*[*]: organisation, tasks in the initial treatment of injuries, assessment of effectiveness;
6) haemorrhage, extrasensory fluid resuscitation;
7) selected procedures for the treatment of arthrosis: airway patency, rescue thoracotomy, pleural drainage, *damage control*[*].

Day V. Emergency treatment of injuries (cont.):

1) the specificity of trauma and trauma in children;

2) selected situations of post-traumatic treatment: injuries in pregnant women, injuries in the elderly, head and spinal cord injuries, craniofacial injuries, eye injuries, chest injuries, limb injuries, abdominal and pelvic injuries, burn injuries, gunshot injuries;
3) mass events and catastrophes, prehospital *triage**.

*(*English cursive in the Polish original text)*

Duration of the course: 5 days (40 teaching hours).

Assessment of the course: confirmation of participation in the course and a test of the knowledge covering the course program conducted by the course manager.

6. Course: "Public health"

Day I. Public health

Scope of knowledge:

1. Introduction to the topic of public health:

1) health protection and public health, origin, the subject of public health as a scientific discipline and practical activity;
2) multisectorality and multidisciplinaarity of health protection, pro-health public policy in highly developed countries;
3) current public health problems in Poland and the EU.

2. Organisation and economics of health:

1) health systems in the world – basic models of organisation and financing, system transformations – their causes, directions and goals of changes;
2) principles of organisation and financing of the healthcare system in Poland;
3) public health institutions in Poland: State Sanitary Inspection, State Agency for Prevention of Alcohol Related Problems, National Bureau for Counteracting Drug Addiction, National Center for AIDS, self-government tasks and central administration tasks: organisation, tasks, instruments of action;
4) Community and international legal regulations for health protection;
5) basic concepts of health economics: demand and supply of health services; dissimilarity of the market of health services from other goods and services, asymmetry of information and power of attorney, concepts of health needs, social equality and justice and efficiency as a criterion of optimal allocation of resources, direct costs and indirect diseases, costs of therapy and consequences of the disease;
6) health technology assessment as a decision making tool for allocating public funds for health care; principles of the functioning of the drug reimbursement system in Poland: objectives and policy tools drug state and community regulations;
7) indicators of health status and functioning of health care in OECD countries.

3. Populaton health and its evaluation:

1) the concept of health and disease – a review of selected theoretical concepts;
2) social and economic determinants of health;
3) basic concepts of epidemiology, measures of the prevalence of health phenomena in the population;
4) epidemiology as a public health tool: source of information about the situation health and determining the health needs of the population;
5) the health situation of Poland against the background of Europe and the world;
6) demographic processes and planning of the objectives of the health care system;
7) epidemiology of selected infectious diseases: nosocomial infections in Poland and in Europe.

4. Health promotion and preventive care:

1) basic definitions: prevention, health promotion, health education;
2) genesis, directions of action and strategies for health promotion;
3) the role of patient education in the health care system;
4) principles of Evidence-Based Public Health;
5) health programs as a tool for the prevention and promotion of health (National Health Program, National Program for Combating Cancer, National Program for Preventing Lifestyle Diseases – POL-HEALTH, National Program for Equalising Accessibility to Prevention and Treatment of Cardiovascular Diseases POLKARD, Program for Limiting Health Consequences of Smoking Tobacco in Poland, National Mental Health Program, review of local government programs).

5. Bioethics:

1) ethical grounds of public health: human rights and the health care system, ethical models of health care systems, individual freedom and its limits in the area of health policy, social solidarity, justice in access to health services, equal access to health services;
2) key values of public health: value of health, value of patient's autonomy, privacy, population health, citizen's responsibility and public authorities' responsibility for their health;
3) selected public health ethical dilemmas: equal access to services and the efficiency of the health care system, high quality of services and effectiveness of the health care system, versatility and equality in access to services, ideological plimatism and actions of public authorities in the field of public health, equalisation of health inequalities, reimbursement of treatment and medicines costs, financing of high-cost procedures, financing of treatment of rare diseases;
4) physician's role in public health: medical ethical standards and their relationship with public health, the doctor in the promotion of health and preventive care, conflicts of interests of health care workers;
5) public health issues in selected bioethical regulations: ethical regulations of self-government of the medical professions, European Bioethical Convention.

