National Training Requirements

Denmark

Specialty

Clinical Pharmacology

(Klinisk farmakologi)

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Curriculum of training in Clinical Pharmacology

The Danish Health Authority
The Danish Society of Clinical Pharmacology

Preface

In accordance with § 2 in declaration no. 96 of February 2nd, 2018 regarding the education of medical specialists the Danish Health Authority approves curriculums of training of medical specialties. The curriculum of training states the theoretical and practical (clinical) skills required to attain the title of specialist of a particular medical specialty.

The curriculums of training of the medical specialties are formulated in close collaboration with the Danish Medical Societies.

The curriculum of training in the medical specialty of clinical pharmacology was formulated in collaboration with the Danish Society of Clinical Pharmacology.

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1 Introduction

In accordance with § 2 in declaration no. 96 of February 2nd, 2018 (including later amendments) regarding the education of medical specialists the Danish Health Authority approves curriculums of training of medical specialties. The curriculum of training states the theoretical and practical (clinical) skills required to attain the title of specialist of a particular medical specialty.

The curriculum of training specifies the level of competencies that has to be attained and approved throughout the education to become a medical specialist.

The Danish Medical Societies have a natural interest in ensuring that the skills listed in the curriculums of training are relevant and updated, both regarding the development of the specialties and based on the experience, that is obtained through the application of curriculums of training and educational programs throughout the course of the educational programs.

Separate curriculums of training in specific medical specialties' introductory programs and main programs have been formulated.

1.1 Transition to the new curriculum of training

The curriculum of training applies to all doctors in training, that commence their specialist training in Clinical Pharmacology after the approval of the current curriculum of training. Doctors who have begun their main program before said time still use the former curriculum of training and web log but may choose to transition to the new curriculum of training.

2 General considerations

Several rules and concepts apply to the training of medical specialists of all specialties. These rules and concepts are identical for curriculums of training of all medical specialties and for introductory programs and main programs. The Danish medical specialist education is described in detail, including the legal foundation, organization, structure, terminology etc., on the Danish Health Authority's webpage

3 Considerations regarding the medical specialty of Clinical Pharmacology

This part of the curriculum of training describes the specialty of Clinical Pharmacology, the minimum level of skills that have to be attained, and the specialty's recommendations regarding strategies of learning and mandatory assessment methods. The mandatory courses of the specialty and research training are also described. This part was formulated by the Danish Medical Societies of the specialty which is responsible for revisions in accordance with the guidelines provided by the Danish Health Authority regarding the formulation and revision of curriculums of training

3.1 Description of the medical specialty of Clinical Pharmacology

Clinical Pharmacology is a medical specialty that combines clinical experience, pharmacology, epidemiology and economy in the health sector in order to promote a rational, safe, and economical use of pharmaceutics. Clinical Pharmacology is a medical discipline that became an independent medical specialty in Denmark in 1996.

3.1.1 Demarcation between clinical pharmacology and other medical specialties

Clinical Pharmacology encompasses functions in relation to development and testing of drugs, clinical work, research, education and servicing of regional and governmental authorities, including departments that deal with regulation and prioritizing of drugs. Therefore, Clinical Pharmacology is an interdisciplinary specialty that contributes to ensure an optimal use of drugs both for the patients and from a societal viewpoint by combining medical, clinical knowledge and considerations of drug effects, safety, and economy.

3.1.2 Demarcation between the functions of the primary and secondary sector

The Clinical Pharmacological core services, counseling and guidance concerning the use of drugs, the servicing of the primary and secondary sectors of the health care system and regional and governmental authorities.

3.1.3 The organization of the specialty of clinical pharmacology

In Denmark Clinical Pharmacology is organized regionally with basis in a clinical pharmacological unit/department. This ensures an efficient, inspirational, academically evolving and functional environment that serves as framework for clinical counseling, medical specialization and research. There are five clinical pharmacological centers in Denmark:

- The Capital Region
  The Department of Clinical Pharmacology, Bispebjerg/Frederiksberg Hospital

- Region of Southern Denmark
  The Department of Clinical Biochemistry and Clinical Pharmacology, Odense University Hospital

- Region of Central Denmark
  The Department of Clinical Pharmacology, Aarhus University hospital

- Region of Northern Jutland
  The Unit of Clinical Pharmacology, Aalborg University hospital

- Region of Zealand
  The Unit of Clinical Pharmacology, Roskilde University hospital

There are currently training positions at all centers, except for that of the Region of Zealand.

According to the Danish Patient Safety Authority there are 76 medical specialists of Clinical Pharmacology in Denmark (including retirees) as of February 10th, 2019.

3.1.4 Expected tendencies of development in clinical pharmacology

The medical specialty of Clinical Pharmacology is expanding dramatically. In Denmark, the core services of pharmacology have assumed an increasingly important role both in the public and private sector. The need of medical specialists in the pharmaceutical industry has not yet been met.
The augmented number of elderly drug users, the increasing focus on rational pharmacotherapy and augmented need for prioritizing the drug treatments and to bridle the escalating drug expenses are factors that are expected to conduce an increase in the demand of clinical pharmacologists even further in the future. Furthermore, the number of options of treatments are continuously rising, both within new and existing areas of therapy.

Job options for clinical pharmacologists
Medical specialists in clinical pharmacology work in both public and private organizations.
Examples of possible places of employment:

- Departments of clinical pharmacology at hospitals
- Clinical departments at hospitals
- The Danish Health Authority
- The Danish Medicines Council
- The pharmaceutical industry
- Research units
- Administrative enheder i sundhedsvæsenet

3.2 General educational outline

3.2.1 General

Due to the interdisciplinary foundation of clinical pharmacology and the varying functions of the specialty the general, clinical profile of competencies of the pharmacologist should be developed and affected in different ways depending on the place of employment. This ensures a nuanced and contemporary development of the specialty with great opportunities for interactions between the places of education. Therefore, it is recommended that the specific doctor in training follow his or her own pharmacotherapeutic interests during the main program.

