National Training Requirements

Denmark

Specialty
Clinical Pharmacology
(Klinisk farmakologi)

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Note: This is not a legally binding document. Any current official regulations must be obtained from the responsible National Medical Association or other organisation in charge of the training of medical specialists.
Description of specialist physician training in Clinical Pharmacology

Danish Health Authority
Danish Society for Clinical Pharmacology
April 2015
Preface

According to section 2 of Executive Order No. 1257 of 25 October 2007 on the training of specialist doctors, the National Board of Health approves target descriptions for medical specialties. Target descriptions indicate the theoretical and practical clinical competencies required to obtain permission (authorisation) as a specialist in the particular field.

Target descriptions for medical specialties are prepared in close collaboration with the scientific societies.

The goal description for the specialist medical training in clinical pharmacology has been prepared in collaboration with the Danish Society for Clinical Pharmacology.

April 2015
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1 Introduction

Pursuant to section 2 of the Danish National Board of Health’s Executive Order No. 1257 of 25 October 2007 (with subsequent additions) concerning the training of specialist doctors, the National Board of Health approves the target descriptions for the medical specialties.

The target descriptions specifying the minimum competencies to be achieved and approved during the doctor’s training as specialist.

The scientific societies have a natural academic interest in ensuring that the competencies in the target descriptions are relevant and updated, partly in relation to the professional development of the specialties, and partly based on the experience gained from the use of goal descriptions and education programs in the education process.

Separate goal descriptions are prepared for specialty-specific introductory and main courses.

1.1 Transition to new statement of aims

As a rule, the Danish Society of Clinical Pharmacology recommends that the new target description applies to all trainees who start training in clinical pharmacology in the first half of 2015 and beyond. Doctors who started the main course before this time use previous target description and logbook, but may choose to change to the new target description.

2 The general part

There are a number of legal rules and concepts for specialist medical training that are the same for all target descriptions, across specialisations and for introductory and main education.

The Danish specialist doctor's training is detailed on the National Board of Health’s website, including legal basis, organisation, structure, actors, terminology and more.

3 The specialty-specific part

This part of the course description describes the specialisation, the minimum competencies and the recommendations of the specialisation for learning strategies and established compulsory assessment skills. Also described are the mandatory specialty-specific courses and research training. This part has been prepared by the scientific society of the specialty, which is also responsible for auditing in accordance with the National Board of Health’s guidance on the preparation and revision of statement of aims.

3.1 Description of the specialty

Clinical pharmacology is a medical specialty that combines clinical, pharmacological, epidemiological and health-economic expertise on a scientific basis in order to promote the
rational, safe and economical use of medicines. Clinical pharmacology is a medical science discipline that only gained status as an independent medical specialty in Denmark in 1996.

3.1.1 Delimitation from others specialties
Clinical pharmacology includes functions related to clinical service, research and teaching, and these functions actually constitute an integrated device. Thus, it is a distinct interdisciplinary specialty that will help ensure optimal use of drugs, both from the patient’s perspective and from the perspective of society. Thus, any drug-using specialty will be subject to clinical pharmacology.

3.1.2 Delimitation between functional management in the primary and secondary sector
The clinical pharmacological basic benefit—counselling and guidance on all matters relating to the use of drugs—serves the healthcare primary sector as well as the secondary sector.

3.1.3 Organisation of the specialisation
Clinical pharmacology in Denmark is organized regionally based on a clinical pharmacological centre. This ensures an efficient, inspiring, professionally developing and well-functioning environment that provides a framework for clinical services, specialist medical training and research. There are five clinical pharmacological centres in Denmark:

- **Region Hovedstaden**
  Department of Clinical Pharmacological (FARM) Bispebjerg Hospital
- **Region Syddanmark**
  Clinical Pharmacology in Odense
  - Department of Clinical Biochemistry and Pharmacology, OUH and
  - Research Unit for Clinical Pharmacology, IST, SDU
- **Region Midtjylland**
  Department of Clinical Pharmacology, Aarhus University Hospital
- **Region Nordjylland**
  Clinical Pharmacology Unit, Aalborg University Hospital
  (The unit has not yet I-doctors)
- **Region Sjælland**
  Clinical Pharmacology Unit, Roskilde Hospital
  (The unit still does not participate in the training of specialist doctors)

In addition, the Department of Rational Pharmacotherapy under the National Board of Health is a natural partner in the practice of clinical pharmacology.

According to the National Board of Health Authorisation, there are 62 specialist physicians in clinical pharmacology in Denmark. (Not all active activists per 1 March 2015)
3.1.4 Expected development trends in clinical pharmacology

The subject of clinical pharmacology is expanding globally, and in Denmark, where the subject has barely reached its final location, either in the healthcare sector or in the private sector, the need is hardly covered. Some specialist physicians in clinical pharmacology are also specialists in another specialty, e.g. general medicine, internal medicine, oncology, psychiatry, neurology, anaesthesiology or paediatrics. In the future, newly appointed specialists in clinical pharmacology are expected to exceptionally have another specialty. The increased focus on rational pharmacotherapy and the increasing drug costs for new medical treatments to be prioritized is further expected to increase the need for clinical pharmacologists.

3.1.5 Job opportunities for clinical pharmacologists

Specialists in clinical pharmacology work in both public and private organisations. Examples of places of employment include:

- Clinical hospital departments (primarily specialist physicians and several specialties)
- Departments of clinical pharmacology
- The National Board of Health (including the Institute of Rational Pharmacotherapy)
- The pharmaceutical industry
- Research units
- Regions

3.2 Description of the overall training progress

3.2.1 In general

The interdisciplinary foundation for clinical pharmacology and the multifaceted functional area of the subject results in the general clinical proficiency profile of the specialist in clinical pharmacology that advantageously allows any variation. It is therefore recommended that the individual training-seeking physician take on own special pharmacotherapeutic interests through a focused clinical stay/study on a pharmacotherapeutic-“heavy” specialised unit.

The total duration of the training in addition to the clinical basic training is 5 years. The education consists of an introductory course of 12 months and a 48-month main course. The main education consists of general clinical competence acquisition and a clinical pharmacological skills acquisition.

3.2.2 Clinical training totalling 60 months

a. Acquiring competencies corresponding to the introduction position in clinical pharmacology (12 months)
   - These are acquired through employment in an introductory position in clinical pharmacology at one of the listed clinical pharmacology centres in Denmark.

b. Acquiring general clinical skills related to the treatment of the most common acute and chronic, primary medical diseases (24 months).
   - These are acquired through employment at internal medical departments where the trainee is included in the general routine functions including emergency preparedness and outpatient clinic functions. Up to 12 months of this employment can take place
in other departments with pharmacotherapeutic interventions as primary treatment or in general practice. Recruitment must include clinical work with patient contact as bearing element.

c. Acquisition of clinical pharmacological skills.
   • These are acquired through employment at institutions with clinical pharmacological functions (24 months).
   • Counselling-related skills are thought to be acquired through appointments at departments of clinical pharmacology with clinical counselling.
   • Additional competencies may also be acquired through appointments by the National Board of Health, the pharmaceutical industry, at a clinical hospital department with clinical pharmacological function (wide use of drugs). After individual discretion, these competences may be obtained during employment, at a basic pharmacology institute or at a drug-related research laboratory.

Main training course structure:
It is the Regional Council for Doctor’s Further Education in the region East, which establishes detailed planning and provides the main training courses in the specialty, covering the entire country. In general, the main course of training will be structured as follows:

First year: Recruitment at an internal medical department with acquisition of competencies similar to those described for the joint internal medical introductory training. During this appointment, the trainee will be included in the solution of the training department’s tasks on similar to the department’s other doctors. During the appointment, the target description, competence card and logbook (documentation) for the common internal medical introductory training, which can be found on the Danish Society for Internal Medicine’s website: www.dsim.dk, are applied.