Duration of part I: 5 days (40 teaching hours).

Day II. Medical certification

Scope of knowledge:

1) the social security system and its consequences in Poland;
2) types of social security benefits and conditions of their acquisition;
3) general rules and procedure for granting benefits to insured persons and their families;
4) the role and tasks of the treating physicians in the process of applying for social security benefits by the patient;
5) the role of medical certification in social security;
6) rules and procedures of medical adjudication about:
   a) temporary incapacity to work,
   b) the need for medical rehabilitation as part of disability prevention,
   c) circumstances justifying the granting of entitlements to a rehabilitation benefit or extended benefit period,
   d) the desirability of retraining,
   e) the right to social pension,
   f) inability to earn a job and its degrees,
   g) total incapacity to work on a farm,
   h) disability of officers and professional soldiers,

i) inability to live independently,
j) duration: inability to work, inability to work on a farm, incapacity for independent existence,
k) disabilities of children and adults,
l) percentage of health detriment;
7) medico-legal opinions;
8) the International Classification of Functioning, Disability and Health (ICF);
9) medical certification in commercial insurance;
10) the role of comprehensive rehabilitation in pension prevention.

Duration of part II: 3 days (24 teaching hours).

Total duration of the course – part I and part II: 8 days (64 teaching hours).

Assessment of the course: confirmation of participation in the course and a test of the knowledge covering the course program conducted by the course manager.

7. Course: „Medical law"

Aim of the course:
It is expected that the physician, after completing the course, will demonstrate knowledge of the basic laws in the practice of the profession of doctor and dentist and responsibility.
Scope of knowledge:
1) the principles of exercising health care in the light of the Constitution of the Republic of Poland;
2) the principles of performing medical activity:
   a) health benefits,
   b) healing entities – registration, operating principles, clinical hospitals, supervision,
   c) medical activity of a doctor or dentist in the form of a professional practice,
   d) specialist supervision and supervision;
3) rules for practicing the medical profession:
   a) definition of the medical profession,
   b) the right to practice the profession,
   c) the doctor's professional qualifications and duties,
   d) professional qualifications,
   e) medical experiment,
   f) rules for conducting clinical trials,
   g) medical records,
   h) the patient's rights and the doctor's obligations (the concept of informed consent, the right to refuse to provide a benefit),
   i) determination of death and determination of causes of death;
4) the principles of universal health insurance:
   a) the rights and obligations of the insured person and the health insurance doctor,
   b) organisation of granting and scope of health insurance benefits,
   c) documentation related to the provision of insurance benefits;
5) rules for writing medical prescriptions and orders for medical devices;
6) operating principles of the medical self-government:
   a) the tasks of the chambers of physicians,
   b) rights and obligations of members of the medical self-government,
   c) professional responsibility of doctors – proceedings before the professional liability officer, proceedings before a medical court,
7) special regulations regarding doctor's conduct in other acts, in particular:
   a) artificial procreation,

   b) transplantation of organs and tissues,
   c) abortion,
   d) aesthetic procedures,
   e) palliative treatment and terminal states,
   f) mental diseases,
   g) certain infectious diseases,
   h) counteracting and treating addictions,
   i) clinical trials;
8) legal liability of the doctor – criminal, civil:
   a) criminal liability (failure to provide assistance, action without consent, breach of medical confidentiality),
   b) civil liability (liability insurance).

B – Internships

The doctor is obliged to complete the following internships. The duration of the internship is given in weeks and working days in the working time of 7 hours 35 minutes a day. The internship should be extended by each day of absence, including public holidays in a given year.

1. Basic internship in the field of clinical pharmacology

Scope of theoretical knowledge:
During the internship the doctor is required to master the following knowledge:

1) knowledge of general pharmacology:
   a) mechanism of action of drugs,
   b) types of interaction,
   c) factors affecting the action of drugs, especially the genotype (pharmacogenetics), physiological status (age, pregnancy, feeding) and pathological (pathopharmacology), tolerance to drugs, drug dependence, side effects and toxic drugs, especially allergy to drugs, drug effects on fetus (teratogenic and embryotoxic), carcinogenic and mutagenic;
2) knowledge of the entire detailed pharmacology;
3) knowledge of the basics of therapy monitored by drug concentrations;
4) knowledge of the legal and administrative bases of conducting controlled clinical trials (in accordance with ICH GCP principles).

