

Austrian Pharmacological Society Österreichische Pharmakologische Gesellschaft (APHAR)

Guidelines for the Certification of Medical Specialists in Pharmacology and Toxicology as European Certified Pharmacologists (EuCP)

based on the diploma "Fachärztin/Facharzt für Pharmakologie und Toxikologie" (Medical Specialist in Pharmacology and Toxicology) issued by the Austrian Medical Chamber

> current as of: 12.11.2015 approved by the EuCP Committee: 24.11.2015



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1. Introduction

The Austrian Pharmacological Society (APHAR) EuCP Program for Medical Specialists in Pharmacology and Toxicology is part of the European Certified Pharmacologists (EuCP) Programme of the Federation of European Pharmacological Society (EPHAR) and the European Association for Clinical Pharmacology and Therapeutics (see <u>www.eucp-certification.org</u>).

The present APHAR EuCP certification is based on the diploma "Medical Specialist in Pharmacology and Toxicology" ("Fachärztin/Facharzt für Pharmakologie und Toxikologie") which is issued by the Austrian Medical Chamber. The training of these medical specialists is governed by Austrian federal law (Regulations for the Training of Physicians 1994, 2006 and 2015; "Ärztinnen-/Ärzte-Ausbildungs-ordnung" 1994¹, 2006² and 2015³).

The Austrian Pharmacological Society has established the following programme to ensure that applicants holding the aforementioned diploma fulfil all requirements as set out by the EuCP Guidelines for Certification⁴⁾.

2. Regulations for the Diploma "Medical Specialist in Pharmacology and Toxicology"

The medical specialty Pharmacology and Toxicology was legally introduced by the Regulations for the Training of Physicians 1994. Training requirements were modified in 2006 (most notably by the introduction of a formal examination) and again in 2015. The present APHAR EuCP Programme hence differentiates between holders of the diploma Medical Specialist in Pharmacology and Toxicology depending on the legal version of the Training Regulations that were the basis for the issuing of the diploma by the Austrian Medical Chamber.

Note: while the present APHAR Guidelines for EuCP Certification describe the Regulations for the Training for Medical Specialists in Pharmacology and Toxicology as set out in the respective legal documents as faithfully as possible, the legal basis for training at any given time are only the respective legislation documents as issued by the Austrian Government (<u>www.ris.gv.at</u>) and the Austrian Medical Chamber (see information at <u>www.aerztekammer.at/arzte-ausbildungsordnung</u>, <u>www.aerztekammer.at/kundmachungen</u>, and <u>www.arztakademie.at</u>).

Any significant changes to the legislation regulations regarding training, the regulations issued by the Austrian Medical Chamber, or future significant changes and amendments to the APHAR Guidelines for EuCP Certification will be communicated in a timely fashion to the EuCP Committee for approval of the APHAR Certification scheme.

2.1 Training Regulations 1994

Training in the medical specialty Pharmacology and Toxicology covers a period 6 years in total. These 6 years were divided into 3 parts: 4 years of training in the main specialty, i.e. Pharmacology and Toxicology, 6 months of training in Internal Medicine, 12 months of training in any one or more of a list of 25 clinical and non-clinical specialties (not including Pharmacology and Toxicology or Clinical Pharmacology) of not less than 3 months duration each, and 6 month of training in any of the 43 medical specialties listed in the Training Regulations 1994. Thus, Medical Specialists in Pharmacology and Toxicology recognised by the Austrian Medical Chamber according to the Regulations for the

¹⁾ Federal Law Gazette, Bundesgesetzblatt BGBl. Nr. 152/1994, BGBl. II Nr. 228/1998, BGBL. I Nr. 169/1998 (BG); BGBl. II 286/2006.

²⁾ Federal Law Gazette, Bundesgesetzblatt BGBl. II Nr. 286/2006, BGBl. II Nr. 167/2010, BGBl. II Nr. 259/2011, BGBl. II 147/2015.

³⁾ Federal Law Gazette, Bundesgesetzblatt BGBl. II Nr. 147/2015 i.d.g.F.

⁴⁾ For current version see www.eucp-certification.org

Training of Physicians 1994 were trained in Pharmacology and Toxicology for a minimum of 4 years and a maximum of 4.5 years before receiving the diploma as Medical Specialists in this discipline.

Pharmacologists who had received or started their training before March 1994 where eligible for the diploma if documentation of training in Pharmacology and Toxicology for a total period of 6 years was provided. Training contents of the Training Regulations 1994 applied.

2.2 Training Regulations 2006

The total duration of training (6 years), the minimum period of training in the main specialty Pharmacology and Toxicology (4 years) and in the secondary specialties (2 years, which could include up to 6 months in Pharmacology and Toxicology) are the same as in the Regulations for the Training of Physicians 1994. The total training in Pharmacology and Toxicology thus also is 4 to 4.5 years.

The important difference to the Training Regulations 1994 was the introduction of a formal final exam for Medical Specialists. The exam requirements and regulations are described further below.

2.3 Training Regulations 2015

The Regulations for the Training of Physicians 2015 reformed the training regulations of all recognised medical specialties in Austria. The 'secondary specialties' required in the previous training regulations were reduced to 9-months on the grounds that all Medical Schools in Austria had introduced one year of intensive clinical training in the pre-graduate curriculum for medical doctors.

Thus, the training in the medical specialty Pharmacology and Toxicology starts with a 9-month training in Internal Medicine and Surgery, followed by 5 years and 3 months training in Pharmacology and Toxicology. The training in Pharmacology and Toxicology is separated into a 3-year period of 'Basic Training', which is common for all trainees in this specialty, and a further 2-year period, which contains 27 months of 'Specialised Training' where trainees can choose 3 out of 6 'elective modules' of 9 months each; the remaining 9 months to complete the full 6 years of training is a 'Scientific Module' which is common to all medical specialties.

2.4 Contents of Training

The content of training for Medical Specialists in Pharmacology and Toxicology is based on the description of this profession as defined by the Regulations for the Training of Physicians 1994, 2006 and 2015: *"The medical specialty Pharmacology and Toxicology encompasses the research on the effects of drugs and harmful substances in animal experiments, in humans and in the environment, the investigation of absorption, distribution, metabolism and elimination of active substances, the collaboration in the development and utilisation of new drugs as well as in the assessment of their therapeutic value, the participation in the detection and assessment of the risk of harmful substances, the counselling of physicians regarding drug therapy and in cases of intoxication, as well as formal assessments or reports."*

The training contents from Regulations 1994 are listed in <u>Appendix 1 – Training Content (Regulations</u> for the Training of Physicians 1994).

The training contents from Regulations 2006 are listed in <u>Appendix 2 – Training Content (Regulations</u> for the Training of Physicians 2006).

The training contents from Regulations 2015 are listed in <u>Appendix 3 – Training Content (Regulations</u> for the Training of Physicians 2015).

2.5 Requirements for Training Institutions

All Regulations for the Training of Physicians (1994, 2006, 2015) require that for each pharmacologist in training at least one Medical Specialist in Pharmacology and Toxicology must be employed fulltime in the institution where the training is to be given. Heads of departments, even if Medical Specialists in Pharmacology and Toxicology, do not count towards this requirement.

