The Spanish Society of Pharmacology (Sociedad Española de Farmacología; SEF)

REFarC
Spanish Certified Pharmacologists Register

Registro Español de Farmacólogos Certificados

Guidelines for the Certification as European Certified Pharmacologist (EuCP)

Spanish Society of Pharmacology –

Version. (18 Apr 2021)

Content

Introduction

The Spanish Society of Pharmacology (SEF) European Certified Pharmacologist (EuCP) Programme for Specialists in Pharmacology is part of the EuCP Programme of the Federation of European Pharmacological Society (EPHAR) and the European Association for Clinical Pharmacology and Therapeutics (EACPT) (see www.eucp-certification.org).

SEF has established the following programme to ensure that applicants holding the aforementioned diploma fulfil all requirements as set out by the EuCP Guidelines for Certification.

1. Targets

REFarC is the Spanish Certified Pharmacologist Register (Registro Español de Farmacólogos Certificados, REFarC) is part of the European Registration Programme started by the EPHAR in 2014.

Targets of REFarC, linked at EuCP Register of EPHAR and EACPT, are:

a) Recognize individual expert pharmacologists or scientists engaged actively in the multidisciplinary field of pharmacology, ranging from basic research to clinical and therapeutic applications, who excel in standards of education, skills, experience and professional standing;
b) Ensure that REFarC and EuCP Certified Pharmacologists maintain high standards of professional expertise;
c) Ensure that Certified Pharmacologist designation is restricted to those who satisfy the REFarC and EuCP criteria for their professional expertise and competence, standards that are equal for all the national societies adhering to EPHAR and EACPT;
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 in the whole discipline of pharmacology;
f) Issue of the EuCP Certificate upon notification by SEF.

2. Association

2.1. General dispositions

a) Candidates who wish to apply for inclusion in the Register must use the Application Form, approved by REFarC Committee and by SEF Executive Council, which is available at the SEF (www.socesfar.es) website.

b) A candidate at REFarC will be duly accepted when complying with the required standards, will have passed the assessment by the National Certification Commission (NCC), and will pay the registration fee described in Chapter 4. This fee will be annually reviewed by the NCC.

c) The suitability of the candidate for the REFarC must be firstly evaluated by the NCC before November 30th of the year in which the request to become a member of the Register was submitted and shall be notified, in writing, within the same year, both in case of a positive or negative result. Requests have to be submitted before June 30th.

d) In the event that the NCC does not approve the association request by the candidate, he will be entitled to additional opportunities for admission to the Register until he has fulfilled the admission criteria that are specified in point.

e) After five years, the European Certified Pharmacologist must resubmit the *Application Form*, where it must be demonstrated a continuous practice of research in Pharmacology, a continuous professional development (CPD) as required by the EuCP Guidelines.

f) Members of REFarC are "Certified Pharmacologists".

g) Members of REFarC may use the abbreviation EuCP (European Certified Pharmacologist).

2.2. Required criteria for being eligible for certification

a) An academic degree (MD, PhD or MSc or equivalent) in a relevant subject such as medicine, pharmaceutical sciences, biomedical sciences, veterinary, biology or chemistry;

b) At least five 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;

c) Knowledge in all major areas of Pharmacology. 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 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.

d) 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.

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 three publications in peer-reviewed scientific journals, confidential reports, or assessments (suitable for submission to regulatory agencies or for regulatory decision-making).

h) Active member of SEF or member of other pharmacological societies providing a formal agreement between the SEF as hosting society and the guest society. The guest society should be a member of EPHAR and/or EACPT. The agreement must be approved by the EuCP Committee before coming into effect.

2.3. Required Documents

a) Fulfil and submit the Application Form, which is available at the SEF (www.socesfar.es) website.

b) A CV containing relevant information about science education and professional career.

c) Copy of academic degrees certificates.

d) 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.

   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 will usually be documented by publications, reports or assessments, confirmations issued by the 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. Re-Certification (Maintenance of Certification)

On a 5-year basis, the EuCP shall re-affirm their certification credentials and submit documentation of the continued professional practice and continuing 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 positions held and of professional activities relating to pharmacology during the past 5-year period.

b) 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.

c) Failure to produce sufficient evidence to support re-certification shall result in the revocation or termination of the certification of this individual as EuCP.