Note: The course in clinical guidance has been completed in connection with the introductory course in clinical pharmacology and should not be repeated.

Second year: Appointment at a clinical pharmacology department or other institution as under c) is indicated to contribute to the clinical pharmacology specialist medical training.

Third year: Appointment(s) at internal medical departments or other departments with pharmacotherapeutic interventions as primary treatment or in general practice. During this/these appointment(s), the trainee will be included in the solution of the training department/practice tasks similar to the department’s other doctors. The appointment must include clinical work with patient contact as a support element. The individual appointments must be of at least 6 months duration.

Fourth year: Appointment at a clinical pharmacology department (ward). The training director at the ward ensures that the acquisition of clinical pharmacological skills is fully implemented. Each training applicant must agree on how to divide the competency between the 2 year employment site and the associated institutions and the ward.
3.2.3 **Theoretical training**

The theoretical training is concentrated in the general courses and the special-specific compulsory courses. Please refer to section 3.3.4 for the introductory training, see section 3.4.4, 3.4.5 and 3.4.6 for the main course.

### 3.3 Introductory Training

#### 3.3.1 Skills

The overall competence of a specialist can be broadly defined as the ability to master a variety of roles and properties, such as:

- Medical expert / physician
- Communicator
- Collaborator
- Administrator / leader / organiser
- Health Promoter
- Academic / researcher and teacher
- Professional

Specialist medical training in clinical pharmacology contains competencies related to all seven roles.

The individual competencies to be assessed are described here to show which of the 7 medical roles are included in the competence. When formulating a competence, the action verb has been chosen, which clearly describes how the competence is to be achieved. There are recommended learning strategies that the department can choose from. On the other hand, the method(s) listed for competence assessment is mandatory. This makes them nationwide so the competence is assessed in the same way wherever the doctor is trained and assessed.

#### 3.3.2 Learning strategies and competence assessment methods

For each of the goals set, how the goal can be achieved with one or most of the learning methods (table column 3), including:

- Apprenticeship
- Department’s training
- Assignment
- Tutorial
- Course
- Feedback
- Reflection
- Group discussion
- Knowledge transfer
- Learning diary
- Self-study
- Focused clinical internship or study stay
Definition and description of learning methods:

Apprenticeship: in the modern sense is a form of reflective learning, not based on a separation between learning and the use of what was learned. It takes place through participation in a practice fellowship: in the department, the emergency room, the operation hall, the ambulatory centre, etc. It entails mutual obligations for master and apprentice in a specific social structure and takes place over a long period of time. Master’s training is thus more than imitation of a more experienced colleague’s behaviour.

Department’s training: is internally organised teaching in the department aimed at all doctors, and where both specialist physicians and educational doctors can teach. May be associated with meetings with colleagues presenting and discussing scientific issues.

Assignment: to independently collect data, evaluate and synthesise a problem. Might be directly related to clinical work or examination of scientific journals, books, and other sources such as the internet, to illustrate a problem. There will typically be an analysis work based on HTA or EBM principles. There may also be actual literature studies, as well as organisational analyses with horizontal and vertical analyses of organisation, communication and resource allocation. Minor tasks may be the preparation of instructions, or assignments related to the treatment of a specific patient. All these tasks are completed either with a written report or oral presentation. In both cases, the performance is evaluated jointly with the educator’s supervisor. The nature of these assignments will be of a significantly smaller extent than projects that are suitable for the compulsory research training module. The assignments will typically be solved in days to a maximum of few weeks.

Self-study: is a form of behaviour in which individuals, with or without the help of others, take the initiative to define their learning needs, formulate their learning goals, identify resources and learning strategies for this, and evaluate the results themselves.

Group discussion: is defined as informal collegial professional activities, which are discussed internally or externally in forums by education-seeking doctors, be it with or without the presence of specialist doctors. For example, regular journal clubs or informal forums may be in connection with meetings of the Danish Society for Clinic Pharmacology.

Reflection: is the trainee’s conscious mind about learning and actions. Feedback: is reflection led by another person, such as a supervisor or other education-seeking doctors (2-way reflection)

Knowledge transfer: is systematically communicating academic knowledge orally or in writing to colleagues or other health professionals.

Course: is a learning framework for formalised theoretical knowledge dissemination or learning of practical skills.

Learning diary: is writing notes for own use on a clinical course that in any way deviates from the expected, with the aim to analyse and assess the situation for own learning. Such notes may be based on a supervisor’s interview (review of the learning diary).

Focused internship or study stay: Short-term stay of not more than 4 weeks at occupational sites covering work areas, which the education-seeking doctor does not gain through employment in introductory or main training.

Competence assessment methods
For each of the goals set, describe how the goal is to be assessed (table column 4):

- Structured observation in the clinic / structured observation
- Structured interview / supervisor interview
- 360-degrees feedback
- Audit of records
- Audit
- Evaluation of assignment
- Approved course
- Review of the learning diary

**Definition and description of competence assessment methods:**

*Structured observation in the clinic / structured observation of skills and behaviour:* is directed to see how a trainee performs a skill and, based on criteria already determined, assess the skill level.

*Structured interview / supervisor interview:* is a conversation between the trainee and the supervisor dealing with previously defined areas, but which does not have the characteristic of a hearing.

*360-degree feedback:* an evaluation performed by several health professionals and on the basis of predefined criteria.

*Audit of records:* is a structured assessment of the quality of records on the basis of predefined criteria.

*Audit:* is a systematic qualitative evaluation of the trainee’s work practice.

*Evaluation of assignment:* is a written opinion from the supervisor or other competent person about the quality of a performed assignment.

*Approved course:* is a written statement from the course leader that the course participant has met the course’s objectives.

*Review of the learning diary:* is a conversation between the trainee and the supervisor based on the learning diary in order to determine how far the trainee has progressed in the training process and to plan its further progress.

These methods are used in determining whether a given competence has been acquired (the goal achieved). In addition, there will be a continuous assessment of the trainee in clinical work assessing the progression in the acquisition of competence and in connection with dialogue with supervisors, where the educator can, at his/her own discretion, also introduce self-assessment and reflections on practice as well as other matters noted in the learning diary.

There are too many goals to make concrete, i.e. an example of what the goal in question includes. *Note that this is the goal to be evaluated.* Consequently, the definitions must be known, but a goal can be achieved without the fact that all the points mentioned under concretisation have been separately evaluated.

See if possible Skills Assessment Methods – An Overview, published by the Danish Health Authority in 2013.