Trainees do not necessarily have to receive all their training in one single institution, but can receive training in different institutions, provided that each of these departments is recognised as a training institution for the respective medical specialty by the Austrian Medical Chamber.

2.6 Documentation of Training Content

All trainees in a medical specialty have to maintain a 'structured logbook' ("Rasterzeugnis") listing all training requirements for the respective medical specialty as defined by the Regulations for the Training of Physicians in the respective version (1994, 2006, 2015). The structured logbooks are defined in a legal enactment by the Austrian Medical Chamber (Regulations on Knowledge, Experiences and Skills and Structured Logbooks; "KEF und RZ Verordnung").

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 and who have also completed are required training periods in the main specialty itself (Pharmacology and Toxicology) as well as in other medical fields (Internal Medicine, Surgery and the like as defined by the respective Training Regulations) are considered by the Austrian Medical Chamber.

2.7 Formal Exam

Introduced by the Regulations on the Training of Physicians 2006, each trainee having completed his/her training under these regulations must pass a formal oral exam in Pharmacology and Toxicology.

The exam in Pharmacology and Toxicology is a structured oral examination before a board of examiners. While for most clinical specialties, the examination boards only are composed from specialists from the respective specialty, 'small' specialties were grouped together in several exam groups. Pharmacology and Toxicology thus is grouped together with Immunology, Serology and Transfusion Medicine, Pathophysiology, Physiology, and Medical Performance Physiology (Sports Physiology).

The examination board of 3 members consists of 1 main examiner (a specialist in Pharmacology and Toxicology registered by the Austrian Medical Chamber), 1 head of the examination board (currently also a Specialist in Pharmacology and Toxicology) and 1 further member from any one of the specialties from the exam group.

All questions to be asked in the exam (6 case descriptions with 5 to 7 questions to each) must be prepared in advance by the Austrian Pharmacological Society and must be supplied to the Austrian Medical Chamber together with possible correct answers and a list of rules how points for correct answers have to be determined.

The content of the exam (the entire exam should equally contain most areas of pharmacology and toxicology) is given in the "Blueprint" for the exam: see <u>Appendix 4 – Blueprint for Examination</u> (Austrian Academy of Physicians / APHAR).

The detailed rules for all exam procedures are given in <u>Appendix 5 – Examination Guideline (Austrian</u> <u>Medical Chamber</u>).

Note that only Medical Specialists in Pharmacology and Toxicology who have completed their training according to the Training Regulations 2006 and 2015 have (or will have) gone through an exam as final assessment. As the EuCP Guidelines for Certification require a formal assessment at the end of the training, either in the form of an exam or an assessment by independent eminent pharmacologists, all Medical Specialists in Pharmacology and Toxicology who have obtained their diploma according to the Training Regulations 1994 will be assessed separately by APHAR (see <u>3.4 Evaluation of Candidates</u>).

3. APHAR EuCP Programme Procedures

3.1 Administrative Requirements and Procedures

Applicants must provide documentation of the following:

- The diplomas Medical Doctor;
- The diploma as Medical Specialist in Pharmacology and Toxicology;
- A scientific CV including all relevant information about periods of academic education, training and current employment/professional engagement. The periods of training as a Medical Specialist in Pharmacology and Toxicology and periods of professional engagement (active employment or self-employed work in the field of pharmacology) must cover at least a total period of 5 years. This period may be interrupted by periods of complementary training in other fields, career breaks, maternity/paternity leaves or similar;
- Evidence must be provided for current professional engagement (active employment or continuing self-employed occupation in the field of pharmacology).
- A list of pharmacological contributions such as publications in peer-reviewed journals, confidential reports, or assessments for regulatory agencies or for regulatory decision-making. A minimum of 5 such contribution is required. Where contributions are confidential, a confirmation of the respective client (industrial company, regulatory body etc.) should be supplied if non-confidential contributions are not available;

Only regular members of the Austrian Pharmacological Society can apply for being certified as European Certified Pharmacologists under these guidelines.

3.2 Specific Requirements and Procedures

3.2.1 Theoretical Training

The requirements for Theoretical Training as defined in the EuCP Guidelines for Certification are fully met by the required Training Content laid down in the Regulations for the Training of Physicians in all legal versions (1994, 2006, 2015; see <u>Appendices 1, 2 and 3</u>). Therefore, no documentation other than the diploma for Medical Specialists in Pharmacology and Toxicology issued by the Austrian Medical Chamber is needed.

3.2.2 Practical Training and Experience

Practical Awareness in the major techniques used in pharmacology as required by the EuCP Guidelines for Certification are also included in the training requirements as both knowledge and experiences (see <u>Appendices 1, 2 and 3</u>). Therefore, no documentation other than the diploma for Medical Specialists in Pharmacology and Toxicology issued by the Austrian Medical Chamber is needed.

In-depth knowledge in at least two of the topics listed in the EuCP Guidelines for Certification shall be documented by publications in peer-reviewed journals or in another suitable manner that allows the

APHAR Certification Commission to determine that the applicants meets the requirements of the EuCP Guidelines.

Written confirmations by the relevant supervisors confirming the content of training is provided by the certified logbooks that the applicants had to submit to the Austrian Medical Chamber before obtaining the diploma as Medical Specialists in Pharmacology and Toxicology. Thus, no further documentation needs to be supplied.

3.3 Ethical Code of Conduct

All applicants for the APHAR EuCP Certification as Medical Specialists in Pharmacology and Toxicology must confirm that they abide by the EPHAR Ethical Code of Conduct⁵⁾.

3.4 Evaluation of Candidates

The EuCP Guidelines for Certification require an evaluation of each candidate's competencies by either a formal exam or by expert opinions of two eminent pharmacologists who are registered EuCPs. The evaluation procedures of the APHAR Certification Commission depend on the regulatory basis of the diploma issued by the Austrian Medical Chamber. The following categories are used:

3.4.1 Training Regulations 2006 and 2015

Candidates who have completed their training as Medical Specialists in Pharmacology and Toxicology according to the Regulations for the Training of Physicians 2006 or 2015 have been examined by the appropriate examination board of the Austrian Medical Chamber. The Blueprint for Examinations (see <u>Appendix 4 – Blueprint for Examination (Austrian Academy of Physicians / APHAR)</u>) and the Examination Guidelines (see <u>Appendix 5 – Examination Guideline (Austrian Medical Chamber</u>)) ensure that the requirements of the EuCP Guidelines for Certification for a final assessment are fully met. Therefore, no further, separate assessment is needed, provided that the diploma was issued by the Austrian Medical Chamber not longer than 5 years before application of the candidate to the Austrian Pharmacological Society for the EuCP diploma.

Candidates who have received the diploma as Medical Specialist in Pharmacology and Toxicology more than 5 years prior to application for the EuCP certification will be assessed by a panel of pharmacologists as described below for candidates having completed their training according to the Training Regulations 1994.

3.4.2 Training Regulations 1994

Candidates who have completed their training as Medical Specialists in Pharmacology and Toxicology according to the Regulations for the Training of Physicians 1994 have received training regarding knowledge, experiences and skills to a similar extent and have provided documentation (certified logbook) for this to the Austrian Medical Chamber. However, no formal final assessment is included in these Training Regulations.

