

## National Training Requirements

### GERMANY

(Medical Chamber North Rhine)

Field of Pharmacology:

Specialty (1)

**Clinical Pharmacology**

(Klinische Pharmakologie)

Specialty (2)

**Pharmacology and Toxicology**

(Pharmakologie und Toxikologie)

Language: English

Deposited: 30.12.2017

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On behalf of (organisation): UEMS Section of Pharmacology Executive Committee

MAAs responsible for training: 17 State Medical Chambers in Germany

This document based on: [www.aekno.de](http://www.aekno.de)  
Medical Chamber North Rhine (*Ärztammer Nordrhein*)

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.

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## 1. Introductory Remarks (UEMS Section of Pharmacology)

Regulations detailing the training of medical specialists in Germany are not the responsibility of a national medical association, but are the responsibility of the medical chambers of the 16 German federal states. Thus, each of the 17 German medical chambers (The state of Northrhine-Westphalia has two separate, regional medical chambers) regulate specialised training independently.

Training for becoming a medical specialist in the field of Pharmacology can be obtained by following either one of two possible versions of curriculum, ending in the diploma as specialist of either Clinical Pharmacology (*Fachärztin/Facharzt für Klinische Pharmakologie*) or Pharmacology and Toxicology (*Fachärztin/Facharzt für Pharmakologie und Toxikologie*).

For both specialties, the curriculum has a duration of 5 years, of which the first 2 years are a common basic training for both specialties; part of this basic training is a 12-month training in direct patient care, which also can be obtained in a recognised training institution during the second, specialised part of training. The curriculum of specialised training in either Clinical Pharmacology or Pharmacology and Toxicology has a duration of 3 years.

The following text describing the structure and content of training for specialists in Clinical Pharmacology and specialists in Pharmacology and Toxicology has been translated from the website of the Medical Chamber North Rhine (*Ärztchamber Nordrhein*) and the documents linked there as of the day of retrieval (29.12.2017).<sup>1</sup>

UEMS Section of Pharmacology

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<sup>1</sup> <https://www.aekno.de/page.asp?pageID=9613> [29.12.2017]

## 2. Structure and Content of Training

### **2.1 Basic training: Pharmacology**

#### *2.1.1 Definition*

The field of pharmacology includes the study of drug effects, development and application of drugs, the study of the effects of foreign substances in animal experiments and in humans, the evaluation of therapeutic benefits, the detection of side effects, as well as counselling and support of those working in the prevention and treatment of patients when administering drug-based therapeutic and diagnostic measures.

#### *2.1.2 Aim of Training*

The aim of training in the field of pharmacology is the acquisition of specialist competencies in (1) Clinical Pharmacology and (2) Pharmacology and Toxicology after completion the mandatory training periods and acquisition of the mandatory training contents.

#### *2.1.3 Duration of Basic Training in Pharmacology*

24 months of basic training under supervision of an authorised instructor at a training institution pursuant to § 5 (1) sentence 1<sup>2</sup>, of which

- 12 months may be completed in areas of direct patient care, which can also be completed during the period of specialized training

#### *2.1.4 Content of Basic Training in Pharmacology*

Acquisition of knowledge, experiences and skills in

- the pharmacological, toxicological, clinical and experimental bases in the research, development and application of medicines
- the detection of adverse drug reactions, including drug legislation and the reporting system
- risk assessment including risk management and communication on the use of active substances and pollutants
- advice and support to physicians involved in screening and treatment on the therapeutic and diagnostic use of drugs and clinical toxicology

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<sup>2</sup> Regulations on Specialised Training of the Medical Chamber North Rhine.

- biometrics/biomathematics, drug epidemiology and application research
- the pharmacokinetics and toxicokinetics as well as the dynamics of relevant active substances and pollutants
- the basics of biochemical, chemical, immunological, microbiological, molecular-biological, physical and physiological working and detection methods
- the foundations of animal experimental research for the analysis of effects of drugs and poisons, including the experimental production of disease states for drug effect analysis and drug testing
- the detection and treatment of acute emergencies and poisoning including life-saving measures to maintain vital signs and resuscitation

### **3.1 Specialised training (1): Clinical Pharmacology**

#### *3.1.1 Aim of Training*

The aim of the specialised training is based on the basic training, the acquisition of the specialist competence Clinical Pharmacology after completion of the mandatory training periods and acquisition of the mandatory training contents.