### 3.3.3 Introductory training compulsory skills

This list indicates the skills the doctor should at least possess at the end of introductory education. Competences and related assessment methods are concretized by using competence cards, help forms or other specific guidance, where clarifies which of the 7 roles that are included.
**Introductory training**

*Medical expert / Medical practitioner*

After completion of introductory training, the doctor should be able to:

<table>
<thead>
<tr>
<th>#</th>
<th>Goal</th>
<th>Specification of goals, incl. roles</th>
<th>Learning methods</th>
<th>Competence assessment methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Consult under supervision in general and specific drug-related health-related issues</td>
<td>Including on matters relating to pharmacodynamics, pharmacokinetics, drug metabolism, drug interactions, special patient populations. <em>Medical expert / medical practitioner, communicator, collaborator</em></td>
<td>Apprenticeship and group discussion and self-study and assignment.</td>
<td>Observation of skills and behaviour and assessment of tasks.</td>
</tr>
<tr>
<td>2</td>
<td>Participate in interdisciplinary problem-oriented therapeutic conferences and in drug committee work</td>
<td><em>Medical expert / medical professional, communicator, collaborator</em></td>
<td>Apprenticeship and group discussion.</td>
<td>Observation of skills and behaviour.</td>
</tr>
<tr>
<td>3</td>
<td>Contribute to evaluation of scientific trials in terms of:</td>
<td><em>Medical expert / medical practitioner, collaborator, academic / researcher and teacher</em></td>
<td>Apprenticeship and group discussion and self-study and assignment.</td>
<td>Observation of skills and behaviour and assessment of tasks.</td>
</tr>
<tr>
<td>#</td>
<td>Goal</td>
<td>Specification of goals, incl. roles</td>
<td>Learning methods</td>
<td>Competence assessment methods</td>
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<tr>
<td>4</td>
<td>Advise on indications and interpretation of drug concentration measurements (TDM)</td>
<td>Medical expert / medical practitioner, communicator, collaborator</td>
<td>apprenticeship and group discussion and self-study and assignment</td>
<td>observation of skills and behaviour and assessment of tasks</td>
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<tr>
<td>5</td>
<td>Contribute to evaluation of drug-related marketing and documentation material</td>
<td>Medical expert / medical practitioner, communicator, collaborator</td>
<td>apprenticeship and group discussion and self-study and assignment</td>
<td>observation of skills and behaviour and assessment of tasks</td>
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**Communicator**

After completion of introductory training, the doctor should be able to:

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<th>Competence assessment methods</th>
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<tr>
<td>6</td>
<td>Collect relevant clinical information for use in drug counselling</td>
<td>Communicator, collaborator, medical expert / medical practitioner</td>
<td>Apprenticeship and assignment and/or group discussion</td>
<td>Structured observation and assessment of task</td>
</tr>
<tr>
<td>#</td>
<td>Goal</td>
<td>Specification of goals, incl. roles</td>
<td>Learning methods</td>
<td>Competence assessment methods</td>
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<tr>
<td>7</td>
<td>Provide gathered knowledge to colleagues, students, other health professionals and other partners under supervision</td>
<td>Communicator, collaborator</td>
<td>Apprenticeship and assignment and/or group discussion</td>
<td>Structured observation and assessment of task</td>
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</table>

**Collaborator**

After completion of introductory training, the doctor should be able to:

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<th>Competence assessment methods</th>
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<tr>
<td>8</td>
<td>Utilise human resources in interdisciplinary teams in relation to tasks related to scientific issues, educational or administrative tasks</td>
<td>Collaborator; leader, administrator, organiser,</td>
<td>Apprenticeship and/or group discussion and/or reflection and/or feedback</td>
<td>Structured observation and/or 360-degree feedback</td>
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**Leader/administrator**

After completion of introductory training, the doctor should be able to:

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<th>Specification of goals, incl. roles</th>
<th>Learning methods</th>
<th>Competence assessment methods</th>
</tr>
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<tbody>
<tr>
<td>9</td>
<td>Take care of work planning, including work allocation, staff roster and instructions for tasks</td>
<td>Leader/administrator/ organiser</td>
<td>Apprenticeship and assignment and/or feedback</td>
<td>Structured observation and assessment of task</td>
</tr>
</tbody>
</table>
**Health promoter**
After completion of introductory training, the doctor should be able to:

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<th>Learning methods</th>
<th>Competence assessment methods</th>
</tr>
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<tbody>
<tr>
<td>10</td>
<td>Work to promote understanding for, the meaning of and implementation of rational pharmacotherapeutic behaviour</td>
<td>Health promoter, communicator</td>
<td>Group discussion and/ reflection and/ feedback</td>
<td>Structured observation</td>
</tr>
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</table>

**Academician**
After completion of introductory training, the doctor should be able to:

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<th>#</th>
<th>Goal</th>
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<th>Learning methods</th>
<th>Competence assessment methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Keep up-to-date with the latest knowledge in clinical pharmacology</td>
<td>Academic / researcher and teacher</td>
<td>Self-study and task and/or feedback</td>
<td>Structured observation and assessment of task</td>
</tr>
<tr>
<td>12</td>
<td>Participate in the dissemination of professional clinical pharmacological information to others</td>
<td>Academic / researcher and teacher, communicator</td>
<td>Dissemination of knowledge and/or task and/or feedback</td>
<td>Structured observation and assessment of task</td>
</tr>
<tr>
<td>13</td>
<td>Actively utilise everyday-life situations for apprenticeship, dialogue and reflection to optimise learning for oneself and others</td>
<td>Academic / researcher and teacher, communicator, professional</td>
<td>Group discussion and/or reflection and/or feedback</td>
<td>Structured observation and/or 360-degree feedback</td>
</tr>
<tr>
<td>14</td>
<td>After completion of introductory training, the trainee under supervision should be able to contribute to the formulation of scientific questions</td>
<td>Including preparation of one project description for answering the scientific question explaining relevant ethical considerations in connection with the scientific study</td>
<td>Self-study and assignment</td>
<td>Structured observation and assessment of task</td>
</tr>
</tbody>
</table>

**Professional**
After completion of introductory training, the doctor should be able to:

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<th>Learning methods</th>
<th>Competence assessment methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>Evaluate own knowledge and skills and recognize own personal academic and ethical boundaries</td>
<td><em>Professional</em></td>
<td>Group discussion and/or reflection and/or feedback</td>
<td>Structured supervisor interview</td>
</tr>
<tr>
<td>16</td>
<td>Develop and implement personal training strategy</td>
<td><em>Professional</em></td>
<td>Group discussion and/or reflection and/or feedback</td>
<td>Structured supervisor interview</td>
</tr>
</tbody>
</table>
3.3.4 **Courses in introductory training**

**Course in clinical guidance (Pedagogy 2):**
To be held in introductory training.

**Purpose:**
- To provide participants with the necessary qualifications to guide and supervise others
- To enhance participants’ knowledge and skills in pedagogical organisation – including identification of participant assumptions and participant needs
- To provide participants with a basic knowledge of which factors promote and inhibit learning processes in order to promote a good learning environment in a department
- To strengthen the participants’ prerequisites to take care of the role and function of the supervisor – including advice, instruction, supervision and evaluation

**Duration:**
2 days residential

Information about registration and course dates can be found on the regional secretariat's websites:

Region South: [http://www.videreuddannelsen-syd.dk/wm130348](http://www.videreuddannelsen-syd.dk/wm130348)
Region East: [http://www.laegeuddannelsen.dk/](http://www.laegeuddannelsen.dk/)
Region North: [http://www.videreuddannelsen-nord.dk/](http://www.videreuddannelsen-nord.dk/)
Danish Health Authority: [http://sundhedsstyrelsen.dk/](http://sundhedsstyrelsen.dk/)

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3.4 **The main program**

3.4.1 **Skills**

The individual competencies to be assessed are described here, so that it is stated which of the 7 medical roles are included in the competence. When formulating a competence, the action book is chosen which clearly describes how the competence is to be achieved. There are recommended learning strategies that the department can choose from. On the other hand, the method(s) listed for competence assessment is mandatory. This makes them nationwide so the competence is assessed in the same way wherever the doctor is trained and assessed.

3.4.2 **Learning strategies and competence assessment methods**

Learning methods and competence assessment methods are described in the introductory training (section 3.3.2).
3.4.3 **Compulsory competences for the main program**

3.4.3.1 **Internal medical skills in the main training program (1st year)**
During the recruitment, the objective description, competence card and logbook (documentation) are used for the common internal medical introductory training, which can be found on the Danish Society for Internal Medicine’s website: [www.dsim.dk](http://www.dsim.dk).