The formal assessment of these candidates shall be made by a panel of two eminent pharmacologists who shall evaluate the documents supplied by the candidates in order to ensure that the candidate's competencies fulfil the requirements as set out by the EuCP Guidelines for Certification.

⁵⁾ www.ephar.org/docs/EPHAR_Ethical_Code_of_Conduct.pdf

3.4.3 Non-Austrian Diplomas

On the basis of Directive 2005/36/EC⁶⁾ the Austrian Medical Chamber may recognise diplomas for medical specialists obtained by physicians in other member states of the European Union or in Switzerland if the responsible authority of the country where the training was undertaken and the original diploma was issued has confirmed that the training was conducted according to article 25 of the aforementioned Directive and the Austrian Medical Chamber has determined that the training received by the applicant is equivalent to the Austrian training requirements. Diplomas from other countries may also be considered by the Austrian Medical Chamber if it determines that the training in the country of origin is equivalent to the Austrian training requirements. The Austrian Medical Chamber decides whether in an individual case a separate formal exam is required or not.

Applicants whose diploma as Medical Specialist in Pharmacology and Toxicology was issued originally by a country other than Austria will only be considered for certification as European Certified Pharmacologist by the Austrian Pharmacological Society if the applicant has been entered into the list of Medical Specialists in Pharmacology and Toxicology by the Austrian Medical Chamber and all other requirements as set out in the present Guidelines are met.

Regardless of whether the Austrian Medical Chamber has required the candidate to take a formal exam or not, a separate assessment by a reviewer panel selected by the APHAR Certification Commission shall be mandatory.

3.4.4 Reviewer Panel

These two reviewers must be selected from institutions independent from the workplace of the applicant. The two reviewers also should come from different institutions. At least one of the reviewers must be from an entirely different employer than that of the applicant; the second reviewer preferably also should fulfil this criterion; however, if this second reviewer is chosen from the same employer, e.g. the same university, he/she must be from a different department. Care shall be taken that both reviewers have no conflict of interest.

Reviewers shall be chosen from the list of Medical Specialists in Pharmacology and Toxicology who are registered as European Certified Pharmacologists. Only for the initial period of the APHAR EuCP Programme, while no such EuCPs are listed yet or all listed EuCPs declare a conflict of interest and other EuCPs are not available, APHAR may select eminent pharmacologists who (1) hold the diploma Medical Specialist in Pharmacology and Toxicology and (2) themselves fulfil the criteria as defined for the assessment of applicants by the reviewers (see <u>3.4.5 Assessment Criteria</u>). The selection of the reviewers shall be the task of the APHAR Certification Commission (see <u>3.5 Certification Commission and Final Decision</u>).

3.4.5 Assessment Criteria

Candidates for the EuCP certification whose application needs to be assessed by a Review Panel — all applicants whose diploma as Medical Specialist in Pharmacology and Toxicology has been issued earlier than 5 years before application to the APHAR Certification Commission or Medical Specialists in Pharmacology and Toxicology having received their diploma under the Regulations for the Training of Physicians 1994 — may submit any documents that they feel appropriate to show that their current competencies cover the entire discipline.

The APHAR Certification Commission shall issue a — non-exhaustive — list of items that may be submitted for this evaluation (see <u>Appendix 6 – APHAR Assessment Criteria for EuCP Certification</u>).

⁶⁾ Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2006 on the recognition of professional qualifications.

The list of suitable items for the evaluation of the candidate's competencies in the discipline of pharmacology shall be reviewed regularly by the APHAR Certification Commission. Reviewers also shall consider any other documents supplied by the applicants and assess these for their suitability to verify that the candidate current competencies meet the requirements of the EuCP Programme.

3.5 Certification Commission and Final Decision

The members of the Certification Commission shall be appointed by the Executive Committee of APHAR and must be registered as European Certified Pharmacologists.⁷⁾ The Certification Commission shall make the final decision on the basis of the reports given by the Reviewer Panel. If the Certification Commission also includes EuCPs who were registered following procedures other than those described in the present document (EuCP certification for Medical Specialists in Pharmacology and Toxicology), the decision cannot be reached against the opinion of those members of the Certification Commission who themselves are Medical Specialists in Pharmacology and Toxicology⁸⁾.

Once the Reviewer Panel has given a positive opinion and the APHAR Certification Commission has confirmed that all requirements of the EUCP Guidelines are met by the candidate, the name of the candidate, together with his/her credentials, shall be communicated promptly by APHAR to the EuCP Committee; the candidates will then receive the certification as European Certified Pharmacologists from the EuCP Committee for the period as defined by the EuCP Guidelines for Certification (currently 5 years).

Should the EuCP Committee have any reservations about the credentials of an individual candidate, the APHAR Certification Commission shall co-operate with the EuCP Committee to resolve any open questions in order to facilitate a positive final decision if possible.

3.6 Maintenance of Certification

According to the EuCP Guidelines for Certification, EuCPs must re-affirm their certification credentials on a 5-year basis and must submit documentation of the continued professional practice and continuing professional development.

Active membership in APHAR for the entire period since the last EuCP (re-)certification as well as current active membership at the time of application for re-certification is a prerequisite for renewal of certification.

3.6.1 Continuing Professional Practice

In order to document the continuing professional practice, EuCPs shall submit an updated CV containing relevant information such as details of post(s) held and of professional activities relating to pharmacology during the past 5-year period. The documentation also must provide evidence for current professional engagement (active employment or continuing self-employed occupation in the field of pharmacology) at the time of application for re-certification.

⁷⁾ During the initial period of the APHAR EuCP programme, members of the Certification Commission must at least fulfil all criteria as defined by the EuCP Guidelines for Certification but must seek certification as soon as this becomes available.

⁸) Note: The tasks of the APHAR Certification Commission will also include the organisation of analogous, but separate, guidelines for the certification of Medical Specialists in Clinical Pharmacology and of non-medically qualified pharmacologists, and thus may also include members from these fields. This clause shall ensure that the interests of the respective speciality are protected.

3.6.2 Continuing Professional Development

According to the Austrian Federal Law on the Exercise of the Medical Profession and the Professional Organisation of Physicians ("Bundesgesetz über die Ausübung des ärztlichen Berufes und die Standesvertretung der Ärzte") 1998 (current version 2000), all medical specialists have to provide evidence for continuing professional development to the extent of 250 CME credits (DFP points, "Diplom-Fortbildungs-Punkte") within a 5-year period to obtain the Diploma for Continuing Training ("Fortbildungs-Diplom") from the Austrian Medical Chamber.

In order to provide evidence for continuing professional development as required by the EuCP Guidelines for Certification, EuCPs shall submit their most recent Diploma for Continuing Training issued by the Austrian Medical Chamber.

In order to minimise the administrative burden for EuCPs and the EuCP Committee it is admissible that EuCPs can shorten the first interval of re-certification as EuCP to that year when they are due to receive their next diploma for continuing training from the Austrian Medical Chamber.

3.6.3 Revocation or Termination of Certification

EuCPs not providing evidence for both continuing professional and continuing professional development shall be informed that their certification as European Certified Pharmacologists is to be revoked or terminated and the name of the individual shall be communicated to the EuCP Committee.