Range of practical skills:
During the internship the doctor is required to acquire the following skills:

1) using methods to assess the pharmacological action of the main groups of drugs, including the assessment of toxicity (acute, subacute, cumulative and chronic), adverse reactions, mechanisms of action and gripping points;
2) using methods of testing drugs in the body, especially pharmacokinetic methods,
3) using medical statistics methods;
4) definition and determination after obtaining the necessary data, constant of elimination rate, half-life, volume of distribution and drug clearance in the one-compartment and two-compartmental model;
5) setting drug dosing rules in conditions of renal and hepatic failure as well as in chronic heart failure;
6) establishing rules and determining the purposefulness of monitoring drug concentrations in the blood;
7) planning controlled clinical trials taking into account ICH GCP principles.

The doctor should practically:

1) read and assist as an observer in ongoing clinical trials of medicines;
2) learn laboratory analysis techniques (HPLC, gas chromatography, etc.);
3) conduct didactic classes on clinical pharmacology for students;
4) present the results of scientific research during scientific and training conferences.

Form of passing the internship (at the head of the specialisation):

1) submission of a colloquium on theoretical knowledge covered by the internship program;
2) passing a test of practical skills – confirmation by the head of the specialisation that the doctor performed the treatments and medical procedures covered by the internship program.

Duration of the internship: 152 weeks (760 working days).

Place of internship: a unit that has obtained accreditation for conducting specialisation training in the field of clinical pharmacology.

2. Internship in the field of psychiatry

Scope of theoretical knowledge:

During the internship the doctor is required to master the following knowledge:

1) detailed pharmacology in the field of neuro- and psychopharmacology;
2) practical aspects of psychiatric pharmacology.

Range of practical skills:

During the internship the doctor is required to acquire the following skills:

1) planning and interpretation of clinical trial results in psychiatry;
2) conducting therapy monitored by drug concentrations in the field of neuro- and psychopharmacology.

Form of passing the internship (at the head of the specialisation):

1) submission of a colloquium on theoretical knowledge covered by the internship program;
2) passing a test of practical skills – confirmation by the head of the specialisation that the doctor performed the treatments and medical procedures covered by the internship program.

Duration of the internship: 4 weeks (20 working days)

Place of internship: a unit that has obtained accreditation for conducting specialisation training in the field of psychiatry, or above internship.

3. Internship in the field of intensive care

Scope of theoretical knowledge:
During the internship the doctor is required to master the following detailed pharmacology knowledge in the field of intensive care and pain therapy.

Range of practical skills:
During the internship the doctor is required to acquire the following skills:

1) methods of therapy of a patient with multiple organ failure;
2) therapy in the perioperative period;
3) therapy of a patient with neutropenia;
4) participating in the planning of therapy and treatment of patients in the ICU.

Form of passing the internship (at the head of the specialisation):

1) submission of a colloquium on theoretical knowledge covered by the internship program;
2) passing a test of practical skills – confirmation by the head of the specialisation that the doctor performed the treatments and medical procedures covered by the internship program.

Duration of the internship: 4 weeks (20 working days)

Place of internship: a unit that has obtained accreditation for conducting specialisation training in the field of anaesthesiology and intensive care, or above internship.

4. Internship in the field of cardiology

Scope of theoretical knowledge:
During the internship the doctor is required to master the following knowledge:

1) detailed pharmacology in the field of cardiology;
2) practical aspects of cardiac pharmacology.

Range of practical skills:
During the internship the doctor is required to acquire the following skills:

1) planning and interpretation of clinical trial results in cardiology;
2) conducting therapy monitored by drug concentrations in the field of internal diseases.

Form of passing the internship (at the head of the specialisation):

1) submission of a colloquium on theoretical knowledge covered by the internship program;
2) passing a test of practical skills – confirmation by the head of the specialisation that the doctor performed the treatments and medical procedures covered by the internship program.

Duration of the internship: 4 weeks (20 working days)

Place of internship: a unit that has obtained accreditation for conducting specialisation training in the field of cardiology, or above internship.