3.4.3.2 **Clinical pharmacological competencies in the main training program (2nd and 4th year)**
This list sets out the competencies the specialist doctor must possess, with the emphasis on the skills, the recommended learning strategies and the required compulsory assessment methods. Competences and the related assessment methods are concretised by using help forms, skills cards or other specific guidance, and links to these are given. This text clarifies which of the 7 medical roles are included.
Clinical pharmacological competencies in the main training program (2\textsuperscript{nd} and 4\textsuperscript{th} year of training)

*Medical expert / Medical practitioner*

After graduation, the doctor should be able to:

<table>
<thead>
<tr>
<th>#</th>
<th>Goal</th>
<th>Concretisation, incl. roles</th>
<th>Learning methods</th>
<th>Competence assessment methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Evaluate the clinical effect of and paraclinal evidence of the effects, side effects and interactions of drugs</td>
<td><em>Medical expert / medical practitioner</em></td>
<td>Apprenticeship and self-study and course</td>
<td>Structured observation and approved course</td>
</tr>
<tr>
<td>2</td>
<td>Advise on diagnosis and treatment of acute and chronic drug poisoning and other toxicological issues</td>
<td>including advising on drug analyses in this context</td>
<td>Apprenticeship and/or course and/or group discussion and/or dissemination of knowledge and/or task</td>
<td>Structured observation and/or approved course and/or evaluation of task</td>
</tr>
<tr>
<td>3</td>
<td>Advise in general and specific drug-related health issues related to drugs application</td>
<td>Including advice regarding:  - pharmacodynamics  - pharmacokinetics  - pharmacogenomics  - drug metabolism  - drug interactions  - special patient populations:  o children  o pregnancy and breastfeeding</td>
<td>Apprenticeship and self-study and specialty-specific courses and analysis tasks and/or interdisciplinary</td>
<td>Audit and/or structured observation and evaluation of task/project and approved courses</td>
</tr>
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<tr>
<td>4</td>
<td>Understand individualised pharmacotherapy based on the individual patient’s phenotypic and genotypic characteristics that are relevant for drug treatment</td>
<td>Medical expert / medical practitioner, communicator</td>
<td>Apprenticeship and/or group discussion and/or dissemination of knowledge</td>
<td>Structured observation and approved course</td>
</tr>
<tr>
<td>5</td>
<td>Participate in interdisciplinary problem-oriented therapeutic conferences</td>
<td>Medical expert / medical practitioner, collaborator</td>
<td>Apprenticeship and self-study and/or course</td>
<td>Structured observation and/or evaluation of task and/or 360-degree feedback</td>
</tr>
<tr>
<td>6</td>
<td>Advise healthcare decision makers in drug-related issues</td>
<td>Medical expert / medical practitioner, communicator</td>
<td>Apprenticeship and/or group discussion and/or interdisciplinary projects and/or task</td>
<td>Structured observation and/or evaluation of task</td>
</tr>
</tbody>
</table>

- o older patients
- o patients with organ failure
- Medical expert / medical practitioner, communicator
- Apprenticeship and/or group discussion and/or dissemination of knowledge
- Structured observation and approved course
- Structured observation and/or evaluation of task and/or 360-degree feedback
- Medical expert / medical practitioner, collaborator
- Apprenticeship and self-study and/or course
- Apprenticeship and/or group discussion and/or interdisciplinary projects and/or task
<table>
<thead>
<tr>
<th></th>
<th>Conduct an evidence-based evaluation of a standard drug</th>
<th>Medical expert / medical practitioner, academic / researcher and teacher</th>
<th>Apprenticeship and/or group discussion and/or task</th>
<th>Evaluation of task Structured supervisor interview</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>Provide functions in drug committees</td>
<td>Medical expert / medical practitioner, collaborator</td>
<td>Apprenticeship and/or group discussion and/or task</td>
<td>Structured observation and evaluation of task</td>
</tr>
<tr>
<td>8</td>
<td>Advise on individual pharmacological treatment using drug concentration measurements (TDM)</td>
<td>Including be able to apply and integrate pharmacokinetic, pharmacodynamics and pharmacogenetic knowledge in the practice and interpretation of TDM advise and guide on drug concentration measurements indicate a strategy for the rational use of TDM for a given drug Medical expert / medical practitioner, communicator</td>
<td>Course and/or apprenticeship and/or task</td>
<td>Approved course audit and/or structured observation and/or evaluation of task</td>
</tr>
<tr>
<td>9</td>
<td>Can participate in parts of planning, design, initiation, organisation, coordination, implementation, analysis, interpretation and reporting of a drug-related project</td>
<td>Including at least one of the following: o a clinical drug trial o a pharmaco-epidemiological study o a pharmacoeconomic study</td>
<td>Apprenticeship and/or task and/or course</td>
<td>structured observation and/or evaluation of task and/or approved course</td>
</tr>
<tr>
<td></td>
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</tr>
</tbody>
</table>
| **11** | Critically evaluate pharmacodynamic, pharmacokinetic, pharmacoepidemiological, pharmacoeconomic and comparative drug trials | Including the following:  
- methodology  
- effect  
- safety  
- economics  
*Medical expert/medical practitioner, academic/researcher and teacher* | Course and self-study and task | Approved course and structured observation and evaluation of task |
| **12** | Critically evaluate drug-related marketing and documentation material from the pharmaceutical industry | Including Summary of Product Characteristics (SPC):  
*Medical expert/medical practitioner* | Apprenticeship self-study and/or task | Structured observation and/or evaluation of task |
| **13** | Oriented and familiar with drug legislation nationally, in EU and internationally | - Geneva, Sydney, Helsinki and Tokyo declarations  
- GCP rules  
- Marketing authorisation  
- Adverse events register  
- MedInfo  
- DSKF hearings  
- Rules for grants  
- Ethical rules  
*Medical expert/medical practitioner* | Course and self-study | Approved course and structured observation |
**Communicator**
**After graduation, the doctor should be able to:**

<table>
<thead>
<tr>
<th>#</th>
<th>Goal</th>
<th>Concretisation, incl. roles</th>
<th>Learning methods</th>
<th>Competence assessment methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>Include the patient’s perspective in diagnostic and therapeutic decisions</td>
<td>In relevant forums, include the patient’s perspective in diagnostic and therapeutic decisions (e.g. in LLK, MedInfo or Mini-MTV)</td>
<td>Apprenticeship</td>
<td>Structured observation in clinical work</td>
</tr>
<tr>
<td></td>
<td><strong>Communicator</strong></td>
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</tr>
</tbody>
</table>
| 15 | Establish contact and communicate in a form of trust, empathy, situational awareness and situational sensibility relative to patients, relatives, colleagues, other healthcare professionals and other collaborators | Including:  
- integrate conversational techniques and personal presence in the communication situation  
- demonstrate requirements and expectations for communication  
- dispose and manage a call in relation to time and purpose  
  
**Communicator, collaborator**                                                                                                                                                                                                                      | Apprenticeship and course and/or feedback | Structured observation and approved course                          |
|    |                                                                      |                                                                                                                                                                                                                                                                                              |                                |                                                                      |
| 16 | Collect relevant clinical information for medical advice            | Including:  
- coordinate and manage the collection of documentation and background for the use of advisory cases relating to medicines  
  
