Portuguese Pharmacological Society
Sociedade Portuguesa de Farmacologia (SPF)

RPFarmC
Portuguese Certified Pharmacologist Register
Registo Português de Farmacologistas Certificados

Guidelines for the Certification as European Certified Pharmacologists (EuCP)

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Content

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1. Targets

RPFarmC (Registo Português de Farmacologistas Certificados)
is the Portuguese Certified Pharmacologist Register and it is part of the European Registration Program started by the EPHAR in 2014.

The aims of the RPFarmC, aligned with the European Certified Pharmacologist (EuCP) Register of EPHAR, are to:

a) Recognize 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.
b) Ensure that RPFarmC and EuCP Certified Pharmacologists maintain high standards of professional expertise;
c) Ensure that the Certified Pharmacologist designation is restricted to those who satisfy the RPFarmC and EuCP criteria for their professional expertise and competence, standards that are equal for all the national societies adhering to EPHAR;
d) Stimulate people to expand personal skills to increase their chances for obtaining high-level positions in an increasingly competitive employment environment, be it academic, industrial, regulatory or self-employed;
e) Recognize, in addition to scientific expertise, professional competence (portfolio) in the whole discipline of pharmacology;
f) Issue of the EuCP Certificate by the EuCP Committee, upon notification by the Portuguese Society of Pharmacology (SPF).

2. Association

2.1 General dispositions

a) Candidates who wish to apply for inclusion in the Register must use the Application Form, approved by RPFarmC Committee and by SPF Executive Council, which is available at the SPF website.
b) A candidate at RPFarmC will be duly accepted to have the final assessment by the EuCP Committee of EPHAR/EACPT when, complying with the required standards, will have passed the assessment by the National Certification Commission (NCC), and have paid the registration fee of € 150.00.
c) The suitability of the candidate for the RPFarmC must be firstly evaluated by the NCC. The applications must be submitted in two periods: period 1 from January 1st to June 31st and period 2 from July 1st to October 30th. The applicants are informed either in case of positive or negative results, until September 30th (period 1) or until December 31st (period 2).
d) In the event that the NCC does not approve the application, the Commission will inform the candidate of which admission criteria were not met (section 2.2.), and of when future applications can be submitted. After five years, the European Certified Pharmacologist must resubmit the Application Form, where a continuous practice of research in Pharmacology or a continuous professional development (CPD), as required by the EuCP Guidelines, must be demonstrated.
e) After the evaluation of the individual proposals by the NCC the certification of an individual as EUCP is done by the EPHAR/EACPT EuCP Committee.
f) Members of RPFarmC are “Certified Pharmacologists” after the applications are approved by the EuCP Committee of EPHAR/EACPT and may use the abbreviation EuCP (European Certified Pharmacologist).

2.2 Required criteria for being eligible for certification:

a) Active member in the Portuguese Society of Pharmacology (Sociedade Portuguesa de Farmacologia- SPF) or member of other pharmacological societies providing a formal agreement between the SPF as hosting society and the guest society. The guest society should be a member of EPHAR and/or EACPT. The agreement has to be approved by the EuCP Committee before coming into effect.
b) An academic degree (MD, PhD or MSc or equivalent) in a relevant subject such as medicine, pharmaceutical sciences, biomedical sciences, biology, biochemistry or chemistry;
c) 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;
d) Knowledge of the major areas of Pharmacology. These can be obtained either by attending appropriate courses, by practical experience or on job training;
e) Documentation of training with respect to knowledge, skills and competencies acquired;
f) Current professional engagement in the practice of Pharmacology;
g) 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).

