EPHAR and EACPT Certification

EUROPEAN CERTIFIED PHARMACOLOGIST (EuCP)

Guidelines for Certification

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1. Introduction

The European Certification of Pharmacologists is a system of The Federation of European Pharmacological Societies (EPHAR) and the European Association for Clinical Pharmacology and Therapeutics (EACPT) for individual pharmacologists or scientists working in the field of pharmacology, in its entirety ranging from basic research to clinical and therapeutic applications, who excel in standards of education, skills, experience and professional standing. Individuals such qualified can apply to be certified as EUROPEAN CERTIFIED PHARMACOLOGIST (EuCP).

The Guidelines for Certification describe the formal requirements and procedures for Certification and Re-certification as well as fields of theoretical and practical knowledge and experience that are relevant for eligibility for certification. In order to cope with the large extent of specialisation in the field of pharmacology today, the Guidelines specify core competencies, which should be mastered by all applicants, as well as elective topics or fields, which may constitute individual elements of training and experience.

Where national or international specialisation certifications or licences already exist (legally regulated or recognised, especially in the medical field) these may provide a basis for EuCP Certification, provided that applicants for EuCP Certification still fulfil all criteria of the EuCP Guidelines. However, it is emphasised that the EuCP Certification does not in any way replace, or interfere with, such specialised certifications or licenses.

Finally, the tasks and responsibilities of the national certifying bodies as well as of EACPT and EPHAR are set out in these Guidelines.

The Guidelines for Certification shall be reviewed and updated at regular intervals (every 5 years or when a need for amendment should arise) according to the development of the science of pharmacology, educational needs and needs for harmonisation within the European context. The EuCP

Committee shall do this in close cooperation and consensus with those national societies of pharmacology that are responsible for the primary certification procedure. Significant changes of these Guidelines are subject to approval by the Executive Committees and ratification by the Councils of EPHAR and EACPT.

2. General Principles of the Certification Procedure

In a first step, a national certification board (a national pharmacological society) evaluates applications of candidates according to a consensual process and admits successful candidates to their national register. The national certifying body is fully responsible for ensuring that the candidate has fulfilled all requirements to be eligible for certification as EuCP. In a second step, the EuCP Committee will certify these individuals as EuCP upon recommendation by the national certification board without further evaluation.

In order to allow a candidate to be included in the European Register of Certified Pharmacologists, the national criteria for admission of an individual need to fulfil the quality criteria as set out in these Guidelines for Certification. The Guidelines shall also provide a framework for assisting national certifying boards or societies to harmonise certification procedures in a European context and for supporting these bodies in setting up appropriate training opportunities for potential EuCP candidates and implementing or providing opportunities for continuing professional development.

3. Requirements for and Implementation of Certification

The European Register of Certified Pharmacologists aims to recognise high standards of knowledge, skills, experience and professional standing of scientists professionally engaged in the field of Pharmacology.

All the following criteria are required for being eligible for certification:

- An academic degree (MD, PhD or MSc or equivalent) in a relevant subject such as medicine, pharmaceutical sciences, biomedical sciences, biology or chemistry;
- At least 5 years of relevant pharmacological experience (in laboratory, clinical, theoretical or regulatory work); this period may be interrupted by periods of complementary training in other fields, career breaks or similar;
- Knowledge of the major areas of Pharmacology. These can be obtained either by attending appropriate courses, by practical experience or on job training;
- Documentation of training with respect to knowledge, skills and competencies acquired;
- Active membership in the national society of pharmacology which is member of EACPT or EPHAR;
- Current professional engagement in the practice of Pharmacology;
- Proven significant contribution in at least 3 publications in peer-reviewed scientific journals, confidential reports, or assessments (suitable for submission to regulatory agencies or for regulatory decision-making).