**Communicator, medical expert /medical practitioner**                                                                                                                                                                                              | Apprenticeship and task         | Structured observation and evaluation of task                      |
<table>
<thead>
<tr>
<th>#</th>
<th>Goal</th>
<th>Concretisation, incl. roles</th>
<th>Learning methods</th>
<th>Competence assessment methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>17</td>
<td>Provide collected knowledge to patients, colleagues, students, other emergency staff and other collaborators</td>
<td><em>Communicator</em></td>
<td>Apprenticeship and task and course</td>
<td>Structured observation and evaluation of task and approved course</td>
</tr>
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<tr>
<td>18</td>
<td>Provide drug-related knowledge to the public, media and decision-makers</td>
<td><em>Communicator</em></td>
<td>Task and/or feedback and/or dissemination of knowledge</td>
<td>Structured observation and/or evaluation of task</td>
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</tbody>
</table>

**Collaborator**
After graduation, the doctor should be able to:

<table>
<thead>
<tr>
<th>#</th>
<th>Goal</th>
<th>Concretisation, incl. roles</th>
<th>Learning methods</th>
<th>Competence assessment methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>19</td>
<td>Determine therapeutic drug treatment plans in collaboration with members of an interdisciplinary treatment team</td>
<td><em>Collaborator, medical expert / medical practitioner</em></td>
<td>Task and/or apprenticeship and/or group discussion and/or feedback</td>
<td>360-degree feedback and/or evaluation of task</td>
</tr>
<tr>
<td>#</td>
<td>Goal</td>
<td>Concretisation, incl. roles</td>
<td>Learning methods</td>
<td>Competence assessment methods</td>
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<tr>
<td>20</td>
<td>Establish and develop cooperative relations, based on mutual respect, in relation to colleagues, other healthcare professionals and other collaborator</td>
<td>Including: utilise human resources in interdisciplinary teams in relation to tasks related to patient care, scientific issues, educational or administrative tasks – while contributing with their own professional expertise Collaborator, medical expert / medical practitioner, professional</td>
<td>Task and/or apprenticeship and/or group discussion and/or feedback</td>
<td>360-degree feedback and/or evaluation of task</td>
</tr>
</tbody>
</table>

*Leader / administrator*

After graduation, the doctor should be able to:

<table>
<thead>
<tr>
<th>#</th>
<th>Goal</th>
<th>Concretisation, incl. roles</th>
<th>Learning methods</th>
<th>Competence assessment methods</th>
</tr>
</thead>
</table>
| 21 | Actively participate in the department meeting | • Structured presentation of a patient’s history  
• manage meeting presentation and follow-up to meeting decisions Leader / administrator / organiser, collaborator | Apprenticeship and interdisciplinary course | Structured observation in the clinic |
<table>
<thead>
<tr>
<th></th>
<th>Task Description</th>
<th>Leader / Administrator / Organiser</th>
<th>Task and/or apprenticeship evaluation and/or feedback and/or reflection</th>
<th>Evaluation of task</th>
</tr>
</thead>
<tbody>
<tr>
<td>22</td>
<td>Identify and undertake medical tasks involving a management function</td>
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<td></td>
<td>Including at least one of the following:</td>
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<tr>
<td></td>
<td>• course management and organization</td>
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<td></td>
<td>• interdisciplinary discussion forums</td>
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<td></td>
<td>• drug committee work</td>
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<tr>
<td></td>
<td>• educational planning</td>
<td></td>
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<tr>
<td></td>
<td>• management of interdisciplinary cooperation</td>
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<tr>
<td></td>
<td><em>Leader / administrator / organiser, professional</em></td>
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<tr>
<td>23</td>
<td>Design written work instructions</td>
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<td></td>
<td><em>Leader / administrator / organiser</em></td>
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<tr>
<td>24</td>
<td>Take care of work planning, including work allocation, schedules and instructions for work tasks</td>
<td><em>Leader / administrator / organiser</em></td>
<td></td>
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</tr>
<tr>
<td>25</td>
<td>Motivate and engage employees and collaborators</td>
<td><em>Leader / administrator / organiser, collaborator, professional</em></td>
<td>Apprenticeship and/or feedback and/or reflection and/or group discussion</td>
<td>Structured observation</td>
</tr>
</tbody>
</table>
### Utilise and prioritise resources in relation to counselling, education and research

**Leader/administrator/organiser, academic/researcher and teacher, professional**

- Apprenticeship and/or task and/or feedback and/or reflection and/or group discussion
- Structured observation and/or evaluation of task

### Manage own resources and own time in balancing counselling, financial aspects, other activities and own quality of life

**Leader/administrator/organiser, professional**

- Apprenticeship and/or feedback and/or reflection and/or group discussion
- Structured observation

---

**Health promoter**

After graduation, the doctor should be able to:

<table>
<thead>
<tr>
<th>#</th>
<th>Goal</th>
<th>Concretisation, incl. roles</th>
<th>Learning methods</th>
<th>Competence assessment methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>28</td>
<td>Work for and advise on how health can be promoted in individual patients, patient populations and in society based on evidence-based knowledge of prevention</td>
<td>concretisation, incl. roles</td>
<td>Apprenticeship and/or test and/or feedback and/or reflection and/or group discussion and/or dissemination of knowledge</td>
<td>Structured observation and/or evaluation of task</td>
</tr>
<tr>
<td></td>
<td>Work to promote understanding, the importance and implementation of rational pharmacotherapeutic behaviour</td>
<td>Apprenticeship and/or task and/or feedback and/or reflection and/or group discussion</td>
<td>Structured observation and/or evaluation of task</td>
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<td>---</td>
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<td>---------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>29</td>
<td>Health promotor, medical expert / medical practitioner, communicator</td>
<td></td>
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<tr>
<td></td>
<td>Work to increase the transparency of the pharmaceutical market</td>
<td>Participate in the debate for increased transparency (e.g. writing letters, articles or discussing with drug consultants)</td>
<td>Apprenticeship and/or task and/or feedback and/or reflection and/or group discussion</td>
<td>Structured observation and/or evaluation of task</td>
</tr>
<tr>
<td>30</td>
<td>Health promotor, medical expert / medical practitioner, communicator</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Identify health-related areas with over and under treatment</td>
<td>Apprenticeship and/or task and/or feedback and/or reflection and/or group discussion</td>
<td>Structured observation and/or evaluation of task</td>
<td></td>
</tr>
<tr>
<td>31</td>
<td>Health promotor, medical expert / medical practitioner</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Academic**

After graduation, the doctor should be able to:

<table>
<thead>
<tr>
<th>#</th>
<th>Goal</th>
<th>Concretisation, incl. roles</th>
<th>Learning methods</th>
<th>Competence assessment methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>32</td>
<td>Keep up to date with the latest knowledge in clinical pharmacology</td>
<td><em>Academic/researcher and teacher, professional</em></td>
<td>Self-study and/or task</td>
<td>Supervisor interview and/or evaluation of task</td>
</tr>
<tr>
<td>33</td>
<td>Make a critical assessment of medical literature</td>
<td><em>Academic/researcher and teacher</em></td>
<td>Self-study and task and/or group discussion and course</td>
<td>Evaluation of task and approved course</td>
</tr>
<tr>
<td>34</td>
<td>Make an evidence-based assessment of clinical drug practice</td>
<td><em>Academic/researcher and teacher</em></td>
<td>Self-study and task and/or group discussion</td>
<td>Structured observation and/or evaluation of task</td>
</tr>
<tr>
<td>35</td>
<td>Provide professional clinical pharmacological information based on knowledge of learning and competence development</td>
<td><em>Academic/researcher and teacher, communicator</em></td>
<td>Self-study and task and/or dissemination of knowledge and/or group discussion and course</td>
<td>Structured observation and/or evaluation of task and approved course</td>
</tr>
<tr>
<td>36</td>
<td>Select appropriate learning strategies for the education of students, younger doctors, colleagues and other professional groups, including considering the framework for teaching</td>
<td>Self-study and task and/or dissemination of knowledge and/or group discussion and course</td>
<td>Structured observation and/or evaluation of task and approved course</td>
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</tr>
<tr>
<td>37</td>
<td>Actively use everyday situations for apprenticeship, dialogue and reflection to optimize learning for oneself and others</td>
<td>Reflection and feedback and/or task and/or dissemination of knowledge and/or group discussion</td>
<td>Structured observation</td>
<td></td>
</tr>
</tbody>
</table>