2.3 Required documents:

a) A CV containing relevant information about scientific education and professional career;
b) Copy of academic degrees certificates;
c) Evidence for achievements of knowledge, skills and competencies with respect to theoretical and practical training and experience;
    I. Acquisition of theoretical knowledge may be documented by credits or certificates from appropriate courses or equivalent qualification (see section 3).
    II. 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.
    III. Practical training (see section 4) will usually be documented by publications, reports or assessments, confirmations issued by employer, or expert opinions.
    IV. Where practical skills are obtained by the attendance of courses, these should be documented by the respective credits or certificates.
    V. Confidential reports may be documented by confirmations of the body (industry, regulatory etc.) for which the report had been written.

3. Theoretical Training and Knowledge

Theoretical training in pharmacology, preferably with associated practical learning, is essential.

The applicants must present documentation attesting basic knowledge of the major areas of pharmacology and should embrace at least nine of 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.

The applicants could either A) acquire the topics 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, the applicants may obtain proper documentation about training received; or B) prove that the required training have been covered in an appropriate previous academic degree (e.g. MSc, PhD or similar).

4. 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.

The applicant for EuCP has to possess practical awareness (not necessarily practical experience) in half of the following topics (both basic and clinical) and in-depth knowledge and experience (according to the individual's specialised training/experience in basic or clinical pharmacology) in 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 treatment optimization and individualization (through expertise in pharmacodynamics, pharmacokinetics, pharmacogenetics, therapeutic drug monitoring etc.);
9. teaching and education in pharmacology;
10. 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 each publication.

It is essential that candidates also document to have obtained high standards of critical thinking 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.

5. Re-Certification (Maintenance of Certification)

On a 5-year basis, the EuCP shall re-affirm their certification credentials and submit documentation of the continuous practice of research in Pharmacology professional practice and continuous professional development in the field of pharmacology. 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:

a) 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.
b) Documentation of Continuing Professional Development, evidenced by regular professional activities in the area of pharmacology like attendance of educational courses and meetings (with attendance certificates), presentations, teaching activities, publications, activities in expert committees and/or similar.
c) 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.

6. Membership Fee

a) A five-year fee of € 150.00 must be paid by each member to RPFarmC to access the Register, within 30 days from the receipt of the payment request.
b) A non-refundable fee of € 30.00 is to be paid by each candidate for examining the application for admission to RPFarmC or for examining the application for renewal.
c) The Commission establishes the application form and the five-year fee, having listened to the opinion of the SPF. The Register is self-financed. Any profit will be used to promote the Register and increase the professional and cultural development of Members, namely by organizing training courses.
d) The fee, which covers the five years of validity of the certification, is to be paid in a lump sum. In case of renewal, the fee will be reduced by 30%.

7. Suspension of Members

At the end of the five years the Members who do not renew their certification, will be removed from the Register. Members may be removed from the Register for ethical reasons.

8. Commission

8.1 Appointment of the Committee

The members of the National Certification Commission (NCC) shall be appointed by the SPF Board and must be registered as European Certified Pharmacologists. During the initial period of the RPFarmC programme, members of the NCC must, at least, fulfil all criteria as defined by the EuCP Guidelines for Certification, but must seek certification as this becomes available.

Composition of the Committee

a) The NCC is composed by the president and vice-president of SPF and one member of each National Medical and Pharmaceutical school appointed by the SPF Board.
b) Three members of the NCC will be responsible for reviewing and assessing the documents of an individual applicant assuring that the members are independent from the applicant´s institution.
c) The members of the NCC shall elect a Secretary.

8.3 Functions of the Committee

a) The evaluation of candidates for inclusion in the Register and for the renewal of certification.
b) Exclude or remove a Member from the Register.
c) Update the criteria for certification upon SPF Board request.
d) Inform and contribute to the RPFarmC development in Portugal;
e) Choose experts to be convened if necessary.

8.4 Duration of Assignment

a) Committee Members may not hold office consecutively for more than six years.
b) The members of the NCC may be renewed after three years.
c) In the event of resignation or retirement of a member or members of the Commission, they will be replaced in accordance with paragraph 8.2 of this article.

9. Secretariat

The Organizing Secretariat of RPFarmC is entrusted to the Committee.