The total duration of the education besides the clinical basic education is five years. The education is comprised of two courses: An introductory program with a duration of 12 months and a main program with a duration of 48 months. The main program consists of a general clinical acquisition of competencies and an acquisition of competencies of clinical pharmacology.

3.2.2 Clinical education, in total 60 months

3.2.2.1 Training positions in the introductory program (12 months)

The acquisition of competencies of the introductory program in clinical pharmacology (section 3.3.3) should happen through training positions in the introductory program in one of the specified departments or units of clinical pharmacology in Denmark.

3.2.2.2 training positions in the main program
a. 18 months of clinical in a training position, where the doctor in training is to acquire general and specialized clinical competencies relating to the treatment of the most common acute and chronic diseases (non-surgical) (see section 3.4.3.1 and 3.4.3.2)

- The main program should consist of at least two different training positions. All training positions must have a duration of at least 6 months. The training positions must be at a hospital ward that specializes in pharmacotherapeutic treatment or in general practice. The training positions must encompass clinical work that focuses on patient contact. The doctor in training must be a part of the everyday routines including on call duties and outpatient functions. At least 6 months of the training positions must take place at a medical department that performs diagnostic workup and pharmacological treatment of most of the most common acute and chronic diseases. This is where the fundamental clinical competencies are achieved.

b. 24 months in a clinical pharmacological training position where the doctor in training will attain clinical pharmacological competencies (see section 3.4.3.3)

- The course must consist of training positions at at least two different places of employment at clinical pharmacological departments or places of employment with clinical pharmacological functions. At least one year of these training positions should take place at a clinical pharmacological department that is located in the same region as the doctor in training.

c. 6 months in a training position at either a hospital ward or in a general practice with direct patient contact and primary pharmacotherapeutic intervention, at a clinical pharmacological department or at another place of employment with clinical pharmacological functions, for instance regulatory and/or administrative authorities.

The composition of the main program:
The Regional Council for the Education of Doctors in eastern Denmark is responsible for determining, planning and posting main programs in clinical pharmacology in all of Denmark. The sequence of employments listed above can be adapted to the particular educational program.

Credit transfer:
Competencies for the clinical training positions can be achieved through training positions in certain other medical specialties, but whether a certain specialty qualifies must be individually determined. The Danish Society of Clinical Pharmacology recommends that competencies achieved more than five years prior to the start of the main program in clinical pharmacology are regarded as outdated. Therefore, credit transfer for these competencies should not be permitted.

Return days:

The doctor in training is entitled to two return days (work days at the department of origin) per six months throughout his/her training positions at other work places than the department of origin. This ensures continuity and a sense of attachment towards the specialty.

3.2.3 Theoretical education

The theoretical education focuses on the general courses and the mandatory courses of clinical pharmacology. Kindly, see section 3.3.4 for the introductory program and section 3.4.4, 3.4.5 and 3.4.6 for the main program.

3.3 Introductory program

3.3.1 Competencies

A medical specialist needs to be able to navigate several roles and competencies.
The medical specialist education in clinical pharmacology features competencies associated with the seven roles of physicians:

- Expert of medicine
- Communicator
- Collaborator
- Administrator/leader/organizer
- Promoter of health
- Academician/researcher/teacher
- Professional

The specific competencies, that needs to be evaluated during the introductory program are described in this curriculum of training. For each objective a clarification has been formulated (in the second column of the table of the curriculum of training) i.e. an exemplification of what the specific objective entails and (in *cursive*) which of the seven roles of physicians that are incorporated in that specific objective. *Please note that the objective is to be evaluated* and that an objective can be achieved even though not all of the points mentioned in the clarification have been individually assessed.

3.3.2 assessment methods of skills and learning

Learning methods
One or more recommended learning methods that the doctor in training in consultation with his/her supervisor can choose between (in the third column of the table of the curriculum of training) are listed when formulating an objective and the associated competencies. The learning methods include the following:

- Apprenticeship
- Assignment
- Course
- Mediation of knowledge
- Self-studies
- Focused clinical stay

Definitions and descriptions of methods of learning

Apprenticeship: Apprenticeship in a modern sense is a sort of reflective learning, that is not based on a separation of learning and utilization of the learned. It takes place by participation in a work community: at the department, the emergency ward, the surgical ward, outpatient clinic etc. It presupposes mutual obligations for the supervisor and apprentice in a specific, social structure that takes place through a longer period of time. Therefore, apprenticeship is a more than imitation of the behavior of a more experienced coworker.

Assignment: Independent collection of data, assessment and synthetization of an issue i.e. In direct relation to clinical work or review of scientific magazines, books and other sources to address a problem. Smaller assignments could be compilation of instructions or tasks related to the treatment of specific patients. All of these assignments must end in either a written report or with an oral presentation. In both cases the performance is assessed in collaboration with the supervisor of the doctor in training. These assignments are much less comprehensive than projects that are suited to the mandatory module of research training. The assignments typically take days to a few weeks at the most.

Course: focused, formalized theoretical learning or training in practical skills.

Mediation of knowledge: Systematically conveying technical knowledge orally or written to coworkers or other health professionals.

Self-studies: Behavior in which the individual, with or without help from others, take initiative to define his/her own needs in terms of learning, formulate his/her own learning objectives, identify resources and strategies of learning and is able to evaluate the results himself/herself.

Focused clinical stay: Short stays of a maximum duration of 4 weeks at places of employment that cover fields of work that the doctor in training have not met during his/her training position in the introductory or main program i.e. The Danish Medicines Agency, The Danish Health Authority, The Danish Poisons Information Center, the pharmaceutical industry etc.