EuCPs certified under the present APHAR Guidelines for EuCP Certification as Medical Specialists in Pharmacology and Toxicology are obliged to inform the APHAR Certification Commission of termination of their professional practice (termination of active employment without actively seeking re-employment, or termination of self-employed occupation in the field of pharmacology).

3.7 Appeals Procedures

When the APHAR Certification Commission should arrive at a negative decision — e.g. decline of certification, revocation or termination of certification, decline of re-certification — the candidate may appeal to the Arbitration Commission as defined by the Statutes of the Austrian Pharmacological Society. None of the members of the Arbitration Commission must have been involved in the making of the contested decision.

3.8 Administrative Fees

Administrative fees payable by applicants for certification as European Certified Pharmacologists will be fixed by the APHAR Executive Committee.

3.9 APHAR EuCP Database

APHAR is responsible for keeping a database of APHAR members who have been granted the certification as European Certified Pharmacologists by the EuCP Committee. The database shall include all data that are necessary for the administration of the EuCP Programme, particularly all personal and contact details necessary to identify EuCPs certified on the basis of the current APHAR Certification Guidelines, dates of certification and period of validity of certification. Data not required for the purposes of the EuCP Programme shall not be included in the database. APHAR is responsible for complying with all legal requirements pertaining to databases and protection of personal data that are in force in Austria.

3.10 Confidentiality Rules

All procedures regarding applications for certification are to be handled in a strictly confidential manner. All members of the APHAR Certification Commission, members of the Reviewer Panel and

administrative staff handling applications must confirm that they will abide by these confidentiality rules before performing their duties with respect to the certification procedures.

4. Use of the Post-Nominal "EuCP"

Applicants who have been approved by the EuCP Committee as European Certified Pharmacologists may use the post-nominal "EuCP". The right to use the post-nominal is limited to the duration of validity of the certification.

If an application for re-certification (see <u>3.6 Maintenance of Certification</u>) is submitted to the Certification Commission of APHAR prior to the expiry of the period of certification, applicants may continue to use the post-nominal until a final decision on the re-certification has been reached by the Certification Commission.

The right to use the post-nominal ceases if the certification is revoked or terminated for any reason as described in <u>3.6.3 Revocation or Termination of Certification</u> by either the APHAR Certification Commission or the EuCP Committee. Should a case be brought before the Arbitration Commission (see <u>3.7 Appeals Procedures</u>), the right to use the post-nominal remains suspended until a final decision has been reached.

5. Appendices

The following appendices contain detailed information to several aspects of the training in the medical specialty Pharmacology and Toxicology as defined by the Austrian laws Regulations on the Training of Physicians ("Ärztinnen-/Ärzte-Ausbildungsordnung") 1994, 2006 and 2015:

Appendix 1 – Training Content (Regulations for the Training of Physicians 1994) Appendix 2 – Training Content (Regulations for the Training of Physicians 2006) Appendix 3 – Training Content (Regulations for the Training of Physicians 2015) Appendix 4 – Blueprint for Examination (Austrian Academy of Physicians / APHAR) Appendix 5 – Examination Guideline (Austrian Medical Chamber) Appendix 6 – APHAR Assessment Criteria for EuCP Certification

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Appendix 1 – Training Content (Regulations for the Training of Physicians 1994)

Note: 'Main specialty' refers to training in Pharmacology and Toxicology. The **Regulations for the Training of Physicians ("Ärzteausbildungsordnung") 1994**⁹⁾ prescribed training in the main specialty, Pharmacology and Toxicology, for a period of 4 years plus training in 'secondary specialties' for 2 years; the latter comprised: 6 months Internal Medicine, 12 months in one or more other, selected, clinical specialties (minimum 3 months each), and 6 months in any one of the medical specialties listed in the regulations (this could also include Pharmacology and Toxicology itself so that the training in the main specialty, Pharmacology and Toxicology, was 4 to 4.5 years in total). A formal final examination was only introduced in the Regulations for the Training of Physicians 2006.

The content of training in Pharmacology and Toxicology is defined in Appendix 32 of the Regulations for the Training of Physicians 1994⁹).

The Regulations 1994 have been superseded by the Regulations for the Training of Physicians 2006 and, recently, by the Regulations 2015 (see there). Pharmacologists having started their training before 4 March 1994 did not have to receive training in 'secondary specialties' but had to document training in the main specialty, Pharmacology and Toxicology, for a total period of 6 years.

Content and Extent of Knowledge and Skills required in the main specialty

- 1. Pharmacology and Toxicology with particular regard to absorption, metabolism, distribution and elimination of drugs and toxic compounds;
- 2. Knowledge of the special pharmacology of drugs as well as the pharmacodynamics principles, kinetics of effects, side effects and dose-response relationships of the respective drug groups;
- 3. Toxicology of drugs, environmental pollutants and toxic compounds in humans including kinetics of effects, therapy of intoxications;
- 4. Physical and chemical methods of determination as well as physical and chemical methods of isolation and detections commonly used in Pharmacology and Toxicology;
- Methods of research and investigation in animals with analysis of effects of drugs and toxic compounds, particularly knowledge of pharmacodynamic and toxicological animal models as well as behavioural pharmacology, knowledge of research techniques in isolated cells and organs;
- 6. Knowledge of methods of standardisation and biologic tests;
- 7. Knowledge of biometric methods;
- 8. Clinical investigation of drugs in humans in short- and long-term studies;
- 9. Knowledge of drugs, toxic compounds and pollutants in body fluids, in the human body and in the environment;
- 10. Side effects and interactions of drugs, detection and interpretation of pollutant effects;
- 11. Rational prescribing;
- 12. Breeding, housing and feeding of laboratory animals; cultivation of isolated cells, isotope techniques including radiation protection, principles of the methods used in the biomedical sciences (histology, biochemistry, physiology, cell and molecular biology), of agents that are present as residues in air, water and foods or are added for special purposes or occur as natural metabolites and which can produce untoward effects, particularly allergies;
- 13. Knowledge of laboratory instruments and apparatus;
- 14. Knowledge of diseases caused by the environment or work environment;

⁹⁾ Federal Law Gazette, Bundesgesetzblatt BGBl. Nr. 152/1994, BGBl. II Nr. 228/1998, BGBL. I Nr. 169/1998 (BG); BGBl. II 286/2006.

- 15. Information and communication with patients on preparation, indication, execution and risks of investigations and treatments;
- 16. Documentation;
- 17. Knowledge of the legislation pertaining to the medical profession, in particular the laws on drugs and chemicals;
- 18. Formal assessments/reports.



Appendix 2 – Training Content (Regulations for the Training of Physicians 2006)

Note: 'Main specialty' refers to training in Pharmacology and Toxicology. The **Regulations for the Training of Physicians ("Ärzteausbildungsordnung") 2006**¹⁰⁾ prescribed training in the main specialty for a minimum period of 4.5 years plus training in a list of compulsory and elective secondary disciplines (clinical and nonclinical) in a total duration of 1.5 years (part of which may also include Pharmacology and Toxicology). (Translation Austrian Pharmacological Society APHAR).

The Training Regulations 2006 have been superseded by the Regulations for the Training of Physicians 2015. Pharmacologists having started their training before 1 June 2015 continued their training according to the Training Regulations 2006; the Training Regulations 2015 concern medical specialists who started their training on or after 1 June 2015.