4. Membership Fee

a) A five-year fee of € 300.00 must be paid by each member to REFarC to access the Register within 30 days from the receipt of the payment request.

b) The five-year fee will be reduced by 40% to candidates who are under 35 years old on November 30th of the year in which the application is made.

c) 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% (40% to renewal candidates under 35).

d) A non-refundable fee of € 30.00 is to be paid by each candidate for examining the application for admission to REFarC or for examining the application for renewal.

e) The NCC establishes the application form and the five-year fee, having listened to the opinion of SEF. The Register is self-financed. Any profit will be used to promote the Register and increase the professional and cultural development of Members by organizing training courses.

5. 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.

6. National Certification Commission

6.1 Appointment of the National Certification Commission (NCC)

The members of the NCC shall be appointed by the Executive Committee of SEF and must be registered as European Certified Pharmacologists. During the initial period of the SEF EuCP (REFarC) 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.

6.2 Composition of the NCC

a) The NCC is composed of three members appointed by SEF and holds office for

three years.

b) The members of the NCC shall elect a Chairman.

c) The NCC members shall agree on a member of the Secretariat (see article 7) that will participate in NCC meetings with the only function of Secretary.

6.3 Functions of the NCC

All issues concerning the REFarC fall within the competence of the NCC:

a) The evaluation of candidates for inclusion in the Register and for the renewal of certification. The NCC ensures that candidates comply with the criteria for certification of EPHAR-EACPT.

b) Include, exclude or remove a Member from the Register.

c) Update the criteria for certification upon the Executive Committees of SEF Board request.

d) Prepare an annual report and define the amount of the fee, in consultation with SEF;

e) Manage the REFarC registry and budgets;

f) Inform and contribute to the REFarC development in Spain;

g) Choose experts to be convened if necessary.

6.4 Duration of Assignment

a) NCC 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 NCC, they will be replaced in accordance with paragraph 6.1 of this article.

6.5 Meetings (Committees)

a) The NCC shall meet at least once a year.

b) The meeting is valid if three members are present.

c) Observers or experts, without the right to vote, can be invited to the Committee at the discretion of the President.

d) The NCC President formulates the agenda and presides over the Committee. In

his absence, the members present at the meeting indicate an Acting President that shall act as President only for the specific meeting. In each case, a meeting is considered valid in the presence of three members. The Committee may be convened at the request of an absolute majority of the NCC.

e) NCC Committees decisions are considered valid even if approved by a majority. To deliberate decisions by the majority, a minority report is required. In the event of a tie, the President will have a casting vote.

f) The Secretary, at the request of the President or at the request of an absolute majority of the NCC, convenes – via e-mail – a meeting of the NCC with reasonable notice of at least 15 days, indicating the agenda.

g) The NCC may elaborate operational rules in accordance with the present Regulation.

h) In case a regulation was not prepared, the President's and Secretary's rights and duties must be agreed and/or determined by the NCC from time to time.

7. Secretariat

The Organizing Secretariat of REFarC is entrusted to the Secretariat of SEF.

7.1. Functions of the Secretariat

The Secretariat is responsible for:

a) Keeping all the documents and REFarC register and keeping REFarC members register, prepare a detailed minute of all meetings and archive Committee documents.

b) Informing interested applicants on the requirements for the applications.

c) Notifying and informing applicants of the NCC Committee decisions as quickly as possible.

d) Preparing certificates once have been approved the candidates, and the fees have been paid.

e) Communicating periodically at EuCP, the new members of REFarC, including dates of certification and certification renewal.

f) issuing an annual report with the NCC analysis and results for submission to the SEF 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 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 NCC and any changes that occurred in the period of the NCC appointment;

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

8. Appeals Against Decisions of the Commission

a) If a candidate disagrees with the NCC's decision, s/he can write to the NCC President reasonably requesting a reevaluation. The NCC has a maximum period of three months to reevaluate the application. In the event that the candidate does not agree after the revaluation made by the NCC, he will be able to ask for an appeal by the independent Appeal Committee.

b) The Appeal Committee consists of three members, a Past President of SEF, and two members of the Executive Council of SEF not belonging to the NCC.

c) The decision of the Appeal Committee will be binding on all parties.

9. General Assembly

The REFarC General Assembly must be convened at the SEF Congress and can be called at any time and place, depending on the decisions of the NCC. 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 REFarC are entitled to participate.