9.1 Functions of the Secretariat

The Secretariat is responsible for:

a) keeping all the documents and RPFarmC register and keeping RPFarmC members register, prepare detailed minutes of all meetings and archive Committee documents;
b) informing interested applicants on the requirements for the applications;
c) notifying and informing applicants of the Council decisions, as quickly as possible;
d) ensuring that the appropriate fees have been paid by the applicants.
e) communicating to the EuCP Committee new candidates for RPFarmC who have been positively evaluated for certification.
f) issuing an annual report with the Commission analysis and results for submission to the SPF Assembly, specifying at least:
   - the number of those who applied to be included in the Register, the outcome of requests and the percentage of approved;
   - the names of those who have been approved and removed from the Register for failure to pay the fee or for any other reason;
   - an evaluation of the quality of the candidates on the basis of what is required for inclusion in the register;
   - the needs for the continuous professional development of members;
   - an analysis of the financial status of the Register;
   - the composition of the Commission and any changes that occurred in the period of the Commission appointment.

g) manage events day by day, including statutory obligations of RPFarmC and implement decisions of SPF in relation to standards of RPFarmC and every need that arises from new regulations for members of EuCP.

10. Operation of the Committee

10.1 Meetings

a) The Commission shall meet twice a year.
b) The meetings are presided by the President of SPF. In his/her absence, the vice-president assumes the coordination of the meeting. If neither the president nor the vice-president is present, the members participating at the meeting indicate an Acting President that shall act as President of RPFarmC only for the specific meeting. In each case, a meeting is considered valid in the presence of 50% of the members. The Committee may be convened at the request of an absolute majority of the Commission.
c) The meeting is valid if 50% of the members are present.
d) Committee decisions are considered valid if approved by a simple majority. To deliberate decisions by majority, a minority report is required.
e) Consultants or experts, without the right to vote, can be invited to the meetings at the discretion of the President.

10.2 Appeals Against Decisions of the Commission

a) If a candidate disagrees with the Commission's decision, the application must be reconsidered. In the event that the candidate does not agree after the revaluation made by the Commission, the candidate will be able to ask for an appeal by the independent Appeal Committee.
b) The Appeal Committee consists of three members, among former Presidents of SPF not belonging to the serving commission.
c) The decision of the Appeal Committee will be binding on all parties.

10.3 General Assembly

The RPFarmC General Assembly must be convened at the SPF Congress and can be called at any time and place, depending on the decisions of the Commission. The secretariat will send notice of the assembly – via e-mail – at least 30 days before, to all members and to all those who are entitled to receive notice. All members of RPFarmC are entitled to participate.

11. Expulsion

The Commission may expel from RPFarmC any member whose misconduct (including, but not limited to, non-payment against the RPFarmC) adversely affects the RPFarmC. Neither RPFarmC, nor its officers, representatives, Commission or any Member shall have any obligation to the person who has been expelled.

12. Variation of the Regulation

a) These Regulations may be changed after proposal of the SPF Board and approval of 2/3 of members present at the SPF General Assembly.
b) It is mandatory that all changes proposed and approved by the SPF General Assembly must be ratified by the EPHAR/EACPT EuCP Committee.
c) The notification of the request to change the existing regulation, must be sent to the Secretariat in writing by the Commission.

13. Disputes and Controversies

Except as specified in this document, any dispute or controversy that may arise from the interpretation of the regulations or the powers or the validity of the minutes of a meeting, will be determined by the Commission, in agreement with the SPF board whose decision shall be final and binding upon all members.