Assessment methods

For each of the specified objectives there is a description of how the objective must be assessed (in the fourth column of the table of the curriculum of training). The assessment method is mandatory. This ensures that the evaluation is the same for all doctors in training no matter where in Denmark their education takes place.

- Competency card
- Case based discussion
- 360 degrees feedback
- Approved course
- Direct observation

Description of assessment methods:

Competency card: Maps of competencies have been formulated for most of the competencies of the catalog of competencies. They can be found at the website of the Danish Society of Clinical Pharmacology and must be specified further in the specific department's educational program and the doctor in training's educational plan. The maps of competencies can be utilized throughout the education, as they are intended to aid in the assessment of the doctor in training's progress. Final approval of the competency card is a prerequisite of approval of the competence in the web log.

Case based discussion: A structured conversation with the supervisor for the purpose of assessing the competencies and give feedback to the doctor in training within areas such as clinical reasoning, decision-making and the use of medical knowledge in relation to the treatment of patients.
360 degrees feedback: An all-around evaluation performed by coworkers of various professions of the doctor in training who are suited to evaluate the behavior of the doctor, i.e. evaluation of qualities such as corporation, communication etc.
Approved course: A written statement from the course administrator as to whether the doctor in training has met the objectives of the course or not.
Direct observation: A form of evaluation where the doctor in training is observed in clinical situations by the supervisor followed by constructive feedback.

These methods are used when determining whether a certain competence has been achieved (whether the objective has been met). Furthermore, a continuous assessment of the doctor in training's everyday work and his/her progression in achieving the competencies through dialog between the coworkers of the doctor in training and other supervisors.

3.3.3 Mandatory skills of the introductory program

This list contains the objectives and competencies, that the doctors in training as a minimum need to attain at the end of their introductory program. The competencies and the assessment methods are concretized in the educational program at the specific department.

The table underneath has three focal points: Clinic (objective 1-6), academic (objective 7-10) and administrative/regulatory (objective 11-14)

Clinical: At the end of his/her education the doctor must:

#	Objective	Clarification of objective, including roles	Recommended learning methods	Mandatory assessment methods of competencies
1	Be able to give relevant suggestions in general and specific drug-related, medical issues.	Including assessment concerning: • Pharmacodynamics • Pharmacokinetics • Drug metabolism • Interactions of drugs • Special populations • Medicine reviews *Medical expert, communicator, cooperator, promotor of health*	• Apprenticeship • Assignment • Mediation of knowledge	• Competency card And/or • Case based discussion
2	Be able to collect relevant, clinical information in	Including • Being able to collect clinical information and literature in order to	• Apprenticeship • Assignment	• Competency card And/or

	order to counsel about drugs	elucidate a specific, clinical issue • Be able to use his/her clinical, medical background to concretize the issue after conferring with a supervisor/medical specialist *Medical expert, communicator, cooperator, promotor of health, Academician/researcher/teacher*		• Case based discussion And/or • 360 degrees feedback
3	Know the indications and evaluation of drug concentration measurements (TDM)	Including • Being able to counsel and guide about the use of drug concentration measurements (TDM) after conferring with a supervisor/medical specialist *Medical expert, communicator, cooperator*	• Apprenticeship • Assignment • Mediation of knowledge	• Competency card And/or • Case based discussion
4	Know potential drug poisonings and how to treat them	Including • Knowing where to find toxicological information • Be able to refer to the proper agency (i.e. The Danish Poisons Information Center) *Medical expert, communicator, cooperator*	• Apprenticeship • Assignment • Mediation of knowledge	• Competency card And/or • Case based discussion
5	Be able to contribute to interdisciplinary, problem oriented, therapeutic conferences	Including • Presenting cases or issues i.e. pharmacological ward rounds/outpatient consultations, meetings of drug committees, conferences etc.	• Apprenticeship • Assignment	• Competency card And/or • Case based discussion And/or • Direct observation

		Medical expert, communicator, cooperator, professional		
6	Be able to establish and develop relations	Including • Communicating in a suitable work-related context • Contribute to a nice at the work environment at the work place *communicator, cooperator, professional, Administrator/leader/organizer*	• Apprentices hip	• 360 degrees feedback

Academic: At the end of his/her education the doctor must:

7	Be able to contribute to the formulation of a scientific question	Including • Making a project description that addresses and answers a scientific question • Account for relevant ethical considerations in relation to the scientific inquiry *Academician/researcher/teacher, Medical expert, communicator, promotor of health*	• Apprentices hip • Assignment • Mediation of knowledge	• Competency card And/or • Case based discussion
8	Be able to convey knowledge to coworkers, students and other health professionals and other associates	Including • Handling the basics of education • Formulating written answers and concisely convey the essence of these answers orally after conferring with a supervisor/medical specialist *Academician/researcher/teacher, communicator, cooperator, professional*	• Apprentices hip • Assignment • Mediation of knowledge	• Competency card And/or • Case based discussion And/or • 360 degrees feedback

9	Have developed an evidence-based medical assignment (EBM)	Including • Defining a problem • Search for literature in order to elucidate the issue • Produce a written product i.e. a scientific paper/article • Present the assignment orally for instance at a presentation at the department/ward *Academician/researcher/teacher, Medical expert, communicator, professional*	• Apprenticeship • Assignment • Mediation of knowledge	• Competency card
10	Be able to contribute in a relevant critical assessment of medical literature	Including • Doing a critical search of literature • Know different types of bias and confounding • Know different types of scientific studies and their strengths and limitations • Know the basic biostatistics and data processing • Assess generalizability *Academician/researcher/teacher, Medical expert*	• Apprenticeship • Assignment • Self-studies • Mediation of knowledge	• Competency card And/or • Case based discussion •

Administrative/regulatory: At the end of his/her education the doctor must:

11	Be able to utilize and prioritize one's own resources	Including • Taking responsibility for one's own learning • Handle planning of one's own time and work tasks *Administrator/leader/organizer, cooperator, professional*	• Apprenticeship • Self-studies • Course	• Competency card And/or • Case based discussion And/or • 360 degrees feedback

12	Be able to aid in guidance of decisionmakers of the health sector in drug-related issues	Including • Participating in the formulation of comments or replies to politicians, groups of health professionals or other forums • Having tasks/assignments in drug committees (under supervision) etc. *Medical expert, communicator, cooperator, promoter of health, Administrator/leader/organizer*	• Apprenticeship • Assignment • Mediation of knowledge	• Competency card And/or • Case based discussion
13	Have knowledge of the pharmaceutical legislation	Including amongst other things knowing the general content of laws regarding • Approval, marketing and ordination of drugs • Medical reimbursements • Patients' charts • Reporting side effects etc. *Medical expert/Administrator/leader/organizer*	• Apprenticeship • Self-studies • Mediation of knowledge	• Competency card And/or • Case based discussion
14	Have knowledge of the local and national administrative structure in pharmaceutics	Including • Drug committees • The Danish Medicines Counsel or similar national counsels • The Reimbursement Committee • The Danish Medicines Agency • The Danish Health Authority etc. *Administrator/leader/organizer*	• Apprenticeship • Self-studies	• Competency card And/or • Case based discussion

3.3.4 courses of the introductory program

Course in clinical guidance (pedagogy 2):
Takes place during the introductory course
Purpose:

- To provide the participants with the prerequisites to guide and supervise others
- To strengthen the participants' knowledge and skills in pedagogical organization, including identifying needs and circumstances of participants
- To give the participants a basic knowledge of which factors that promote and inhibit learning processes in order to promote a good learning environment in a department or ward
- To strengthen the participants' ability to carry out a guiding role and function - including guidance, instructing, supervising and assessing

Duration:

Two days
Information about applying and course dates can be found on the regional secretariats'' web pages:

Region of Southern Denmark:
http://www.videreuddannelsen-syd.dk/
The Capital Region:
http://www.laegeuddannelsen.dk/
Region of Northern Jutland:
http://www.videreuddannelsen-nord.dk/
The Danish Health Authority:
http://www.sst.dk/

3.4 The main program

3.4.1 Competencies

The specific competencies, that needs to be evaluated during the main program are described in this curriculum of training. For each objective a clarification has been formulated (in the second column of the table of the curriculum of training) i.e. an exemplification of what the specific objective entails and (in *cursive*) which of the seven roles of physicians that are incorporated in that specific objective. *Please note that the objective is to be evaluated* and that an objective can be achieved even though not all of the points mentioned in the clarification have been individually assessed.

3.4.2 Strategies of learning and assessment methods

Strategies of learning and assessment methods are described under introductory program (section 3.3.2)

3.4.3 Mandatory skills of the main program

This list contains the objectives and compentencies, that the doctors in training as a minimum need to attain at the end of their program. The competencies and the assessment methods are concretized in the educational program at the specific department. Objective 1-7 cover the fundamental clinical competencies, objective 8-12 cover the specialized clinical competencies, objective 13-32 cover pharmacological competencies (13-18 clinical, 19-25 academic and 26-32 administrative/regulatory)

3.4.3.1 Clinical competencies of the main program, fundamental clinical competencies

#	Objective	Clarification of objective, including roles	Recommended learning methods	Mandatory assessment methods of competencies
1	Be able to handle patient contact with empathy while taking ethical aspects into consideration	i.e. in relation to outpatient functions, writing patients' charts or other patient consultations *medical expert* *communicator* *promotor of health* *professional*	• Apprenticeship	• Direct observation • Case based discussion And/or • 360 degrees feedback
2	Be able to problematize, condense and present patient cases	For instance, in relation to rendering, debriefing of the shift, conferences and training at the department/ward *Medical expert, communicator, Academician/researcher/teacher, professional*	• Apprenticeship • Mediation of knowledge	• Direct observation • Case based discussion And/or • 360 degrees feedback
3	Identify medical issues that require guidance from a senior colleague or be presented at the department conference	For instance, issues identified in the daily clinical work *Medical expert* *communicator* *Academician/researcher/teacher* *professional* *cooperator*	• Apprenticeship • Mediation of knowledge	• Direct observation • Case based discussion And/or

				• 360 degrees feedback
4	Analyze and assess newly ordinated and current pharmacotherapy and react correspondingly	For instance, in relation to medical reviews of hospitalized patients and in the outpatient clinic *Medical expert* *Communicator* *Academician/researcher/teacher* *Promotor of health* Professional	• Apprenticeship • Mediation of knowledge • course	• Direct observation • Case based discussion
5	Carry out diagnostics, treatment and prophylactics of common, primary medical manifestations of illnesses	For instance, determining whether a patient should be referred to another specialty, knowing and following the procedures and treatment guidelines of current diseases *Medical expert* *Promotor of health* *Academician/researcher/teacher* *Administrator/leader/organizer* Professional	• Apprenticeship • Mediation of knowledge	• Direct observation • Case based discussion
6	Have a profound knowledge of the most common drugs of the department/ward, including effect, side effects, interactions etc.	For instance, in relation to medical reviews of patients, new ordinations, reporting of side effect etc. *Medical expert* *Promotor of health* *Academician/researcher/teacher* *Professional*	• Apprenticeship • Self-studies	• Direct observation • Case based discussion
7	Be able to contribute to bettering the quality of the drug treatment	For instance, in relation to medical reviews, updating the instructions of the department/ward, education in topics of clinical pharmacology,	• Assignment • Mediation of knowledge • Self-studies	• Case based discussion

	at the department	facilitating the reporting of side effects etc. *Medical expert* *Promotor of health* *Academician/researcher/teacher* *Administrator/leader/organizer* *Professional* *Cooperator*		