5. Internship in the field of pediatrics

Scope of theoretical knowledge:
During the internship the doctor is required to master the following knowledge:

1) detailed pharmacology in the field of paediatrics;
2) practical aspects of pediatric pharmacology;
3) specifics of pediatric pharmacotherapy;
4) the specifics of the pharmacotherapy of infants;
5) the specifics of clinical trials in paediatrics.

Range of practical skills:
During the internship the doctor is required to acquire the following skills:

1) participating in the planning and therapy of infants and children;
2) planning and interpretation of clinical trials in pediatrics or above internship.

Form of passing the internship (at the head of the specialisation):

1) submission of a colloquium on theoretical knowledge covered by the internship program;
2) passing a test of practical skills – confirmation by the head of the specialisation that the doctor performed the treatments and medical procedures covered by the internship program.

Duration of the internship: 4 weeks (20 working days)

Place of internship: a unit that has obtained accreditation for conducting specialisation training in the field of pediatrics, or above internship.

6. Internship at the Agency for Health Technology Assessment

Scope of theoretical knowledge:
During the internship the doctor is required to master the following knowledge:

1) models of health technology assessment agencies in different countries;
2) the concept of health technology;
3) purposes of using health technology assessment;
4) methods for implementing health technology assessment depending on the agency's model;
5) the role of patients, carers, public opinion and their participation in the health technology assessment process depending on the agency's model;
6) getting to know the guidelines of the Polish Agency for Health Technology Assessment;
7) valuation assessment.

Range of practical skills:
During the internship the physician is required to prepare a verification analysis and in particular to calculate the threshold value of the medicinal product sales price in accordance with the current provisions of the method and procedures for the preparation of the Agency for Health Technology Assessment verification analysis and the fee for this analysis.

Form of passing the internship (at the head of the specialisation):

1) submission of a colloquium on theoretical knowledge covered by the internship program;
2) passing a test of practical skills – confirmation by the head of the specialisation that the doctor performed the treatments and medical procedures covered by the internship program.

Duration of the internship: 1 week (5 working days)

Place of internship: a unit that has obtained accreditation to run the abovementioned internship.

C – Training in performing treatments and medical procedures

Wykaz i liczba procedur medycznych, które lekarz jest zobowiązany samodzielnie wykonać:

1) estimation (based on the provided experimental data) of the biological availability of the drug;
2) establishing drug dosing schedules based on known values of pharmacokinetic parameters;
3) preparation of a plan of controlled clinical trials for an original and a generic drug;

D – Self-study

The doctor is obliged to continuous and active self-education in order to deepen his knowledge, track progress in the field, and in particular using recommended references, participate in meetings of educational scientific societies, write publications and participate in other forms of self-education indicated by the head of specialisation.

1. Studying literature
The physician should use the current textbooks and scientific journals in the field of internal medicine as well as other sources of knowledge indicated by the head of specialisation.

2. Participation in educational activities of scientific societies
The physician should take active part in the work of the medical scientific society; deliver two papers on scientific topics related to the subject of specialisation at scientific meetings.

3. Preparation of a publication
The doctor is obliged to write a scientific paper, published in a refereed journal, the doctor of which is the author or co-author, or a review paper, on the subject covered by the specialisation program in the field of clinical pharmacology.

V. METHODS FOR EVALUATION OF KNOWLEDGE AND PRACTICAL SKILLS

1. Examination and colloquium of theoretical knowledge
The doctor is obliged to:

1) pass the test at the end of the specialisation course in the field of knowledge covered by the course program – with the course manager;
2) submitting the colloquium at the end of each internship within the scope of knowledge covered by the internship program – at the internship/specialisation manager.

2. Partial colloquia
The doctor is required to pass 8 specialist tests conducted by the head of specialisation:

1) colloquium on chemotherapy of infections;
2) colloquium for the treatment of acute poisoning with medicines;
3) colloquium on clinical pharmacology of pain;
4) colloquium on clinical pharmacology of diseases of the central nervous system;
5) colloquium on clinical pharmacology of diseases of the cardiovascular system and clotting disorders;
6) colloquium on clinical pharmacology of respiratory and allergic diseases;
7) colloquium on clinical pharmacology of endocrine systems;
8) colloquium on clinical pharmacology of diseases of the digestive system and metabolic disorders.