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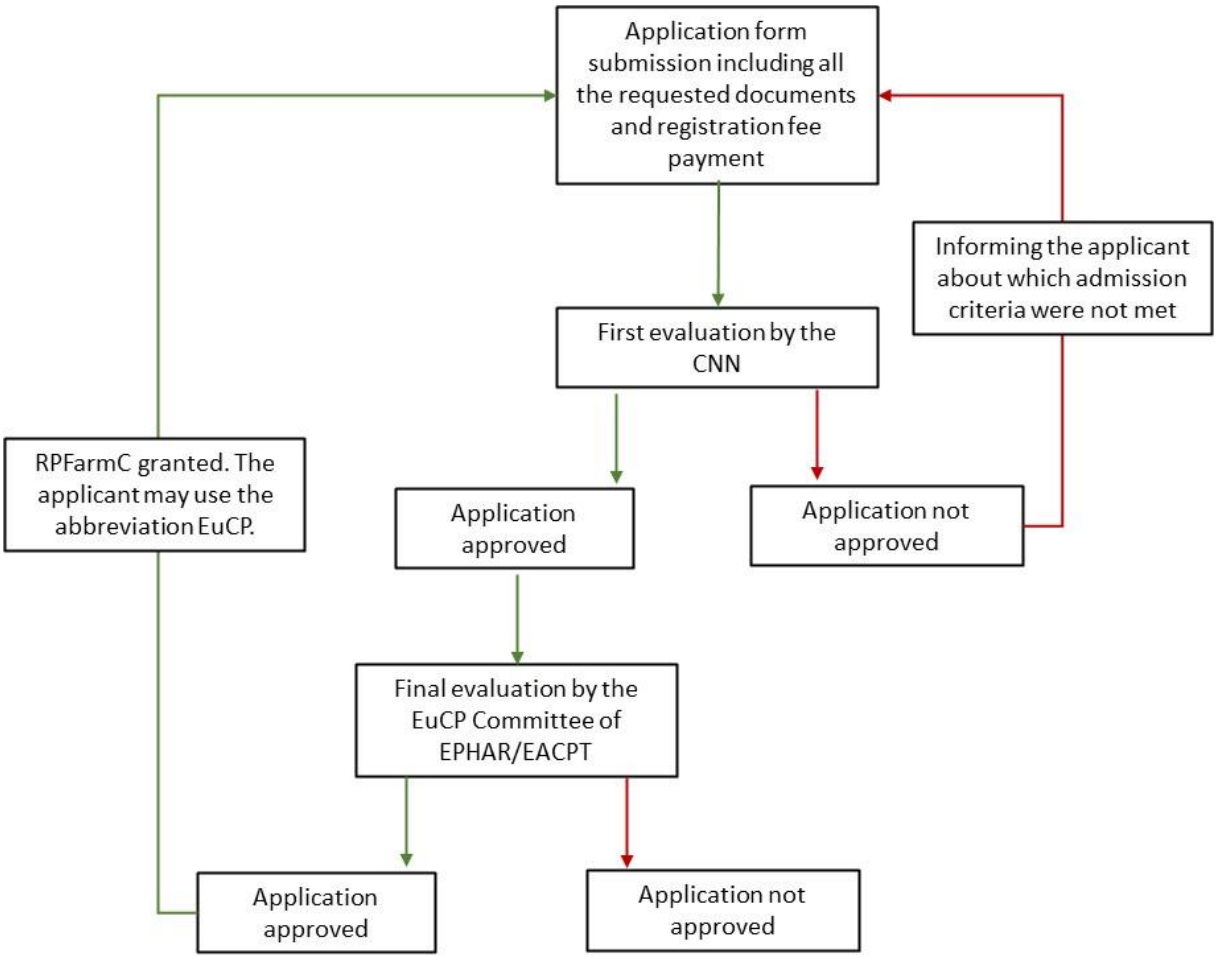
Appendix 1 – Flow chart of the process



Abbreviations:
EPHAR/EACPT-The Federation of European Pharmacological Societies/Association for Clinical Pharmacology and Therapeutics
EuCP-European Certified Pharmacologist
CNN-National Certification Commission
RPFarmC- *Registo Português de Farmacologistas Certificados*

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