In order to consider a candidate for Certification, the national certifying body will require and evaluate the following documentation:

- A CV containing relevant information about scientific education and professional career;
- Documentation of academic education before commencing training in Pharmacology. This will be documented by a university degree in a relevant subject;
- Evidence for achievements of knowledge, skills and competencies as set out in the subsequent sections of the Guidelines specifying the basic/minimal standards with respect to theoretical and practical training and experience;
    - Acquisition of theoretical knowledge may be documented by credits or certificates from appropriate courses or equivalent qualification.
    - Alternatively, theoretical knowledge may also be acquired by professional experience and/or job training; this should be documented by peer-reviewed publications, confidential reports, assessments, teaching activities, knowledge-based decision making or advisory activities, confirmations/certificates issued by the employer or equivalent means of documentation.
    - Practical training will usually be documented by publications, reports or assessments, confirmations issued by employer or expert opinions.
    - Where practical skills are obtained by the attendance of courses, these should be documented by the respective credits or certificates.
    - Confidential reports may be documented by confirmations of the body (industry, regulatory etc.) for which the report had been written.
- Evaluation of the candidate's competencies by either a formal exam or by expert opinions of two eminent pharmacologists who are registered EuCPs. Preferably both, but at least one, of the EuCPs acting as examiners or referees/reviewers must not be from the applicant's current employer.

4. Theoretical Training and Knowledge

Theoretical training in pharmacology, preferably with associated practical learning, is essential. Such training can be provided on a modular basis. It should provide basic knowledge of the major areas of pharmacology (in both basic and clinical aspects) and should embrace at least the following topics:

1. principles of basic and clinical pharmacology (pharmacodynamics, pharmacokinetics;
2. cellular, biochemical and molecular bases of drug action (therapeutic and toxic);
3. drug interactions;
4. experimental design, biometry and biostatistics;
5. principles of organ pharmacology;
6. R & D processes;
7. ethical aspects of preclinical (including the 3R principle) and clinical research;
8. specific aspects of pharmacology such as gender, age, ethnicity;
9. pharmacogenetics and -genomics;
10. procedures and rules that govern marketing authorization and market access;
11. pharmacovigilance;
12. pharmacoepidemiology;
13. pharmacoeconomics;

Additional elective topics (such as systems pharmacology, regulatory affairs, safety pharmacology, or others) can be offered upon prior notification of the EuCP Committee.

Topics may be presented as modules consisting of predefined course elements such as lectures, site visits, demonstrations or similar, or may be part of a comprehensive working and educational environment. In both cases, care has to be taken that applicants may obtain proper documentation about training received so that this can eventually be submitted for evaluation by the national certifying body at the time of application for certification.

Where parts of the required training have been covered in an appropriate previous academic degree (e.g. MSc, PhD or similar), this may be certified partly or entirely by the national certifying body.

5. Practical Training, Experience and Awareness

Practical training and experience must be related to Pharmacology and must span a period of not less than 5 years, of which a maximum period of 4 years may be obtained during training for a PhD degree. Training can be performed in an employment situation based on laboratory, clinical or regulatory work in Pharmacology, or can be obtained in specific courses meeting EuCP quality criteria. When potential candidates for application begin training in a single department or laboratory, it is advisable that their intended course of study or employment is seen by a senior EuCP or member of the national EuCP certifying body to ensure that the applicant will gather the training and experience appropriate for the eventual target of certification.

Practical training and experience must be suitable so that candidates obtain at least knowledge of the major techniques and their merits and limitations, i.e. Practical Awareness. A candidate for EuCP has to possess

(a) practical awareness (not necessarily practical experience) in half of the following topics (both basic and clinical) and

(b) in-depth knowledge and experience (according to the individual's specialised training/experience in basic or clinical pharmacology) of at least two of the following topics:

1. preclinical experiment design, biometrical and statistical methods, data retrieval and derivation and performance of in-vitro and ex-vivo studies;
2. preclinical experiment design, biometrical and statistical methods, data retrieval and derivation and performance of in-vivo studies;
3. biochemical and molecular techniques and diagnostics;
4. clinical trial design and management;
5. biometrical and biostatistical methods used in clinical research;
6. pharmacogenetics and -genomics, epigenetics and other -omics;
7. determination of pharmacokinetic parameters and compound metabolism (drug concentrations in biological fluids and tissues, and therapeutic drug monitoring);
8. pharmacoepidemiology, pharmaco-utilisation and/or
9. treatment optimization and individualization (through expertise in pharmacodynamics, pharmacokinetics, pharmacogenetics, therapeutic drug monitoring etc.);
10. teaching and education in pharmacology;
11. pharmacoeconomics and/or regulatory affairs.