*Academic/researcher and teacher, leader/administrator/organiser*
<p>| 38 | Contribute to the development of clinical drug-related knowledge | Including: formulate a problem based on current clinical practice within own specialty and detect present and missing knowledge about the problem; conduct a systematic search in the research literature to illuminate a given problem; critically interpret the results of the literature and apply the results to a critical assessment of established practice; assess any organizational, economic and ethical consequences of changing practice through the use of knowledge acquired by the literature review; communicate the results of the literature review and any other considerations. <em>Academic/researcher and teacher, communicator</em> | Self-study and task and/or dissemination of knowledge and/or group discussion and course | Evaluation of task and approved course |
| 39 | Identify research-relevant areas | <em>Academic/researcher and teacher</em> | Self-study and/or task and/or dissemination of knowledge and/or group discussion | Structured observation and/or evaluation of task |</p>
<table>
<thead>
<tr>
<th></th>
<th>Contribute to the development of scientific knowledge</th>
<th>Self-study an and/or dissemination of knowledge and/or group discussion</th>
<th>Structured observation and/or evaluation of task</th>
</tr>
</thead>
<tbody>
<tr>
<td>40</td>
<td><strong>Academic/researcher and teacher</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Explain relevant ethical considerations in connection with the scientific study</td>
<td>Self-study an and/or dissemination of knowledge and/or group discussion and approved course</td>
<td></td>
</tr>
<tr>
<td>41</td>
<td><strong>Academic/researcher and teacher, communicator</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Apply basic theory of science in relation to research</td>
<td>• Research training • Journal clubs</td>
<td>Structured observation and/or evaluation of task and approved course</td>
</tr>
<tr>
<td>42</td>
<td><strong>Academic/researcher and teacher</strong></td>
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</tr>
</tbody>
</table>

32
**Professional**  
After graduation, the doctor should be able to:

<table>
<thead>
<tr>
<th>#</th>
<th>Goal</th>
<th>Concretisation, incl. roles</th>
<th>Learning methods</th>
<th>Competence assessment methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>43</td>
<td>Assess own professional ability and openly declare limitations of this and seek assistance when needed.</td>
<td></td>
<td>Apprenticeship and/or departmental training and/or theoretical course</td>
<td>360-degree feedback and/or approved course</td>
</tr>
<tr>
<td></td>
<td><strong>Professional</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>44</td>
<td>Establish, maintain and terminate a professional relationship, including taking responsibility for your own business and practicing in accordance with the professional, regulatory and ethical code that doctors are bound by</td>
<td></td>
<td>Apprenticeship and reflection and feedback and/or group discussion</td>
<td>Structured observation</td>
</tr>
<tr>
<td></td>
<td><strong>Professional</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 45 | Take care of ethical questions in clinical practice                 | • storage and disclosure of information  
• obtain informed consent  
• obtaining power of attorney  
• observe confidentiality  
• manage resource allocation  
• handle conflicts of interest  
• clarify conflicts of interest in collaborative situations involving commercial interests | Apprenticeship and reflection and feedback and/or group discussion | Structured observation |
|    | **Professional**                                                     |                              |                                                          |                                                   |
| 46 | Continuously evaluate knowledge and skills and recognize own personal academic and ethical limitations | Including:  
- use appropriate strategies to maintain and develop professional competence  
- achieve a balance between personal and professional roles and personal responsibility  
- recognize the areas of strength and limitation  
- involve other competent forces in task solving | Apprenticeship and reflection and feedback and/or group discussion | Structured supervisor interview |
3.4.3.3 Supplementary clinical / internal medical competencies in the main part of training (3rd year)

Recruitment(s) at internal medical departments or other departments with pharmacotherapeutic interventions as primary treatment or general practice with acquisition of additional clinical skills and competencies. During this appointment(s), the trainee is included in the execution of the training department’s duties on the same basis as the department’s other doctors. Recruitment must include clinical work with patient contact as a support element. Individual appointments must be of a duration of at least 6 months.

After completion of specialist medical training, the doctor should be able to:

<table>
<thead>
<tr>
<th>#</th>
<th>Goal</th>
<th>Roles</th>
<th>Competence assessment methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>47</td>
<td>Problematize, condense and present a medical history</td>
<td>Medical expert, academic</td>
<td>360-degree feedback or approved course</td>
</tr>
<tr>
<td>48</td>
<td>Identify professional issues that require presentation at the department meeting</td>
<td>Medical expert, professional</td>
<td>Structured observation</td>
</tr>
<tr>
<td>49</td>
<td>Analyze and evaluate prescribed pharmacotherapy and act on it.</td>
<td>Medical expert</td>
<td>Structured observation, audit or short/structured interview of competence</td>
</tr>
<tr>
<td>50</td>
<td>Take care of diagnostics, treatment, prophylaxis of common primary medical manifestations*, including determining whether the patient should be referred to other specialists or not.</td>
<td>Medical expert, Health promoter</td>
<td>Generic skills card / structured interview</td>
</tr>
</tbody>
</table>

These goals can be optionally obtained in connection with attendance work, ambulatory function, guard work or practice work.

*At 12 months of employment in the relevant specialty, knowledge of the treatment of at least 10 of the most common disease manifestations in the specialty is expected. At 6 months of employment in the specialty, knowledge of the treatment of at least 5 of the most common disease manifestations in the thesis is expected.

Goal 4 must be approved on the basis of the 10 competence cards.
**Generic skills card for case-based structured interviews**

The structured interview is a conversation between the trainee and a supervisor. The competency card is used as an interview guide to ensure that during the conversation important aspects of the competence are addressed. The 10 different disease manifestations are discussed using the same skills card (which is thus copied in 10 copies). Each disease manifestation can be discussed from 1–3 patient courses.

**Doctor’s name:** ____________________________  **Date:** ___________

**Disease manifestation:** ____________________________

<table>
<thead>
<tr>
<th><strong>Competence goal H-doctor</strong></th>
<th><strong>Evaluation</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Must be improved</td>
</tr>
<tr>
<td><strong>1</strong> Relevant presentation of the problem, action and outcome of the observed patients.</td>
<td></td>
</tr>
<tr>
<td><strong>2</strong> Can discuss course and outcome based on detailed evidence-based knowledge about disease, diagnosis, complications and treatment.</td>
<td></td>
</tr>
<tr>
<td><strong>3</strong> Consider and initiate possible deviations from the general treatment plan, justifying these and taking into account significant comorbidity.</td>
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<tr>
<td><strong>4</strong> Have relied on ethical conditions.</td>
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</tr>
<tr>
<td><strong>5</strong> Diagnostics, treatment, interpretation of vital parameters and examination results for the patient course.</td>
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<tr>
<td><strong>6</strong> Critically relate to the entire patient process, including the assessment of the need for reassessment and treatment adjustment.</td>
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<tr>
<td><strong>7</strong> Differential diagnostic considerations.</td>
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<tr>
<td><strong>8</strong> Opinion on need for further referral / conference with other specialists, follow-up check, rehabilitation, and secondary prophylaxis.</td>
<td></td>
</tr>
<tr>
<td><strong>9</strong> Information for patient and relatives on prognosis, consequences, precautions including further plan. Ensures that relevant partners get information about progress and plan.</td>
<td></td>
</tr>
</tbody>
</table>

**Possible comments:** __________________________________________________________

The entire competency goal is approved:

________________________________________

*Date*

*Name and signature of evaluating supervisor*
3.4.4 **Compulsory specialty-specific courses**

Total duration of course: 28 days / 196 hours

Time allocation: Within the 48 months of employment in the main course of training.

