

National Training Requirements

AUSTRIA

Additive Specialty Clinical Pharmacology

“Additivfach Klinische Pharmakologie”

Language:	English
Deposited:	28.12.2017
Prepared by (name):	T. Griesbacher, M. Brunner
On behalf of (organisation):	Austrian Pharmacological Society (APHAR)
NMA responsible for training:	Austrian Medical Chamber (<i>Österreichische Ärztekammer</i>)

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.

Table of Content

1. Introduction and Disclaimer	3
2. Regulations for the Diploma “Additive Specialty Clinical Pharmacology”	3
2.1 Training Regulations 1994	3
2.2 Training Regulations 2006 (current).....	3
2.3 Training Regulations 2015 (future)	3
2.4 Definition of the Specialty	4
2.5 Current Contents of Training.....	4
2.6 Training Institutions.....	4
2.7 Documentation of Training Content	4
2.8 Final Appraisal	4
3. Training Content	5
3.1 Knowledge	5
3.2 Experiences and Skills.....	5
4. Requirements for Continuing Professional Development	6



1. Introduction and Disclaimer

The diploma “Additive Specialty Pharmacology and Toxicology” (“Additivfach Pharmakologie und Toxikologie”) is issued by the Austrian Medical Chamber (Österreichische Ärztekammer). The training of these medical specialists is governed by Austrian federal law (Regulations for the Training of Physicians 2006; “Ärztinnen-/Ärzte-Ausbildungsordnung” 2006).

Note: The training Regulations 2006 have been amended in 2015. The ‘additive specialty’ will be replaced by a ‘specialisation’, but the detailed regulations for this specialisation have not yet been finalised. In the meantime, the former Training Regulations of 2006 will remain in effect for all doctors currently pursuing their training in Clinical Pharmacology.

The current document was prepared by the Austrian Pharmacological Society (APHAR) as a faithful description of the current legal framework regarding the training in the additive specialty Clinical Pharmacology in Austria, but is not in any way a legally binding document. All current regulations can be obtained directly from the Austrian Medical Chamber who is solely responsible for executing these regulations.

2. Regulations for the Diploma “Additive Specialty Clinical Pharmacology”

The additive specialty Clinical Pharmacology was introduced by the Regulations for the Training of Physicians 1994 and was defined as a specialised additive training for specialists in Anaesthesiology and Intensive Care Medicine, Internal Medicine, Neurology, Pharmacology and Toxicology, and Psychiatry.¹ In 2006 the Regulations for the Training of Physicians were modified and since then the additive specialty Clinical Pharmacology can only be obtained by specialists in Internal Medicine.

[2.1 Training Regulations 1994](#)

The total duration of training was defined as 3 years (in addition of the main specialty); of these, 18 months had to be spent in Pharmacology and another 18 months in Clinical Pharmacology.

[2.2 Training Regulations 2006 \(current\)](#)

The total duration of training in the additive specialty again was defined as 3 years; of these, 18 months have to be spent in Clinical Pharmacology and another 18 months in Pharmacology.

Note: Until the detailed new regulations for the training in the future specialisation Clinical Pharmacology have not been published, the regulations for training in the present additive specialty Clinical Pharmacology remain in force.

[2.3 Training Regulations 2015 \(future\)](#)

With the amendment of the Regulations for Training 2015, Clinical Pharmacology as an ‘additive specialty’ will be replaced by the ‘specialisation’ in Clinical Pharmacology. Details for duration of training, training, training content, and main specialties for which this specialisation will be available (presently Internal Medicine only) are currently under negotiation between the Austrian Medical Chamber and the Austria Pharmacological Society.

For the time being, Clinical Pharmacologists in training follow their training under the Training Regulations 2006.

¹ §28 (1) Z 12 ÄAO 1994.

[2.4 Definition of the Specialty](#)

The Training Regulations 2006² specify the additive specialty as follows:

“The additive specialty Clinical Pharmacology encompasses the investigation and monitoring of the use of medicinal drugs in healthy and diseased humans, the investigation of pharmacokinetics and pharmacodynamics with regard to age, pathophysiological particularities, routes of application, and interactions when using different drugs, identification of side effects and intoxications by drugs as well as specialty-specific evaluation and advice-giving.”

[2.5 Current Contents of Training](#)

The content of training for the additive specialty Clinical Pharmacology is based on the description of this profession as defined by the Regulations for the Training of Physicians 2006 (see above).

The training content is defined by the Regulations on Knowledge, Experiences and Skills and Structured Logbooks (“KEF und RZ Verordnung” 2015) of the Austrian Medical Chamber (Appendix 15: Internal Medicine, Section 2, IX. Additive Specialty Clinical Pharmacology).