3.4.3.2 Clinical competencies of the main program, specialized clinical competencies

8	Be able to integrate medical history, paraclinical and objective examination and plan further examination to help diagnose, non-pharmacological and pharmacological treatment and prognosis within the most important diseases of the specialty	For instance, in outpatient consultations and hospital rounds *Medical expert* *Communicator* *Cooperator* *Academician/researcher/teacher* *Administrator/leader/organizer* *Promotor of health* *Professional*	• Apprenticeship	• Case based discussion
9	Be able to initiate, adjust and end a pharmacological treatment, including planning follow-up	Including facing challenges relating to rational pharmacotherapy in the clinical context of the department/ward i.e. patients at risk (pregnant, breast feeding, children, patients with organ dysfunction, elderly	• Apprenticeship • Assignment	• Case based discussion

		etc.), compliance, preferences of the patients and economy etc. *Medical expert* *Promotor of health* *Professional*		
10	Be able to identify signs of insufficient treatment (over-/under dosing, substance abuse and poisonings) and commence a relevant intervention	For instance, in relation to medical reviews of hospitalized patients or in the outpatient clinic *Medical expert* *Promotor of health* *Professional*	• Apprenticeship • Assignment	• Case based discussion

Administrative/regulatory: At the end of his/her education the doctor must:

11	Have knowledge of the areas of illness of the specialty and a deep understanding of the interface between the specialty and clinical pharmacology	Be able to account for the specialty's challenges regarding practicing rational pharmacotherapy, i.e. special concerns of the most used drugs of the specialty Including: • Effect assessment • Special side effects • Most common interactions and challenges relating to the population who will receive the treatment *Medical expert* *Promotor of health* *Professional*	• Apprenticeship • Self-studies	• Case based discussion
12	Contribute to the procedures of rational	i.e. updating the instructions of the department/ward, constructive/critical	• Apprenticeship • Assignment	• Case based

	pharmacotherapy at the work place	evaluation of the drug consumption and patterns, conduction of educational programs on pharmacological topics etc. *Medical expert* *Communicator* *Cooperator* *Academician/researcher/teacher* *Administrator/leader/organizer* *Promotor of health* *Professional*	• Mediation of knowledge	discussion

3.4.3.3 Clinical pharmacological competencies of the main program

Clinical: At the end of his/her main program the doctor in training must:

#	Objective	Clarification of objective, including roles	Recommended learning methods	Mandatory assessment methods of competencies
13	Autonomously guide in general and specific drug related health issues	Including assuming the role of expert concerning: • Pharmacodynamics • Pharmacokinetics • Drug effects and side effects • Drug metabolism • Interactions of drugs • Special populations • Integration of the above in a patient specific medicine review *Medical expert, communicator, cooperator, promotor of health*	• Apprenticeship • Assignment • Mediation of knowledge	• Competency card And/or • Case based discussion
14	Independently be able to collect relevant, clinical	Including • Be able to critically search for literature • Have a profound knowledge of different	• Apprenticeship • Assignment • Self-studies	• Competency card And/or

	information and literature in order to counsel about drugs	types of studies and databases and their strengths and limitations *Medical expert, communicator, cooperator, Academician/researcher/teacher, Administrator/leader/organizer*		• Case based discussion •
15	Be able to independently counsel about the indications and evaluation of drug concentration measurements (TDM)	Including • Being able to apply and integrate pharmacokinetic, pharmacodynamic and pharmacogenetic knowledge in the use and evaluation of TDM • Determining which drugs should be utilized • Indicate a strategy for rational use of TDM for a specific drug in a particular situation • Advise about the evaluation of a TDM-test of a specific patient *Medical expert, communicator, cooperator*	• Apprenticeship • course • Mediation of knowledge • Focused clinical stay	• Competency card And/or • Case based discussion and • Approved course
16	Be able to independently counsel on diagnostics and treatment of acute and chronic drug related poisonings and other toxicological issues	Including • Knowing where to find toxicological information • Knowing the toxicological potential of the drug • Determine the distinction between side effects and poisonings • Be able to assess the risk in a specific	• Apprenticeship • course • Mediation of knowledge • Focused clinical stay	• Competency card And/or • Case based discussion and • Approved course

		situation of poisoning in a patient • Based on the above be capable of advising on relevant approaches *Medical expert, communicator, cooperator, promoter of health*		
17	Be able to carry out interdisciplinary problem oriented, therapeutic conferences	Including for instance, pharmacological ward rounds/outpatient consultations, medical reviews, common conferences, participation in work groups • Presenting cases or issues i.e. pharmacological ward rounds/outpatient consultations, meetings of drug committees, conferences etc. *Medical expert, communicator, cooperator, professional, Administrator/leader/organizer*	• Apprenticeship • Mediation of knowledge	• Competency card And/or • Case based discussion
18	Be able to establish and develop relations with mutual respect	Including • Taking responsibility for one's own actions and work within the professional, legal and ethical codex of doctors • Communicating in a suitable work-related context *communicator, cooperator, professional*	• Apprenticeship • Mediation of knowledge	• 360 degrees feedback

Academic: At the end of his/her main program the doctor in training must:

#	Objective	Clarification of objective, including roles	Recommended learning methods	Mandatory assessment methods of competencies
19	Be able to contribute to a drug related research project	Including: Planning, design, initiation, organization, analyzation, interpretation and reporting a drug related project, i.e. as a minimum one of the following • A clinical drug trial • An epidemiological drug study • A pharmacoeconomic drug study • A basic pharmacological or toxicological study • A literature study *Medical expert, cooperator, Academician/researcher/teacher*	• Apprenticeship • Assignment • Self-studies • Mediation of knowledge	• Competency card And/or • Case based discussion
20	Be able to contribute to the development of clinical drug related knowledge	Including • Identifying areas with lack of knowledge • Performing a systematical search of literature to elucidate the chosen issue • Critical interpretation of the literature, critically assess the established practice and convey the following result *Medical expert, communicator, promotor of health, Academician/researcher/teacher*	• Apprenticeship • Assignment • Self-studies • Mediation of knowledge	• Competency card And/or • Case based discussion
21	Be able to critically	Including	• Apprenticeship	• Competency card

	evaluate drug trials	• Preclinical and clinical data with pharmacodynamic and pharmacokinetic end points • Epidemiological studies • Comparative drug studies • Indirect comparisons • Pharmacoeconomic studies Including methods, effect, clinical vs. statistic significance, safety and economy *Medical expert, Academician/researcher/teacher*	• Assignment • course • Mediation of knowledge	And/or • Case based discussion and • Approved course
2 2	Be able to critically assess drug related marketing and documentation	Including • Knowing the background and structure of Summary f Product Characteristics (SPC) and validation reports from drug agencies • Know the rules of drug advertisement and meetings with the pharmaceutical industry etc. *Medical expert, communicator, cooperator*	• Apprenticeship • course • Mediation of knowledge • Focused clinical stay	• Competency card And/or • Case based discussion and • Approved course
2 3	Be able to independently convey knowledge to coworkers, students, other health professionals and other associates	Including • Conducting and planning an educational program • Formulating written answers and concisely convey the essence of these answers *Medical expert, communicator, cooperator, Academician/researcher/teacher*	• Apprenticeship • Assignment • Mediation of knowledge	• Competency card And/or • 360 degrees feedback
2 4	Be able to conduct an evidence-based assessment	Including identifying areas with unsuitable treatment (i.e. uneconomical, unindicated and/or over- or undertreatment) at	• Apprenticeship • Assignment	• Competency card And/or

	of a clinical drug practice	• The specific patient • Patient populations • In the society *Medical expert, cooperator, promotor of health, Academician/researcher/teacher*		• Case based discussion
25	Know and be able to utilize different teaching methods and principles, select appropriate learnings strategies and consider the framework of teaching	Including planning education pre- and postgraduate and of other professions in clinical pharmacological subjects for example by using • Lectures • Case based teaching (PBL) • E-learning • Aids (e-polling etc.) *communicator, Academician/researcher/teacher, professional*	• Apprentices hip • Self-studies • course • Mediation of knowledge	• Competency card And/or • Approved course

Administrative/regulatory: At the end of his/her main program the doctor in training must:

#	Objective	Clarification of objective, including roles	Recommended learning methods	Mandatory assessment methods of competencies
26	Take advantage of and prioritize one's own resources	Including: • Planning work distribution for instance work schedules, instructions for work tasks etc. • Administrating one's own time and resources • Management function for younger colleagues and other professions, for instance supervisor functions	• Apprentices hip • Assignment • Self-studies	• Competency card And/or • 360 degrees feedback

		• Take responsibility for one's own career planning *communicator, cooperator, Administrator/leader/organizer*		
27	Be able to contribute to the implementation of rational pharmacotherapy	Including for example analyzing and monitoring drug use and economy, ensuring that regional and national guidelines are followed *Medical expert, communicator, cooperator, promotor of health, Administrator/leader/organizer, promoter of health, Academician/researcher/teacher, professional*	• Apprenticeship • Assignment • course • Mediation of knowledge • Focused clinical stay	• Competency card And/or • Case based discussion and • Approved course
28	Independently be able to guide decisionmakers in the health care system on issues regarding drugs	I.e. other health professionals and politicians on departmental, hospital, regional or national level *Medical expert, communicator, cooperator, Administrator/leader/organizer, professional*	• Apprenticeship • Assignment • Mediation of knowledge	• Competency card And/or • Case based discussion
29	Independently take part in the work of drug authorities	For instance, local and regional drug committees and regional or national working groups and specialist groups *Medical expert, communicator, cooperator, Administrator/leader/organizer, professional*	• Apprenticeship • Mediation of knowledge	• Competency card And/or • Case based discussion
30	Be updated on national and international drug legislation	Specifically regarding • The Geneva and Helsinki declarations • GCP	• Apprenticeship • Assignment • Self-studies • Course	• Competency card And/or • Case based

		• Advertisement permissions • Side effects • Drug reimbursement • Prescription and patients' charts *Medical expert, Administrator/leader/organizer, Academician/researcher/teacher*		discussion and • Approved course
3 1	Have a broad knowledge of local, national and international structures concerning drugs	Including • Accounting for the political organization of the health system, including Amgros, the Danish Health Authority, the Danish Medicines Agency, the Reimbursement Committee, the Danish Medicines Counsel, EMA etc. • Knowing the work methods in the above i.e. GRADE etc. • Knowledge of billing systems in the health sector *Medical expert, Administrator/leader/organizer, Academician/researcher/teacher*	• Apprenticeship • Self-studies • course • Focused clinical stay	• Competency card And/or • Approved course
3 2	Have knowledge of the ethical guidelines regarding work	Including: • Conflicts of interests and impartiality in working groups and drug committees	• Apprenticeship • Assignment • Course	• Competency card And/or • Case based

	as a health professional	• Research and publication • Correct conduct when dealing with sensitive patient information etc. *Administrator/leader/organizer, Academician/researcher/teacher, professional*		discussion and • Approved course

3.4.4 Mandatory courses of the main program

Total duration of the courses: 30 days/210 hours
Timing: Within the 60 months of training positions in the introductory and main course.
Reasoning: The courses have been selected in order to support the learning of the competencies of the catalog of competencies. To perform this function at a specialist level it is necessary to ensure that the doctor in training has completed a program that systematically support learning of the competencies of a medical expert and academician in particular, since both represent the focal point of clinical pharmacology: Advising in matters concerning clinical use of drugs. It is the view of The Danish Society of Clinical Pharmacology that the following courses ensure just that.
Objective: The objective of the courses of the specialty in clinical pharmacology is to support the learning of the competencies in the catalog of competencies and ensure focus on the patient and the clinical significance of clinical pharmacological issues. The courses primarily support the competencies of the medical expert and academician/researcher/teacher.
The evaluation of the participant's achievement of competencies: The Danish Society of Clinical Pharmacology has deselected a direct evaluation of the acquired knowledge of the mandatory courses of the specialty (se section 3.4.4.x). The acquired knowledge of the courses of the specialty can be assessed as an integrated part of the assessment of competencies. The courses are regularly evaluated in order to continuously better and adjust the specific courses.