#### *3.1.2 Duration of Training*

24 months basic training in the field of Pharmacology and

36 months specialised training as a Specialist in Clinical Pharmacology under supervision of an authorised instructor at a training institution pursuant to § 5 (1) sentence 1<sup>3</sup>, of which up to

- 12 months may be completed in areas of direct patient care

#### *3.1.3 Content of Training*

Acquisition of knowledge, experiences and skills in

- the ethical and legal basis for clinical drug testing in humans
- the basics of clinical pharmacology as well as biometric methods, the reporting systems and the different types of clinical trials

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<sup>3</sup> Regulations on Specialised Training of the Medical Chamber North Rhine.

- the analysis of drug effects in humans including the phases of clinical trials
- the testing of new medicinal products in humans and the necessary studies in phases I to IV, including the preparation of study plans
- the evaluation of medicinal products in collaboration with the attending physician or clinical trial physician
- counselling in drug therapy and poisoning
- the planning of multicenter long-term trials, as well as of clinical study designs and evaluation criteria for efficacy testing
- drug determinations in body fluids and their evaluation
- the authorization of medicinal products
- drug safety and benefit / risk assessment
- the application of Good Clinical and Laboratory Practice (GCP, GLP) guidelines in clinical trials
- the pharmaceutical, preclinical and clinical development of new substances
- the evaluation of therapeutic procedures and research reports
- the creation, evaluation and implementation of therapeutic guidelines

Defined investigation and treatment procedures:

	Quantity
• participation in clinical trials, planning and conduct of controlled clinical trials of medicinal products in humans in Phases I–IV	
Phase I – III .....	100
Phase IV .....	300
• human pharmacokinetic studies including bioavailability, metabolism, excretion and pharmacokinetic interaction studies .....	10
• assessment of dose / concentration–response relationships .....	25
• evaluation of reports on drug safety including benefit / risk assessment .....	100
• therapeutic drug monitoring, pharmacogenetic analyses .....	100

## **4.1 Specialised training (2): Pharmacology and Toxicology**

### *4.1.1 Aim of Training*

The aim of the specialised training is based on the basic training, the acquisition of the specialist competence Pharmacology and Toxicology after completion of the mandatory training periods and acquisition of the mandatory training contents.

### *4.1.2 Duration of Training*

24 months basic training in the field of Pharmacology and

36 months specialised training as a Specialist in Pharmacology and Toxicology under supervision of an authorised instructor at a training institution pursuant to § 5 (1) sentence 1<sup>4</sup>.

### *4.1.3 Content of Training*

Acquisition of knowledge, experiences and skills in

- the legal basis for development, approval and handling of medicines
- the experimental design, execution and evaluation of studies including the ethical basis for human and animal testing
- biological testing and standardisation procedures as well as the common methods of examination and measurements used in pharmacology and toxicology including chemical-analytical, electrophysiological, cell- and molecular-biological methods
- the analysis and evaluation of toxicological effects in humans, including medically important poisons and their antidotes
- clinical toxicological advice
- the theoretical basis of (animal) experimental research for the analysis of the desired or harmful effects of drugs and foreign substances
- the experimental production of curative and harmful effects in animals
- the experimental production of diseases and their influence by drugs and foreign substances and their detection and evaluation

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<sup>4</sup> Regulations on Specialised Training of the Medical Chamber North Rhine.

with biochemical, chemical, immunological, microbiological, molecular-biological and physical and physiological methods

- anaesthesia and analgesia of experimental animals
- behavioural-pharmacological examination method
- In-vitro methods to study the effect of drugs and foreign substances on isolated organs, cell cultures and subcellular reaction systems
- Fundamentals of morphological and histological examination procedures
- common isolation and analysis methods for the identification and quantification of drugs and foreign substances and their metabolites, e.g. in body fluids and environmental media
- Fundamentals of the analysis of experimental data, biostatistics, biometrics and bioinformatics
- dose–response relationships

Defined investigation and treatment procedures:

- |   | Quantity |
|---|----------|
| • participation in experimental / pharmacological / toxicological studies   |          |
| • pharmacological / toxicological experiments with molecular biological / biochemical and integrative / physiological methods ..... | 400      |
| • drug reviews .....  | 25       |

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