The training contents are detailed in

² BGBl. II Nr. 286/2006 idF BGBl. II Nr. 259/2011.

3. Training Content.

[2.6 Training Institutions](#)

Currently, there is only one institution recognised by the Austrian Medical Chamber as training institution for the additive specialty Clinical Pharmacology, i.e. the Department of Clinical Medicine of the Medical University of Vienna.

[2.7 Documentation of Training Content](#)

All trainees in the additive specialty Clinical Pharmacology have to maintain a 'structured logbook' ("Rasterzeugnis") listing all training requirements for the specialty as defined by the Regulations for the Training of Physicians. The training requirements are defined in a legal enactment by the Austrian Medical Chamber (Regulations on Knowledge, Experiences and Skills and Structured Logbooks; "*KEF und RZ Verordnung*") (see

3. Training Content).

Completed training items must be confirmed by the training institution for each item in the structured logbook. Only applicants who submit a completed structured logbook to the Austrian Medical Chamber are considered by the Austrian Medical Chamber.

[2.8 Final Appraisal](#)

Presently, no exam is mandatory for the additive specialty Clinical Pharmacology and it is expected this will remain the case also when the new regulations for the specialisation Clinical Pharmacology are agreed upon. The diploma for the additive specialty is awarded by the Austrian Medical Chamber upon presentation and evaluation of the structured logbook presented by the applicant.

3. Training Content

Note: The Regulations for the Training of Physicians 2006 ("Ärztinnen-/Ärzte-Ausbildungsordnung 2006")³⁾ have been superseded by the new Training Regulations 2015, where the former additive specialty Clinical Pharmacology has been replaced by a 'specialisation' in Clinical Pharmacology. However, since detailed regulations on the structure and content of the new specialisation have not yet been defined, all doctors currently undergoing training in the additive specialty Clinical Pharmacology continue their training according to the previous regulations of 2006.

The content of training in the additive specialty Clinical Pharmacology is defined in the Regulations on Knowledge, Experiences and Skills and Structured Logbooks 2006 ("KEF und RZ Verordnung" 2006) of the Austrian Medical Chamber as follows:

3.1 Knowledge

1. Ethical foundations of trials in humans according to the Declaration of Helsinki and Good Clinical Practice (GCP)
2. Basics of drug approval, pharmacoeconomics and drug policy
3. National and international legal provisions concerning pharmaceuticals, medical devices, genetic engineering and insurance-related issues related to clinical trials
4. Principles of pharmaceutical, preclinical and clinical development of new drugs
5. General pharmacology, in particular laws of absorption, distribution, metabolism and excretion of medicinal products ("pharmacokinetics") and of drug effects ("pharmacodynamics") and basics of pharmacogenomics
6. Mode of action, site of action, dose–response relationship and kinetics of the most commonly used drugs
7. Mode of action, site of action, dose–response relationship as well as kinetics of medically relevant poisons, as well as treatment of poisoning
8. Design and evaluation of interventional and observational studies
9. Biometric methods
10. Principles of drug analysis and isotope techniques
11. Drug risk reporting systems, pharmacovigilance
12. Practice of drug prescription and recording of medical prescriptions and of taking habits of patients

3.2 Experiences and Skills

1. First use of new drugs in humans
2. Identification of therapeutic doses of new drugs
3. Planning and execution of controlled trials in humans (phase 1–4) including preparation of trial plans, case report forms, patient information and declarations of consent, as well as required documents for authorities in charge
4. Pharmacokinetic and pharmacodynamic evaluation of clinical studies
5. Detection and treatment of disorders of vital signs
6. Clinical examination procedures and evaluation criteria for the efficacy testing of the most important groups of drugs
7. Assessment of drug risks, especially drug side effects and interactions
8. Advice on drug therapy issues
9. Evaluations regarding the efficacy and safety of medicinal products

³⁾ Federal Law Gazette, Bundesgesetzblatt BGBl. II Nr. 286/2006 idF BGBl. II Nr. 259/2011.

4. Requirements for Continuing Professional Development

The current Regulations for the Training of Physicians require that each physician must engage in continuing professional development and must report these activities to the Austrian Medical Chamber at intervals of at least every 5 years.

The Austrian Medical Chamber currently issues a CPD diploma covering periods of 5 years. For each 5-year CPD period at least 250 CME/CPD credits have to be collected; of these, at least 200 credits must be obtained in medical educational activities and at least 80 credits must be derived from live educational events.

Physicians not presenting evidence of sufficient CPD/CME activities within these 5-year periods face disciplinary action by the Austrian Medical Chamber.