3.4.41 Pharmacokinetics and measurement of drugs/TDM

Recommended duration: 2+2 days/28 hours
Timing: Within the 60 months of training positions in the introductory and main course.
Purpose:

- Be able to perform basic pharmacokinetic calculations
- Acquire knowledge about principles of advanced methods in pharmacokinetic calculations, including compartment models, kinetic modelling and non-linear methods
- Be able to interpret drug analyses
- Acquire knowledge about the principles of methods of drug analyses including advantages and limitations
- Be able to counsel health professionals in therapeutic drug monitoring based on analyses of drugs
- Identify drug issues in which pharmacokinetics play a part and qualify and quantify the significance and be able to integrate it in the answer

Content and methods:

- Physiological non-compartmental methods (black box analyses)
- Pharmacokinetic compartmental methods (p.o. & i.v.)
- Pharmacokinetic models when selecting the dosage
- Paths of elimination in the kinetic model
- Protein binding of drugs
- Kinetics of metabolites
- Saturation-kinetics
- Population-kinetics
- How kinetics is utilized in drug development
- Theoretical review of different principles of drug analyses methods, advantages, limitations, possible misinterpretations, specificity and sensitivity
- Review of analyses validation and ensuring analyses quality (GLP)
- Reasoning and principles of the use of drug analyses in therapeutic drug monitoring

3.4.4.2 Pharmacogenetics and genomics, metabolism and excretion of drugs

Recommended duration: 2+2 days/28 hours
Timing: Within the 60 months of training positions in the introductory and main course.
Purpose:

- Have knowledge of the principles of drug metabolism and excretion and be able to perform a qualitative and quantitative assessment of intra- and interindividual causes of variations in drug responses
- Have a basic knowledge of the significance of inheritable biological variations in the effects of drugs
- Be able to recommend drugs and dosage based on pharmacogenetic tests

Content and methods

- Basic principles of drugs' phase I and phase II metabolism
- Basic principles of drug transportation
- Cytochrome P450 gene-super family
- SLC and ABC gene super-families
- Metabolism of enzymes, model substances and in vitro-methods when exploring drug metabolisms
- Inhibition and induction of drug metabolism and transport
- The consequences of genetical variations in drug metabolizing enzymes and transporter genes
- Basic principles and quantitative assessment of renal excretion of drugs
- Drug interactions caused by inhibition and induction of drug metabolism and/or drug transport or effect on renal excretion
- The human genome's significance for discovery, development and use of drugs

3.4.4.3 Pharmacoeconomics

Recommended duration: 2 days/14 hours
Timing: Within the 60 months of training positions in the introductory and main course.
Purpose:

- Have knowledge of the basic principles of pharmacoeconomic studies
- Be able to critically assess pharmacoeconomic studies

Content and methods

- Basic concepts of health economy
- Analyze benefits and costs
- Types of pharmacoeconomic studies
- Review of certain studies by using approved checklists
- Exercises in the use of simple pharmacoeconomic analyses

3.4.4.4 Pharmacodynamics
Recommended duration: 3 days/21 hours
Timing: Within the 60 months of training positions in the introductory and main course.
Purpose:

- Have general knowledge of clinically relevant receptor pharmacology, clinical models of effect evaluation and dosage studies
- Be able to perform basic pharmacoeconomic calculations

Content and methods

- Know different types, classification, physiology, polymorphic and mathematical description of receptors
- Clinically assessment of drug effects
- The significance of the choice of efficacy parameters on the overall evaluation of drug effects
- Dosage effect models
- Practical therapeutic drug monitoring
- PK-PD-models
- Bayesian Forecast
- Clinical dosage-time-effect studies

3.4.4.5 Pharmacoepidemiology
Recommended duration: 3 days/21 hours
Timing: Within the 60 months of training positions in the introductory and main course.
Purpose:

- Have knowledge of the most important methods of pharmacoepidemiology
- Be able to critically and independently interpret pharmacoepidemiologic publications

Content and methods

- Basic concepts of epidemiology
- Association objectives
- Cohort and case-control studies
- Other designs
- Bias and confounding in pharmacoepidemiologic studies
- Use of registered data
- Methods of mapping drug use

3.4.4.6 Drug side effects and poisonings
Recommended duration: 2 /14 hours
Timing: Within the 60 months of training positions in the introductory and main course.
Purpose:

- Have thorough knowledge of the occurrence of drug side effects
- Have knowledge of the tools of handling and preventing drug side effects
- Be able to diagnose and suggest relevant treatment for poisonings

Content and methods
- Ethical and economic aspects of drug side effects
- Rational pharmacotherapy and optimized administration of drugs in relation to side effects
- Spontaneous reporting of drug side effects versus foreign models
- Ensuring quality of drugs (including minimizing medical errors, improved documentation within drug treatment)
- The Danish Medicines Agency's handling of side effects
- Drugs with enhanced risk of side effects
- Diagnostics of poisonings
- Reasoning and principles of the use of drug analyses in poisoning treatment
- Rational treatment of drug poisonings
- Doping/substance abuse
- Drug Allergies

3.4.4.7 drug development and administrative pharmacology
Recommended duration: 5 days/35 hours
Timing: Within the 60 months of training positions the introductory and main course.
Purpose:

- Have an extensive knowledge of the process of new drug development
- Have knowledge of theory and practice of clinical studies, including a basic knowledge of statistical methods of planning and analyzing randomizes clinical studies
- Know the authorities' guidelines, including GCP/GLP
- Be able to describe background, rules and practical concerns in relation to drugs' societal and trade wise significance, especially regarding national concerns

Content and methods

- Medical chemistry and drug development
- Characterization of modes of effect
- Toxicological and non-clinical pharmacology
- Metabolism studies in development of drugs
- Trial Modelling and Simulation
- The randomized clinical trial, including
  - Regulations concerning clinical testing
  - The clinical phases (phase I-III studies, planning and interpretations)
- Regulatory /legal aspects: EMA, FDA and ICH. GCP/GLP guide lines, WHO, EU-regulations
- Drug economy: health economic concerns regarding drug development, rules of drug reimbursement
- Legislation on drugs, laws of registration, rules for naming drugs
- Organization of the Danish Medicines Agency
- Concerns of responsibility and reimbursement
- Pharmacies, drug committees, drug information and rules of advertisement
- Education in pharmacology for different professions

3.4.4.8 Evidence-based pharmacotherapy
Recommended duration: 2 /14 hours
Purpose:

- Have knowledge of current methods of evaluating new medicine, evidence, prioritizing and clinical guidelines
- Be able to perform evaluation of evidence

Content and methods
- What is rational pharmacotherapy?
- How do we work to ensure a rational use of new medicine?
- What do we do when we lack controlled clinical trials?
- Which methods do we use to assess evidence in relation to hospital-oriented service to authorities (GRADE, AMSTAR etc.)?
- How to interpret effect sizes (including statistical vs. clinical significance)?
- What is the difference between efficacy and efficiency?
- Who prioritize, and how are decisions on prioritizing made?
- What role does economy play?
- How are guidelines of treatment drafted, national clinical guidelines and lists of recommendation?
- How are guidelines implemented?

3.4.4.9 Rational pharmacotherapy for groups at risk
Recommended duration: 3 days/21 hours
Timing: Within the 60 months of training positions in the introductory and main course.
Purpose:

- Be able to assess current issues in pharmacotherapy with special risks i.e. children, elderly, pregnant, breastfeeding, organ failure, critical illness, while considering the relation between practice and scientific studies

Content and methods

- Groups at risk, other demands of documentation
- Kidney insufficiency and drug dosage
- Pharmacotherapy and liver disease, including liver failure
- Choice of drugs and dosage when treating children and elderly
- Usage of drugs when pregnant or breastfeeding
- Drug related issues concerning the treatment of critically ill patients, including multiple organ failure
- Polypharmacy – often groups at risk
- Bariatrics

3.4.4.10 Teaching methods and pedagogics in clinical pharmacology

Recommended duration: 2 days/14 hours
Purpose:

- Be able to use current teaching methods and pedagogics in clinical pharmacology at a level that greatly surpasses the learning course of the clinical basic education

Content and methods

- What can one know of didactics and teaching pedagogics as a new teacher?
- How and why must one activate one's audience when teaching?
- Which methods can one utilize when teaching students, clinicians, experts etc.?
- How does one convey difficult and fact heavy material to the audience in an accessible way?
- How does one organize an area of learning that improves the audience's activation and learning?
- How does one deal with an antagonistic audience?
- Introduction to future teaching methods, including other media, gamification, e-polling etc.

3.4.5 Mandatory research training

Recommended duration: In total 20 days/148 hours
Timing: Within the first 36 months at a training position in the main program, but ended at least six months before the end of the main program

Objective:
The module of research training is specially aimed at training the role of academician towards development of a professional approach to solving the tasks of the health sector. The research

training contributes to building and strengthening competencies so the medical specialist can seek, assess and develop new knowledge, and so the medical specialist can utilize and convey this knowledge to critically evaluate the established practice within one's own specialty and adjacent specialties.

The overall time frame of the research training module in the introductory and main program is 20 days. 10 days of theoretical courses and 10 days of practical work.

The content of the theoretical courses can vary between regions but must always take at least 10 days. The rest of the research training module is an integrated part of the clinical and theoretical work. These 10 days are used for an independent project. The research training module has a duration of 148 hours, or 20 regular work days spread over the different course dates, independent work with a minor project and guidance and evaluation.

There must always be an individual arrangement in place as to the completion of the research training module. The arrangement must be made between the doctor in training and his/her main supervisor. The arrangement must be approved by the supervisor in charge of the research training module.

Assessment method: Overall evaluation of the program.

3.4.6 General courses of the main program

SOL-courses (SOL I, II & III)
Course in "the organization and management of the health sector", named SOL, I, II and III, take place during the main program. The doctor in training must himself/herself sign up for the SOL courses. SOL I and III are arranged locally by the three regions and consist of two course dates. SOL II is arranged by the Danish Health Authority.
Information about registration and timing can be found on the secretariats' web pages:

Region of Southern Denmark:
http://www.videreuddannelsen-syd.dk/wm130348
The Capital Region:
http://www.laegeuddannelsen.dk/
Region of Northern Jutland:
http://www.videreuddannelsen-nord.dk/
The Danish Health Authority:
http://sundhedsstyrelsen.dk/

4 Documentation

Documentation of acquired competencies and approved course happen through logbog.net

5 Useful links

The Danish Health Authority:

Sundhedsstyrelsen, special- og videreuddannelse

The Organisation of Danish Medical Societies
Organisationen af lægevidenskabelige selskaber (Tidligere Dansk Medicinsk Selskab)

the regional secretariats of education:
North:
Videreuddannelsesregion Nord
South:
Videreuddannelsesregion Syd
East:
Videreuddannelsesregion Øst

The Danish Society of Clinical Pharmacology
Dansk Selskab for Klinisk Farmakologi www.kliniskfarmakologi.dk