Practical training and experience of candidates must be documented in a suitable manner. This may consist of regular progress reports by the candidate's mentors or heads of department (if possible by

a senior EuCP), and by at least 3 publications, reports, or assessments. Reports and assessments, whether confidential or non-confidential, must be suitable to allow judging the applicant's knowledge and experience by the national certifying body. Publications must have appeared in peer-reviewed journals and must allow the determination of the extent of individual contribution of the applicant to this publication.

It is essential that candidates also document to have obtained high standards of critical ability and communication skills. These may be documented by publications as well as a record of oral presentations and/or by authorship of written reviews or theses.

It is expected that suitable written confirmations by the relevant supervisors is provided, either in the form of progress reports/testimonials or certified logbooks etc.

6. Maintenance of Certification (Re-certification)

On a 5-year basis, European Certified Pharmacologists shall re-affirm their certification credentials and submit documentation of the continued professional practice and continuing professional development. As a minimum, to remain registered, a EuCP must be employed or be active or seek employment in the field of Pharmacology and must submit to the certifying body:

- 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.
- Documentation of Continuing Professional Development, such as evidence of attendance of educational courses and meetings (preferably by submitting attendance certificates of courses associated with CPD credits or similar), presentations, teaching activities, publications, activities in expert committees and/or similar. The minimum extent of these activities shall be determined by the national certifying body and must be approved by the EuCP Committee.

Failure to produce sufficient evidence to support re-certification shall result in the revocation or termination of the certification of this individual as European Certified Pharmacologist.

7. The National Certifying Body

A participating body issuing a national certification for pharmacologists (either the national society of pharmacology itself or another society appointed by the EuCP Committee) shall lodge its criteria for certifying pharmacologists with the EuCP Committee. Normally, only one certifying body shall be accepted per country.

Where separate societies exist in one country representing basic and clinical pharmacology, respectively, the EuCP Committee and the Executive Committees of EPHAR and EACPT strongly encourage the creation of a single, joint EuCP certifying body in order to promote the closer cooperation of the involved societies. A separate certifying body for each of these national societies should be the exception and requires the approval of the EuCP Committee. EuCP programmes submitted by one of these societies separately must not interfere with the interests of pharmacologists represented by the respective other society.

The criteria of the participating certifying body shall address the following:

- Legislative aspects (i.e. rules for successful application): a clear outline of what is expected from candidates for the national certification.
- Executive aspects (i.e. rules for evaluation of candidates and their application): a constitution or modus operandi for the assessment panel which is to validate and approve the candidate's application.
- Judicial aspects (i.e. rules for appeal): an outline of steps to be taken in the event that there is an objection to the certifying body's decision.

The national certifying body/bodies will notify the EuCP Committee of significant changes in their criteria for certification.

The national certifying body shall handle and process all applications by candidates according to the rules for certification as approved by EACPT and EPHAR. The national certifying body shall maintain a database of all individuals registered as EuCP via their certification scheme.

8. Accreditation of the National EuCP Guidelines with the EuCP Programme

The national certifying body shall submit all relevant information about training requirements, required theoretical and practical knowledge and skills for evaluation and approval by the EuCP Committee.

Upon approval by the EuCP Committee, the national certification scheme shall be entered into a list of accredited EuCP schemes and made public via the website of the EuCP Programme.

When a certification scheme is newly set up by a national certifying body, it is typically the case that many distinguished scientists will have been working as pharmacological professionals already for a prolonged period of time in the country of competence of that certifying body. Clear rules for evaluation of applications in such instances must be included in the national certifying scheme that must be suitable to allow judging the credentials of such individuals as being equivalent to satisfy the standard of education, skills, experience and professional standing required for EuCP certification.