The content of training in the medical specialty Pharmacology and Toxicology is defined in the Regulations on Knowledge, Experiences and Skills and Certified Logbooks¹¹⁾ of the Austrian Medical Chamber.

A) Knowledge

- 1. Methods of standardisation and biologic tests
- 2. Biometric methods
- 3. Drugs, toxins and pollutants in body fluids, in the human body and in the environment
- 4. Substances that occur in air, water or in food as either unavoidable residues, or are added for particular reasons or that occur as natural metabolites, and which cause adverse effects including, in particular, allergies
- 5. Diseases caused by the environment and the work environment
- 6. Laws that relevant to the exercise of the medical profession, in particular the laws regarding drugs, chemicals and food law as well as the laws on addictive drugs and on medical devices, the social, welfare and health care system including the respective institutions
 - the Austrian health care system and the social insurance system
 - Legal aspects of documentation and medical liability
 - Collaboration with other medical occupations
- 7. Principles of multidisciplinary coordination and cooperation
- 8. Clinical drug trials in humans, including the ethical foundations of the experimental procedure involving humans in accordance with the Declaration of Helsinki and Good Clinical Practice (GCP)
- 9. Ethical principles of the use of animal testing in accordance with the Principles for Care and Use of Laboratory Animals, as well as the relevant legislation

B) Experiences and Skills

- 1. Pharmacology and Toxicology with special reference to resorption, metabolism, distribution and elimination of drugs, toxic substances and foods
- 2. Pharmacology of drugs and their pharmaceutical, pharmacodynamic and pharmacokinetic principles, pharmaceutical technology, kinetics of therapeutic effects, side effects and

^{10]} Federal Law Gazette, Bundesgesetzblatt BGBl. II Nr. 286/2006, BGBl. II Nr. 167/2010, BGBl. II Nr. 259/2011, BGBl. II 147/2015.

¹¹⁾ Verordnung der Österreichischen Ärztekammer über Kenntnisse, Erfahrungen und Fertigkeiten in der Ausbildung zur Ärztin für Allgemeinmedizin/zum Arzt für Allgemeinmedizin und zur Fachärztin/zum Facharzt, sowie über die Ausgestaltung und Form der Rasterzeugnisse und Prüfungszertifikate (KEF und RZ VO), 2007, Anlage 33.

dose-response relationships, and interactions with other drugs, foods and other materials with special consideration of age

- 3. Toxicology of drugs, environmental pollutants and toxins and their effects on humans including kinetics of toxic effects and dose-response relationships, treatment of poisoning
- 4. Physical and chemical measurement methods as well as techniques of isolation and detection commonly used in the pharmacology and toxicology, including enzymatic, molecular biology and isotope methods
- 5. Research and examination techniques for analysis of drugs and toxins, particularly pharmacodynamic animal models and behavioral pharmacology, research on isolated cells and organs
- 6. Planning and execution of experimental studies for pharmacological and toxicological drug testing
- 7. Side effects and interaction of drugs, detection and evaluation of health effects of pollutants or toxins
- 8. Rational Prescribing
- 9. Breeding, keeping and feeding of laboratory animals, cultivation of isolated cells, isotope techniques including radiation protection, principles of the methods used in the biological sciences (histology, biochemistry, physiology, cell and molecular biology)
- 10. Counselling on preparation, indication, performing and risks of drug treatments and the administration of drugs-related investigations
- 11. Quality assurance and documentation specific for the discipline
- 12. Pharmacological assessments/reports (minimum: 5)



Appendix 3 – Training Content (Regulations for the Training of Physicians 2015)

Note: According to the law Regulations for the Training of Physicians ("Ärztinnen-/Ärzte-

Ausbildungsordnung") 2015¹²⁾ the training in all medical specialties recognised in Austria starts with a clinical "Common Trunk", i.e. a basic training in Internal Medicine and Surgery, followed by the training in the respective medical specialty. The training in the medical specialty begins with a "Basic Training" of 36 months, which contains training in those areas of the specialty that every specialist of that particular specialty must receive. The Basic Training is followed by a 27-month period of "Specialised Training" where trainees have to choose 3 out of a list of 6 specialised "Modules" plus a compulsory "Scientific Module" (the list of training contents of this is common to all medical specialties). Training contents (Basic Training and Specialised Modules) are listed in Appendix 24 of the Regulations for the Training of Physicians 2015, the content of the compulsory Scientific Module is listed in Appendix 34 of the aforementioned law.

The Training Regulations 2015 applies to all medical specialists who start their training on or after 1 June 2015; trainees who have started their training before this date will continue their training according to the Training Regulations 2006. (Training Regulations 2015, below, translated by APHAR)

The content of training in the medical specialty Pharmacology and Toxicology is defined in the Regulations on Knowledge, Experiences and Skills and Structured Logbooks¹³⁾ of the Austrian Medical Chamber.

Basic Training (36 months)

A) Knowledge

- 1. Methods of standardisation and biological tests
- 2. Biometrical Methods
- 3. Drugs, toxins and pollutants in body fluids, in the human body and in the environment
- 4. Substances that occur in air, water or in food as either unavoidable residues, or are added for particular reasons or that occur as natural metabolites, and which cause adverse effects including, in particular, allergies
- 5. Diseases caused by the environment and the work environment
- 6. Clinical drug trials in humans, including the ethical foundations of the experimental procedure involving humans in accordance with the Declaration of Helsinki and Good Clinical Practice (GCP)
- 7. Ethical principles of the use of animal testing in accordance with the Principles for Care and Use of Laboratory Animals, as well as the relevant legislation
- 8. Principles of physical and chemical methods of measurement as well as methods of isolation and detection commonly used in pharmacology and toxicology
- 9. Special features of gender and age relevant for the exercise of the medical specialty
- 10. Reporting system for drug risks, pharmacovigilance
- 11. Pharmacoeconomics, optimisation of therapy by utilisation of efficiency reserves
- 12. Principles of the methods used in the biomedical sciences

¹²⁾ Federal Law Gazette, Bundesgesetzblatt BGBl. II Nr. 147/2015 i.d.g.F.

¹³⁾ Verordnung der Österreichischen Ärztekammer über Kenntnisse, Erfahrungen und Fertigkeiten in der Ausbildung zur Ärztin für Allgemeinmedizin/zum Arzt für Allgemeinmedizin und zur Fachärztin/zum Facharzt, sowie über die Ausgestaltung und Form der Rasterzeugnisse, Prüfungszertifikate und Ausbildungsbücher (KEF und RZ-V 2015), Anlage 24.