3. Ongoing assessment and practical skills tests
The current assessment of the practical skills acquired by a physician is made by the head of specialisation or the internship manager during particular internships. The doctor is required to pass a practical test after each internship, i.e. performed by the doctor alone or as a first aid for medical treatments and procedures covered by the internship program, which is recorded in the specialisation training card in the form of an internship certificate.

In addition, the doctor is assessed the ability to perform practical tasks in the form of practical tests at the head of the specialisation:

1) a test of selected issues of pharmacokinetics,
2) a test regarding drug interactions,
3) a test of selected issues of pharmacogenetics,
4) a test on the proper conduct of clinical trials,
   a) planning a phase I trial,
   b) planning a phase II trial,
   c) planning a phase III trial,
   d) planning a phase IV trial,
   e) provisions of ICH GCP (rules for the proper conduct of clinical trials).

4. Evaluation of the original or review paper

Assessment and acceptance of the review work prepared by the doctor is carried out by the head of specialisation.

VI. DURATION OF THE SPECIALISATION TRAINING

The duration of the specialisation training in the field of clinical pharmacology is 4 years.

No.	Training course	Duration	
		number of weeks	number of working days
1	Basic internship in the field of clinical pharmacology	152	760
2	Internship in the field of psychiatry	4	20
3	Internship in the field of intensive care	4	20
4	Internship in the field of caardiology	4	20
5	Internship in the field of pediatrics	4	20
6	Internship at the Agency for Health Technology Assessment	1	5
7	Specialisation courses	6 wks & 4 days	34
8	Holidays	20 wks & 4 days	104
9	Public holidays	10 wks & 2 days	52
10	Self-study	2 wks	10
	Total	**209 wks**	**1045**

VII. STATE SPECIALISATION EXAM

Specialisation training in the field of clinical pharmacology ends with a State Specialisation Examination, consisting of a written test and an oral exam:

1) the written test is a set of multiple-choice questions in the scope of the required knowledge specified in the specialisation program;
2) the oral examination contains oral questions regarding the required knowledge specified in the specialisation program.

Annex to the specialisation program in the field of clinical pharmacology for physicians with no second degree specialisation or the title of specialist in the field of medicine

ACCREDITING STANDARDS OF TRAINING ENTITIES

– the conditions that the unit must meet to ensure the implementation of the specialisation program in the field of clinical pharmacology

The entity that conducts the specialisation training is required to meet the following accreditation standards:

1. *In the scope of conducting activity corresponding to the profile of specialist training:*

   – having in its organisational structure a branch/unit of clinical pharmacology or another organisational unit with the status of an entity performing an activity, providing specialist health care services in the field of clinical pharmacology.

2. *Within the scope of providing organisational conditions enabling the implementation of the specialisation program to a certain number of doctors:*

   – having a properly equipped didactic room equipped with audiovisual equipment, access to the internet and basic textbooks and scientific journals in the area covered by the program of specialisation.

3. *In the scope of ensuring supervision over the quality of specialist training:*

– having a committee or appointing a person responsible for evaluating the quality of training, organising periodic meetings with doctors conducting specialisation training, accepting and analysing the comments made by doctors regarding problems in the implementation of the above-mentioned training.

4. *In the scope of ensuring monitoring of the specialist training documentation of a given doctor:*

   a) periodical inspection of specialisation training cards and indexes of performed procedures and medical procedures of doctors conducting specialisation training,
   b) verification of the timely completion and passing of specialisation courses, internships and the performance of medical procedures and treatments covered by the specialisation program, carried out by the commission or a person responsible for assessing the quality of the training.

5. *In the scope of providing appropriate staff:*

   – having a team of specialists who can act as specialisation or manager of the directional internship in the specialisation program.

6. *In the scope of providing equipment and apparatus necessary for the implementation of the specialisation program:*

   – possession of equipment and materials for performing tests and access to research important in the activity in the field of clinical pharmacology

7. *In the scope of providing health services enabling the implementation of the specialisation program to a certain number of doctors:*
   a) conducting the activity of providing specialised health care services in the field of clinical pharmacology,
   b) providing specialised health care services, including performing examinations and procedures of this type, in the scope and number enabling all physicians who are training in specialisation, in a given unit, implementation of the specialisation program, including carrying out medical examinations and procedures specified in the specialisation program, including a number of internships .

Original text:
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