9. The Lead Body (EuCP Committee)

The EuCP Committee shall consist of ten members, of whom two are members of the EPHAR Executive Committee, two members are from the EACPT Executive Committee, and six are selected from candidates nominated by the EPHAR and EACPT member societies; of the latter six, four shall be from larger member societies (500 or more individual members for EPHAR and 250 or more individual members for EACPT) and two from smaller member societies. The term of office of the EuCP Committee is 2 years. Re-election of committee members is possible.

The EuCP Committee shall review the curricula, programmes and national certification schemes that are submitted by the national certification bodies. The EuCP Committee is responsible for checking whether these programmes meet the requirements set out in these Guidelines before approval and shall ensure that all national EuCP certification schemes meet the same, high standards. The EuCP

Committee shall maintain records of all curricula, programmes and national certification schemes accredited for the EuCP certification.

In cases where the EuCP Committee determines that a national certification programme or scheme exhibits serious deficiencies, which are incompatible with the quality standards described in the present Guidelines, the Committee shall give advice how to improve the procedures or contents concerned. If improvements are rejected or performed insufficiently, the Executive Committees of EPHAR and EACPT, by information and advice of the EuCP Committee, will ratify whether certifications by that certifying body will be excluded from the EuCP register.

The EuCP Committee will confirm the acceptance of an individual applicant as EuCP when the respective national certifying body has confirmed that the individual has fulfilled the national certification criteria approved by the EuCP Committee. The EuCP Committee will issue a diploma for this individual confirming the certification as EuCP for the period as set out in Maintenance of Certification (Re-certification). The EuCP Committee will maintain a list of all EuCPs currently entitled to bear this title.

The EuCP Committee shall supply relevant information about the certification procedures and shall aim at harmonising standards for certification within Europe.

The EuCP Committee shall endorse training courses or programmes that are suitable to help individuals to obtain the required qualifications. It is highly desirable that national societies of pharmacology develop such programmes anew and further expand and improve existing programmes. EACPT and EPHAR encourage the development of training courses and programmes which are open to individuals from European countries other than that of the organising body. Programmes of this type meeting the EuCP standards shall be endorsed by the EuCP Programme and shall be publicised among the member societies of EPHAR and EACPT in order to promote international co-operation in post-graduate education and training programmes in the field of Pharmacology within Europe.

Regular meetings of the EuCP Committee shall be held once a year at an EACPT or EPHAR Congress. Additional meetings may be held as physical meetings, in the form of telephone- or web-based conferences, or as e-mail consultations.

The EuCP Committee shall report at regular intervals or at special request to the Executive Committees of EPHAR and EACPT. The Executive Committees in turn will report on activities of the EuCP Committee at meetings of their Councils.

10. Appeals Committee

In cases where a certification scheme has been excluded from the EuCP system, the national certifying body responsible for this scheme may appeal against this exclusion to an Appeals Committee. The Appeals Committee consists of four members, namely, a former president of EPHAR and a former president of EACPT and two current chairpersons of national certifying bodies accredited by the EuCP system. Current members of the Executive Committees of EACPT and EPHAR or the EuCP Committee are not eligible. If the chairperson of the excluded certification scheme is an elected member of an EPHAR organ, he/she is replaced by a deputy in hearings before the Appeals Committee.

11. Use of the Post-Nominal "EuCP"

An applicant who has been approved by the EuCP Committee as a European Certified Pharmacologist 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 is submitted to the National Certifying Body prior to the expiry of a period of certification, the applicant may continue to use the post-nominal until the National Certifying Body has reached a final decision on the re-certification.

The right to use the post-nominal ceases if the certification is revoked or terminated for any reason by either the National Certifying Body or the EuCP Committee. Should a case be brought before the responsible Appeals Committee, the right to use the post-nominal remains suspended until a decision has been reached by the Appeal Committee.

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