B) Experiences

- 1. Pharmacology and Toxicology with particular reference to resorption, metabolism, distribution and elimination of drugs, toxic substances and pollutants
- 2. Pharmacology of drugs:
 - pharmaceutical principles, galenics
 - principles of pharmacodynamics, pharmacokinetics and pharmacogenetics
 - kinetics of therapeutic effects
 - adverse drug effects and dose-response relationships
 - interaction with other drugs, foods
- 3. Pharmacology of the various stages of life and of gender
- 4. Toxicology of:
 - drugs, environmental pollutants and toxins, and their impact on humans including
 - kinetics of effects and dose-response-relationships
 - pharmacological principles of the therapy of intoxications
- 5. Pharmacological appraisal of adverse drug effects and interactions
- 6. Quality assurance and documentation specific for the specialty
- 7. Pharmacological and toxicological assessments/reports

C) Skills (quantity¹⁴) 1. Quality assurance and documentation specific for the specialty 2. Written summary, documentation and assessment of courses of disease, as well as prognoses derived therefrom (ability to write reports, assessments etc.) 3. Pharmacological and toxicological assessment/reports 5 4. Providing information and advice to physicians

Specialised Training (27 months)

Module 1: Pharmacological Mechanisms of Action

A) Knowledge

1. Fundamentals and consequences of pharmacological mechanisms of action

B) Experiences

13. Fundamentals and consequences of pharmacological mechanisms of action

C) Skills

- 1. Experimental studies of biological mechanisms of action of drugs, toxic compounds and pollutants
- Experimental studies of the biological, biochemical and biophysical properties of molecules and structures, which are targets of effects of drugs, toxic compounds and pollutants, including methods of genetics and molecular biology

(quantity)

10

¹⁴⁾ 'Quantities' ("Richtzahlen") given in the Regulations on Knowledge, Experiences and Skills and Structured Logbooks ("KEF und RZ Verordnung" 2015) of the Austrian Medical Chamber are guidance values of how many times the trainee is expected normally to have performed the respective task independently; where no number is given the respective skill must be trained to an extent that allows the independent performance of the skill (KEF und RZ V 2015 § 3 Abs. 4).

3. Creation and experimental investigation of genetically modified organisms

(quantity)

5

including laboratory animal science 4. Experimental investigation of pharmacophores using computer-aided methods 5. Experimental research techniques using isolated cells, organs and animal models 6. Physical and chemical methods of isolation and detection including enzymatic, 10 molecular biology and isotope techniques Module 2: Pharmacodynamics A) Knowledge 1. Fundamentals of pharmacodynamics **B)** Experiences 1. Fundamentals of pharmacodynamics C) Skills (quantity) 1. Experimental studies of the pharmacodynamic properties of drugs, toxic compounds and pollutants 5 2. Establishing dose-response relationships and interactions with other drugs, foods and toxic compounds 3. Experimental investigations of consecutive effects following immediate effects of drugs 4. Transplantation of autologous or xenobiotic tissues or cells (design and execution for pharmacodynamics purposes) including laboratory animal science 5. Behavioural pharmacology including laboratory animal science 6. Physical and chemical methods of isolation and detection including 10 enzymatic and isotope techniques 7. Experimental research techniques: – on isolated cells or organs - in laboratory animals including laboratory animal science Module 3: Pharmacokinetics A) Knowledge 1. Fundamentals of pharmacokinetics and their application in pharmacotherapy

B) Experiences

1. Fundamentals of pharmacokinetics and their application in pharmacotherapy

C) Skills

- 1. Experimental studies of the pharmacokinetic properties of drugs, toxic compounds and pollutants
- 2. Design and execution of pharmacokinetic studies in laboratory animals including laboratory animal science

| 3. | Experiments to investigate metabolism, absorption and distribution of drugs in cells and organs | 5 |
|----|---|---|
| 4. | Experiments to investigate distribution and fate of drugs in the human | 5 |
| 5. | body Experimental studies of interactions of drugs, toxic compounds or | |
| - | pollutants | |
| 6. | Physical and chemical methods of isolation and detection including | 5 |

 Physical and chemical methods of isolation and detection including enzymatic and isotope methods

Module 4: Toxicology

A) Knowledge

1. Fundamentals of toxicology and their application in pharmacotherapy

B) Experiences

1. Fundamentals of toxicology and their application in pharmacotherapy

C) Skills

(quantity)

10

- 1. Investigation of drugs which may cause toxic effects or allergies
- 2. Establishing dose-response relationships and interactions with other drugs, foods and toxic compounds
- 3. Experimental investigations of consecutive effects following immediate 10 effects of drugs
- 4. Establishing kinetics of effects of drugs
- 5. Behavioural pharmacology
- 6. Experimental studies on the therapy of intoxications
- 7. Immunotoxicology
- 8. Physical and chemical methods of isolation and detection
- 9. Experimental research techniques:
 - in isolated cells or organs
 - in laboratory animals including laboratory animal science

Module 5: Pharmacology/Pharmacotherapy of Gender and Stages of Life

A) Knowledge

1. Fundamentals and consequences of pharmacology/pharmacology of gender and stages of life

B) Experiences

1. Fundamentals and consequences of pharmacology/pharmacology of gender and stages of life

C) Skills

(quantity)

- 1. Pharmacotherapy of the various stages of life with particular reference to
 - Geriatrics
 - Paediatrics and Adolescent Medicine

(quantity)

- 2. Pharmacogenetics: Investigations for the determination of genetic variants with pharmacologically relevant consequences
- 3. Gender Pharmacology
- 4. Gender-specific special features in pharmacotherapy with reference to – gender-specific pharmacokinetics and pharmacodynamics
 - therapy of gender-specific diseases

Module 6: Clinical Pharmacology

A) Knowledge

1. Fundamentals and clinical pharmacology

B) Experiences

1. Fundamentals and clinical pharmacology

C) Skills

- 1. Principles of the pharmaceutical, pre-clinical and clinical development of novel drugs
- 2. Design and Evaluation of interventional and observational studies
- 3. Pharmacokinetic and pharmacodynamics evaluation of clinical studies
- 4. Assessment of drug risks, particularly of side effects and interactions
- 5. Counselling regarding preparation, indication, execution and risks of drug therapies, and examinations in connections with drug applications
- 6. Reporting system for drug risks, pharmacovigilance
- 7. Interdisciplinary identification and assessment of
 - unwanted side effects of drugs
 - dose-response relationships
 - interactions with other drugs, foods
 - individual, patient-centred optimisation of drug therapy

Scientific Module

A) Knowledge

- 1. Biomedical ethics
- 2. Good Scientific Practice
- 3. Clinical and Experimental study designs
- 4. Philosophy of Science
- 5. Statistical methods

B) Experiences

- 1. Writing an abstract, a scientific presentation or publication
- 2. Scientific project/time management
- 3. Statistics
- 4. Choice and use of methods for the research project

C) Skills

- 1. Report of the research project: thematic subject(s)
- 2. Identification and choice of a biomedical/bioethical problem
- 3. Formulation and handling of a specific hypothesis
- 4. Writing a project application or project presentation
- 5. Planning of a project including time and financial management
- 6. Presentation of research results n written and oral form
- 7. Documentation of scientific data
- 8. Choice, appraisal and interpretation of suitable statistical methods
- 9. Defence of the research results in a peer-reviewed process



Appendix 4 – Blueprint for Examination (Austrian Academy of Physicians/APHAR)

Note: The "Blueprint" defines the content of the formal examination of Medical Specialists in Pharmacology and Toxicology as required in the Austrian Federal Law "Ärzteausbildungsordnung 2006" and "Ärztinnen-/Ärzte-Ausbildungsordnung 2015" (Regulations for Medical Training 2006 and 2015).

The Blueprint is defined by the Austrian Pharmacological Society APHAR as the responsible medical scientific society for the Board of Examiners of the Academy of Physicians ("Arztakademie") of the Austrian Medical Chamber. Examiners are appointed by the Austrian Medical Chamber on nomination by the Austrian Pharmacological Society.