The rationale: Resolving course series are selected with the specific purpose of supporting learning of the competencies in the competence catalogue. Special attention has been paid to competencies of medical experts and academics, as these competences represent the core of the profession: counselling in relation to pharmaceuticals. In order to perform this function at the specialist level, it is imperative to ensure that the trainee has undergone a course that systematically supports the learning of skills as a medical expert and academic.

It is the Danish Society of Clinical Pharmacology's opinion that this is ensured by the following course features.

The goal: The purpose of the specialty-specific course series is to support the learning of the competencies in the competence catalogue, primarily the competencies of medical expert / physician and academic / researcher and teacher.

Evaluation of the course’s competence achievement: The Danish Society of Clinical Pharmacology has chosen a direct assessment of acquired knowledge in connection with the individual courses. The evaluation of the individual courses takes place at the response level with subsequent systematic analysis with the aim of improving and adapting the individual courses on an ongoing basis. Voting for the specialty-specific courses is considered as an integral part of the competence evaluation.

### 3.4.4.1 Pharmacokinetics and measurements of drugs / TDM

Recommended duration: 2 + 2 days / 28 hours

Time allocation: Within the 60 months of employment in the introductory training and the main course of training.

Purpose:
- Introduce participants to the prerequisites for a kinetic analysis of drug metabolism and to review compartmental analysis, kinetic modelling and nonlinear kinetic methods.
- To gain knowledge of the principles, benefits and limitations of different drug analysis methods and to use drug analyses for therapy.

Content and methods:
- Physiological non-compartmental methods (black-box analyses).
- Pharmacokinetic compartmental models (p.o. & i.v).
- Pharmacokinetic models in the choice of dose regimen.
- Elimination routes in relation to kinetic model.
- Protein binding of drugs.
- Metabolites kinetics.
- Saturation kinetics.
- Population kinetics.
- How to use kinetics in drug development.
- Theoretical review of the principles, advantages, limitations, misinterpretation possibilities, specificity and sensitivity of different drug analysis methods.
- Examination of analysis validation and assurance of analytical quality (GLP).
- Rationale and principles for the use of drug analyses for therapy.
Assessment: The Danish Society of Clinical Pharmacology has opted for a direct assessment of acquired knowledge in connection with the individual courses. The evaluation of the individual courses takes place at a response level with subsequent systematic analysis with the aim of improving and adapting the individual courses on an ongoing basis. Voting for the specialty-specific courses is considered as an integral part of the competence evaluation.

3.4.4.2 Pharmacogenetics/-genomics, metabolism and excretion of drugs

Recommended duration: 2 + 2 days / 28 hours

Time allocation: Within the 60 months of employment in the introductory training and the main course of training.

Purpose:
- To provide participants with a general knowledge of the principles of drug metabolism and excretion, including methods for qualitative and quantitative assessment as well as factors relevant to individual variations.
- To provide participants with a general knowledge of the importance of genetic biology for variation in the effects of drugs.

Content and methods:
- General principles for drug oxidation, conjugation and hydrolysis.
- Cytochrome P450 gene superfamily.
- Stereoselective metabolism.
- Isozyme-specific metabolism, modelling agents, human liver microsomal preparation.
- In vitro techniques for drug metabolism investigation.
- Inhibition and induction.
- Individual variations in metabolism.
- Genetic oxidation and acetylation polymorphisms.
- General principles for renal excretion of drugs.
- Interaction in renal excretion.
- Quantitative assessment of renal excretion.
- Cellular drug transport.
- Drug interactions (including tobacco and food products).
- The importance of the human genome for discovery, development and use of drugs.
- Genetic variation with regard to pharmacodynamics of drugs.

Assessment: The Danish Society of Clinical Pharmacology has opted for a direct assessment of acquired knowledge in connection with the individual courses. The evaluation of the individual courses takes place at a response level with subsequent systematic analysis with the aim of improving and adapting the individual courses on an ongoing basis. Voting for the specialty-specific courses is considered as an integral part of the competence evaluation.
3.4.4.3 Pharmacoeconomics
Recommended duration: 2 days / 14 hours
Time allocation: Within the 60 months of employment in the introductory training and the main course of training.
Purpose:
- To introduce participants to basic principles of pharmacoeconomic studies and to provide prerequisites for assessing the subject area's literature.
Content and methods:
- Basics of health economics.
- Analysis of utility and costs.
- Pharmacoeconomic study types.
- Review of selected studies.
- Exercises in the implementation of simple pharmacoeconomic analyses.
Assessment: The Danish Society of Clinical Pharmacology has opted for a direct assessment of acquired knowledge in connection with the individual courses. The evaluation of the individual courses takes place at a response level with subsequent systematic analysis with the aim of improving and adapting the individual courses on an ongoing basis. Voting for the specialty-specific courses is considered as an integral part of the competence evaluation.

3.4.4.4 Pharmacodynamics
Recommended duration: 3 days / 21 hours
Time allocation: Within the 60 months of employment in the introductory training and the main course of training.
Purpose:
- Provide participants with a thorough introduction to clinically relevant receptor pharmacology, clinical models for effect evaluation and dose/efficacy studies.
Content and methods:
- Recipe concept with regard to types – classification – physiology – polymorphism – measurement description.
- Clinical evaluation of the effects of medicinal products.
- Meaning of choice of effect parameter for the overall assessment of a drug’s effect.
- Dose/effect models.
- Practical therapeutic management of drugs used in relevant therapeutic areas.
- PK-PD models.
- Bayesian Forecast.
- Clinical dose/time efficacy studies.
Assessment: The Danish Society of Clinical Pharmacology has opted for a direct assessment of acquired knowledge in connection with the individual courses. The evaluation of the individual courses takes place at a response level with subsequent systematic analysis with the aim of improving and adapting the individual courses on an ongoing basis. Voting for the specialty-specific courses is considered as an integral part of the competence evaluation.
3.4.4.5 **Pharmacoepidemiology**
Recommended duration: 3 days / 21 hours
Time allocation: Within the 60 months of employment in the introductory training and the main course of training.
Purpose:
- To introduce participants in the most important methods of pharmacoepidemiology.
Content and methods:
- Epidemiological basic concepts.
- Association measures.
- Cohort and case-control studies.
- Other designs.
- Bias and confounding in pharmacoepidemiological studies.
- Use of registry data.
- Methods for mapping drug use.

Assessment: The Danish Society of Clinical Pharmacology has opted for a direct assessment of acquired knowledge in connection with the individual courses. The evaluation of the individual courses takes place at a response level with subsequent systematic analysis with the aim of improving and adapting the individual courses on an ongoing basis. Voting for the specialty-specific courses is considered as an integral part of the competence evaluation.