Categories are not listed/numbered in any particular order of importance. The formal examination should comprise content requiring knowledge and competencies equally covering all categories.

Category 1 – Pharmacology of the Central Nervous System

Morbus Parkinson, Psychopharmaceuticals, Narcotics, Pharmacology of Sleep Disorders and State of Agitation, Antiepileptics, Analgetics and Co-Analgetics, Central Muscle Relaxants

Category 2 – Immunopharmacology and Chemotherapy

Drugs acting on the Arachidonic Acid System, Antiphlogistics, Immunotherapeutics, Antibiotics and Basics of Antibacterial Therapy, Anti-Tumour Drugs, Antimykotics, Antiviral Drugs, Antiprotozoals

Category 3 – Metabolism and Endocrinology

Lipid Metabolism and Lipid-Lowering Agents, Pharmacology of Energy Metabolism, Glucose Metabolism and Purine Metabolism, Hypothalamic and Pituitary Hormones, Thyreoid Hormones, Sexual Hormones, Hormones of the Suprarenal Gland, Calcium Metabolism, Iron and Vitamines

Category 4 – Basic Pharmacology and Toxicology

Basic Pharmacodynamics and Pharmacokinetics, Drug Registration and Pharmacovigilance, Drug Risk Assessment

Category 5 – Cardiovascular Pharmacology

Drugs acting on the Heart and on the Vascular System, Pharmacotherapy of Hypertension and Hypotension, Diuretics, Drugs affecting the Haemostatic System

Category 6 – Toxicology

Chemical Carcinogens, Heavy Metals, Organic Solvents and Alcohols, Pesticides, Plant and Fungal Toxins, Irritant Gases, Toxins inducing Methaemoglobinaemia, Toxicology of Tabacco Products, Halogenated Aromatic Carbohydrogens

Category 7 – Autonomous Nervous System and Neurotransmitters

Serotonin, Histamine, Pharmacology of Adrenergic and Noradrenergic Systems, Drugs acting on the Gastrointestinal Tract, Pharmacology of Cholinergic Systems, Local Anaesthetics



Appendix 5 – Examination Guideline (Austrian Medical Chamber)

Note: The Specialty-specific Guideline for the Medical Specialty Pharmacology and Toxicology¹⁵⁾ is issued by the Austrian Medical Chamber, based on the Law on Training of Physicians (*"Ärzteausbildungsordnung"*). (Translation Austrian Pharmacological Society APHAR)

1. Description of the Profession

The profession of Medical Specialists in Pharmacology and Toxicology embraces

- 1. The experimental study and evaluation of effects of drugs and toxic agents.
- 2. Investigation and evaluation of the pharmacokinetic properties of active substances (drugs and other agents).
- 3. Development and application of new pharmaceuticals, evaluation of their therapeutic value.
- 4. Development and application of new pharmaceuticals, evaluation of their therapeutic discovery and evaluation of pollutant risks.
- 5. Determination and evaluation of the risks of harmful substances.
- 6. Consultancy in drug therapy and in cases of poisoning, including formal assessments.

2. Objective and Content of the Examination

Objective:

The aim of the specialist examination is the proof of the competence to meet in a competent and independent manner the common demands for the specialist according to the description of the profession.

Proof of expertise in pharmacology and toxicology with the following main focus:

- 1. Assessing the effects of drugs and pollutants in the preclinical and clinical trials, in clinical pharmacotherapy or in poisoning cases.
- 2. Critical evaluation of scientific concepts: in particular, the ability to interpret and evaluate scientific findings based on the current doctrine should be assessed.
- 3. Evaluation of the therapeutic value of drugs (indications, efficacy, safety in use) and assessment of the risks posed by drugs and toxic substances.

Content:

The exam content is based on the training content according to Regulations for the Training of Physicians for the medical specialty Pharmacology and Toxicology.

Key Competencies:

- Expertise in the testing of drugs and toxic substances, as well as in clinical pharmacotherapy. This is the assessment of drug and impact of toxic substances, the evaluation of the therapeutic benefit or the health risks posed by pharmaceuticals and toxic substances, and the justifications of therapy and study plans.
- 2. Evaluation of drugs (in preclinical and clinical studies) and experimental research on the scientific basis in pharmacology and toxicology, including documentation (e.g. publication) of the results obtained therein.
- 3. Advisory activities for physicians and patients on the basis of reliable scientific data.

¹⁵⁾ Fachspezifische Prüfungsrichtlinie für das Sonderfach Pharmakologie und Toxikologie (beschlossen von der Prüfungskommission im November 2001, in der Fassung Juli 2013).

| Classification: | Drug testing, | Experimental | Evaluation of Drugs and |
|-----------------|-------------------------|-----------------------|-------------------------|
| Categories → | Registration procedures | Basics | Toxic Substances; |
| Dimensions ↓ | | | Counselling |
| 1. | Specific Pharmacology | Measurement methods | Specific Pharmacology |
| 2. | Specific Toxicology | Laboratory methods | Specific Toxicology |
| 3. | General Pharmacology | Preclinical testing | Adverse effects and |
| | | | interactions |
| 4. | Research techniques | General Pharmacology | General Pharmacology |
| 5. | Clinical testing | Documentation | Clinical testing |
| 6. | Adverse effects and | Standardisation | Cumulating toxins |
| | interactions | | |
| 7. | Standardisation | Biometrics | Environmental toxins |
| | | | and diseases |
| 8. | Biometrics | Experimental devices | Legislation and ethical |
| | | | aspects |
| 9. | Formal assessments | Specific Pharmacology | Rational Prescribing |
| 10. | | | Information/Advice |

3. Possibilities for Preparations for the Exam

The specialist examination should not simply assess textbook knowledge, but should check especially those skills that enable the specialist to independently and responsibly meet everyday needs due to his training.

Recommended Literature:

- Journal: Pharmainformation (last 5 years).
- Standard textbook of pharmacology and toxicology (e.g. Forth, Henschler, Rummel, latest edition).

4. Exam Method(s) and Procedures

- Method: Structured oral exam.
- Number of questions: 30 to 40 (= maximum number of points), divided into 6 case examples with 5 to 7 questions each.
- Length of exam: 5 to 10 minutes per case example, preparation time 5 minutes per case example, total duration 50 to 60 minutes.
- The number of examiners depends on the number of candidates.
- Approved aid: Austria Codex.

5. Rating

The assessment is rated exclusively as either "passed" or "failed". Candidates will be informed of the test results in writing within 8 weeks from the exam date. If the test results can be determined immediately at the end of the test, the result may be communicated to the candidates orally – independently of the written notice. Telephone inquiries are not possible.

6. Exam Commission

The Exam/Audit Committee is responsible for the selection of exam questions, conducting the audit, establish the pass mark and the quality of the exam questions. The Audit Committee consists of

1 Chairman, 2 members and 3 alternate members. (s. PO § 25¹⁶) The Audit Committee has been nominated for 5 years. Re-election is possible.

The members are:

Chairperson group 3171:...181Vice Chairperson group 3:...Member group 3:...Deputy Member group 3:...Expert Member¹⁹:...

Deputy Expert Member: ...

7. Date of Exam / Repeat Tests / Place of Exam

The test takes place once a year, at the same time for all Specialist exams in the Medical Specialties Serology and Transfusion Medicine, Immunology, Pathophysiology, Physiology and Medical Exercise Physiology (Sports Medicine), at the same venue.

The number of attempts at the test is limited to 5 examinations taken. The last (fifth) test commencement will be held in the form of an oral examination in front of a board examination committee of three persons in the form of a structured, oral examination. (For details see the Regulations for Exams of the Austrian Medical Chamber § 11.a.)

Exam date, exam venue and time are published in a timely manner in the following media:

- Homepage of the Academy of Physicians: www.arztakademie.at
- Österreichische Ärztezeitung (Austrian Physicians' Magazine)

The registration form is available from the State Medical Chambers or from www.arztakademie.at

8. Quality Assurance

The quality inspection of test questions is made by the members and deputy members of the Audit Committee.

9. Contact for Candidates

If you have queries please contact the Austrian Academy of Physicians GmbH. Your inquiry will be forwarded to a member of the Audit Committee.



¹⁶⁾ Prüfungsordnung der Österreichischen Ärztekammer für die Prüfung zum Arzt für Allgemeinmedizin und die Facharztprüfung, 2006 (Regulations for Exams for General Practitioners and for Medical Specialists of the Austrian Medical Chamber 2006).

¹⁷ Note: Group 3 comprises to the medical specialties Immunology, Serology and Transfusion Medicine, Pathophysiology, Physiology, Pharmacology and Toxicology, and Medical Exercise Physiology (Sports Physiology)

¹⁸⁾ Note: Names of members of the board of exams are entered here each time the Austrian Medical Chamber appoints the position.

¹⁹⁾ Note: The expert member (or his/her deputy) is the main examiner and must be Medical Specialist in Pharmacology and Toxicology.

Appendix 6 – APHAR Assessment Criteria for EuCP Certification

Before the APHAR Certification Commission can reach a positive evaluation on a candidate's application, it must be determined whether the candidate fulfils the requirement of the EuCP Guidelines for Certification.

As detailed in chapter 3.4 of these Guidelines, candidates who have received their diploma as Medical Specialists in Pharmacology and Toxicology from the Austrian Medical Chamber according to the Training Regulations 2006 and 2015 not longer than 5 years before application fulfil the abovementioned requirement of the EuCP Guidelines for Certification by having passed a formal exam before the Examination Board of the Austrian Medical Chamber.

Candidates who have completed their training according to the Training Regulations 1994, or whose diploma by the Austrian Medical Chamber was issued more than 5 years before application for certification as EuCP, will be assessed by a panel of reviewers selected according to the regulations detailed in chapter 3.4.4 Reviewer Panel of these Guidelines.

Principles of Assessment

- The assessment by the Reviewer Panel shall be made on the basis of the documents submitted by the candidate applying for certification as EuCP.
- The evaluation shall be based on the entirety of the submitted material.
- The candidate's competencies should be evaluated regarding the intentions of the EuCP Guidelines for Certification²⁰⁾ and the description of the role of Medical Specialists in Pharmacology and Toxicology as defined in the Regulations for the Training of Physicians 1994, 2006 and 2015²¹⁾.
- Care should be taken that evaluation sufficiently observes that the sum of the individual's competencies cover the entire discipline of pharmacology.
- Each member of the Review Panel shall evaluate the submission individually and shall communicate to the APHAR Certification Commission directly the result of his/her evaluation in the form of a summative and informative statement
- The final decision will be made by the APHAR Certification Commission on the basis of the evaluation of all Reviewers.
- Should the Reviewers arrive at contradictory results, the APHAR Certification Commission shall seek to clarify the discrepancies in co-operation with all Reviewers of the respective case. If disagreements cannot be resolved, the APHAR Certification Commission may appoint one or more additional Reviewers.
- All members of the Review Panel as well as all members of the APHAR Certification Commission must sign a secrecy agreement before taking on their function. No personal details of candidates or details of the candidates' application documents may be disclosed or made public by any of the involved individuals.

²⁰⁾ "The European Certification of Pharmacologists is a system of The Federation of European Pharmacological Societies (EPHAR) to identify individual pharmacologists or scientists working in the field of pharmacology who excel in standards of education, skills, experience and professional standing".

²¹⁾ "The medical specialty Pharmacology and Toxicology encompasses the research on the effects of drugs and harmful substances in animal experiments, in humans and in the environment, the investigation of absorption, distribution, metabolism and elimination of active substances, the collaboration in the collaboration in the development and utilisation of new drugs as well as in the assessment of their therapeutic value, the participation in the detection and assessment of the risk of harmful substances, the counselling of physicians regarding drug therapy and in cases of intoxication, as well as formal assessments or reports."

Items that may be considered

In the following, non-exhaustive, list examples of items that may serve as indicators of the candidate's competencies are commented.

Items of evaluation need not necessarily be fully met by the candidate in each case, but it is rather the entirety of the full set of documents that should be the basis of the evaluation by the Review Panel.

Examples of evaluation items, with special considerations:

- <u>Positions held</u> should be considered according to the tasks and duties to be performed by the individual. For example, being head of a research group or unit generally will be evidence for the scientific competency of the candidate in a given research area but not evidence for the (required) competencies across the entire discipline.
- <u>Teaching activities</u> may be considered evidence for competencies in the field of pharmacology if these activities

(1) were carried out for at least several years,

(2) continue to be performed at the time of application for certification as EuCP and(3) cover a significant part (typically more than half) of the entire discipline of pharmacology. Teaching activities also include (regular and continued) activities as responsible member of examination boards, teaching units, curricular commissions etc.

- <u>Habilitation</u> requirements differ in the various university institutions. Generally, most emphasis is placed on the scientific achievements of applicants in their respective personal field of research. Thus, a habilitation seems to be a suitable indicator for an applicant's competencies regarding practical training and experience according to the EuCP Guidelines for Certification (the 'scientific dimension') but less so for evaluation of the applicant's competencies across the entire discipline (theoretical knowledge and experiences, practical awareness etc., i.e. the 'professional dimension').
- <u>List of publications</u>: Candidates must provide evidence of proven scientific contributions. These may be in the form of publications in peer-reviewed journals or also confidential reports or assessments (compare <u>3.1 Administrative Requirements and Procedures</u>). A minimum of 5 such contributions is required. Reviewers shall evaluate the list of contributions according to the following points:

(1) whether scientific contributions support the required practical skills (in a minimum of 2 of the major pharmacological techniques as defined by the EuCP Guidelines for Certification), and (2) whether these publications, in their entirety, document knowledge of the majority of the areas of pharmacology.

- <u>Functions in the public health system</u> shall be considered evidence for the candidate's competencies according to the EuCP Guidelines for Certification if these functions require knowledge, experiences or skills spanning a significant part of the entire discipline of pharmacology.
- <u>Other diplomas</u> should be considered depending on the kind and extent of expertise these certify. Special attention should be given to those diplomas or certificates that provide evidence for wide-ranging knowledge, experiences or skills.
- Honorary titles and awards normally should not be considered in the evaluation.

Any other item submitted by the applicant shall also be considered by the Reviewers according to the general Principles of Assessment given above.