3.4.4.6 **Drug side effects and poisoning**
Recommended duration: 2 days / 14 hours
Time allocation: Within the 60 months of employment in the introductory training and the main course of training.
Purpose:
- To give participants a thorough knowledge of the occurrence of drug side effects.
- To give the trainees knowledge about tools for handling and preventing drug side effects.
- To gain knowledge about the diagnosis and treatment of poisoning.
Content and methods:
- Ethical and health-economic aspects of drug side effects.
- Rational pharmacotherapy and optimised drug administration in relation to side effects.
- Spontaneous reporting of drug side effects versus foreign models.
- Quality assurance in the field of medicine (including minimisation of medication errors, improved documentation in drug treatment).
- Medicinal Products Agency’s handling of side effects.
- Medicinal products with special risk of side effects.
- Poisoning diagnostics.
- Rationale and principles for the use of drug analyses for poisoning treatment.
- Rational treatment of drug poisoning.
- Doping / abuse.
- Drug allergies.
Assessment: The Danish Society of Clinical Pharmacology has opted for a direct assessment of acquired knowledge in connection with the individual courses. The evaluation of the individual courses takes place at a response level with subsequent systematic analysis with the aim of improving and adapting the individual courses on an ongoing basis. Voting for the specialty-specific courses is considered as an integral part of the competence evaluation.

3.4.4.7 Lægemiddeludvikling og administrativ farmakologi

 Recommended duration: 5 days / 35 hours

Time allocation: Within the 60 months of employment in the introductory training and the main course of training.

Purpose:
- To give the participants a broad knowledge of the development process for new drugs.
- Introduce participants in the theory and practice of clinical trials, including a basic introduction to statistical methods for planning and analysis of randomized clinical trials.
- To familiarize the students with the regulatory framework of the authorities, including GCP/GLP.
- Describe the background, rules and practical issues regarding the social and commercial importance of drugs, especially with regard to national conditions.

Content and methods:
- Medicinal chemistry and drug development.
- Characterisation of effect profile.
- Toxicology and non-clinical pharmacology.
- Metabolism studies in the development of drugs.
- Trial modelling and simulation.
- The randomised clinical trial, including
  - clinical trials
  - the clinical phases (Phase I–III studies, planning and interpretation)
  - ethical aspects (cooperation between industry, hospital and universities).
- Medicine economics: Health economics considerations on drug development, drug addiction rules.
- Medicines Act, registration regulations, delivery circulars, rules for drug names.
- Building the Danish Medicines Agency.
- Liability and compensation.
- Pharmacy, drug committees, pharmaceutical information, advertising rules.
- Education in pharmaceuticals for different professions.

Assessment: The Danish Society of Clinical Pharmacology has opted for a direct assessment of acquired knowledge in connection with the individual courses. The evaluation of the individual courses takes place at a response level with subsequent systematic analysis with the aim of improving and adapting the individual courses on an ongoing basis. Voting for the specialty-specific courses is considered as an integral part of the competence evaluation.
3.4.4.8 Evidence-based pharmacotherapy
Recommended duration: 3 days / 21 hours
Time allocation: Within the 60 months of employment in the introductory training and the main course of training.

Purpose:
- Introduce participants to current issues regarding the most common pharmacotherapy, taking special account of the relationship between practice and scientific evidence (evidence-based treatment).

Content and methods:
- What is rational pharmacotherapy?
- What do we do when we lack clinically controlled studies?
- Consistency between knowledge-based therapy and common practice.
- Is newer therapy better than old?
- What measures can optimise rational pharmacotherapy?
- How can health professionals’ behaviour in relation to medication be affected?
- Educational methods of behavioural change.
- Current pharmacotherapeutic areas will be reviewed for evidence-based therapy.
- How much effect is required (including statistical versus clinical significance, economics).
- Efficacy versus efficiency.

Assessment: The Danish Society of Clinical Pharmacology has opted for a direct assessment of acquired knowledge in connection with the individual courses. The evaluation of the individual courses takes place at a response level with subsequent systematic analysis with the aim of improving and adapting the individual courses on an ongoing basis. Voting for the specialty-specific courses is considered as an integral part of the competence evaluation.

3.4.4.9 Rational pharmacotherapy for risk groups
Recommended duration: 3 days / 21 hours
Time allocation: Within the 60 months of employment in the introductory training and the main course of training.

Purpose:
- To introduce participants into current issues regarding pharmacotherapy at special risks, such as children, elderly, pregnancy, breastfeeding, organ failure, critical illness, taking into account the relationship between practice and scientific evidence (evidence-based treatment).

Content and methods:
- Risk groups, other requirements for documentation.
- Drug dosage in renal insufficiency.
- Pharmacotherapy in liver disease, including hepatic failure.
- Choice of medicines and dosage for the treatment of children and the elderly, respectively.
- Use of medicines during pregnancy and lactation.
- Drug-related issues in the treatment of critically ill patients, including multi-organ failure.
- Polypharmacy - often in risk groups.
- Bariatrics
Assessment: The Danish Society of Clinical Pharmacology has opted for a direct assessment of acquired knowledge in connection with the individual courses. The evaluation of the individual courses takes place at a response level with subsequent systematic analysis with the aim of improving and adapting the individual courses on an ongoing basis. Voting for the specialty-specific courses is considered as an integral part of the competence evaluation.

### 3.4.5 Compulsory research training

**Recommended duration:** 20 days / 148 hours  
**Time allocation:** Within the last 36 months of employment in the main education position, completed at least 6 months for the completion of the main course.

**Purpose:**
The research training module is specifically aimed at training the academic role, towards the development of a professional approach to solving the healthcare tasks. The research training should help build and strengthen competencies so that the specialist may independently seek, assess and develop new knowledge, and that the specialist may apply and disseminate this knowledge for critical assessment of established practice within his own specialty and related subjects.

The overall time frame allocated for a research training module in specialist medical training is 20 days. 10 days for theoretical course activities and 10 days for practical activities.

The content of the theoretical course activity may vary between regions, but it should always be at least 10 days. The remaining part of the research training module forms part of the clinical and theoretical work. These 10 days are used for an independent project. For the individual doctor, the research training module thus has a total of 148 hours corresponding to 20 normal working days by course days, self-employment with a smaller project, as well as guidance and assessment.

**Skills assessment method:** Overall assessment of both the course and the final report.

### 3.4.6 Generelle kurser

**SOL course (SOL I, II & III):**
Course in “Health Organization and Management”, referred to as SOL I, II and III, is located under the main training. The younger doctor in training must register for the SOL courses themselves. SOL I and III are organised locally by the 3 education regions and comprise 2 course days. SOL II is an internship course held by the National Board of Health.  
Information about registration and course dates can be found on the regional secretariat’s websites:
Region South:
http://www.videreuddannelsen-syd.dk/wm130348
Region East:
http://www.laegeuddannelsen.dk/
Region North:
http://www.videreuddannelsen-nord.dk/
Danish Health Authority:
http://sundhedsstyrelsen.dk/
4 Documentation section

This part contains the documentation that will be available for the doctor in the introductory position to have this approved and that the doctor in the main raining can obtain specialist medical attention.

The documentation consists of:

1. Approval of compulsory competences and courses
2. Certificate of timely completed education in the medical training and for the research training module

Note: This section has not been translated from the original as it contains logbooks and other forms. Please refer to the original document if you need these materials (see note at the end of this text.)
5 Useful links

5.1 General links

Danish National Board of Health, Special and Further Education

The Organisation of Medical Societies (formerly Danish Medical Society)

The regional further education secretariats:
Continuing Education Region North
Continuing Education Region South
Continuing Education Region East

5.2 Specialty-specific links

Danish Society of Internal Medicine www.dsim.dk

Danish Society of Clinical Pharmacology www.kliniskfarmakologi.dk

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