10.Expulsion

The NCC may expel from REFarC every member whose misconduct (which will include but will not be limited to non-payment against the REFarC) is, in the opinion of the NCC, adversely affecting the REFarC. Neither REFarC, its officers, employees nor representatives, nor the NCC nor any Member shall have any obligation to the person who has been expelled

11.Variation of the Regulation

a) These Regulations may be only changed when the NCC, unanimously, and the SEF Executive Committee, with three-fourths of the members present, approve the amendment.

b) The notification of the request to change the existing Regulation must be sent to the Secretariat in writing by the NCC.

12.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 NCC, in agreement with the SEF Executive Committee. Its decisions will be final and binding upon all members.

13.Legend

Appeal Committee: Eminent Pharmacologists' Committee that consists of three members, a Past President of SEF and two members of the Executive Council of SEF.

EPHAR: The Federation of European Pharmacological Societies.

EACPT: The European Association for Clinical Pharmacology and Therapeutics.

EuCP: European Certified Pharmacologist

NCC (National Certification Commission): The Commission for candidates' evaluation and approval for inclusion in REFarC.

REFarC (Registro Español de Farmacólogos Certificados): The Spanish Certified Pharmacologists Register.

Register: The Spanish Register of Certified Pharmacologists.

SEF: The Spanish Society of Pharmacology

14.Contact

Secretariat SEF

E-mail: socesfar@socesfar.com

Web site: http://www.socesfar.es

Anexo1. **Procedimiento de evaluación**

A. Impreso de solicitud de evaluación[1] con:

A.1. Nombre y Apellidos:……..

A.2. DNI o Pasaporte[2]:……..

A.3. Titulación principal de acceso[3]

A.4. Miembro de sociedades[2]:

SEF: (si/no)

Miembro de otra Sociedad perteneciente a EPHAR/EACPT (indicar cuál):…….

A.5. Fecha y Firma

B. Curriculum Vitae en formato CVN[4].

El editor está disponible en: https://cvn.fecyt.es/editor/#HOME

C. Documentación[5] y Esquema de evaluación.

Parte 1. Requisitos sobre conocimientos teóricos y prácticos

	Marcar si se dispone de formación teórica específica documentada
Principios básicos de farmacología básica y clínica (farmacodinamia y farmacocinética)	
Bases celulares, bioquímicas y moleculares de la actividad de los fármacos (relativas a sus acciones terapéuticas y a su toxicidad)	
Interacciones de fármacos	
Diseño experimental, biometría y bioestadística	
Principios de farmacología de los órganos	
Proceso de I+D	
Aspectos éticos de la investigación preclínica (incluyendo los principios 3R) y clínica	
Aspectos específicos que afectan a la farmacología, como género, raza y edad.	
Farmacogenética y farmacogenómica	
Procedimientos y reglamentación en la autorización de fármacos y acceso al mercado	
Farmacovigilancia	
Farmacoepidemiología	
Farmacoeconomía	

	Marcar si se dispone de conocimientos prácticos generales documentados	Marcar si se dispone de amplia experiencia práctica directa documentada
Diseño de experimentos preclínicos, métodos biométricos y estadísticos, obtención y tratamiento de datos y realización de estudios in vitro y ex vivo		
Diseño de experimentos preclínicos, métodos biométricos y estadísticos, obtención y tratamiento de datos y realización de estudios in vivo		
Técnicas moleculares y bioquímicas y diagnóstico		
Diseño y gestión de ensayos clínicos		
Métodos biométricos y estadísticos utilizados en investigación clínica		
Farmacogenética y farmacogenómica, epigenética y otras -ómicas		
Determinación de parámetros farmacocinéticos y estudios de metabolismo (concentraciones de fármaco en fluidos biológicos y tejidos, así como en la monitorización de fármacos en terapéutica)		
Farmacoepidemiología, uso de fármacos y/o optimización e individualización de tratamientos (a través de experiencia en farmacodinámica, farmacocinética, farmacogenética, monitorización de fármacos en terapéutica, etc.)		
Enseñanza de la farmacología		
Farmacoeconomía y asuntos regulatorios.		

Parte 2. Formación académica en Farmacología:

1.1. Titulación (será obligatorio obtener un mínimo de 20):

1.1.1. Licenciaturas de 5 o 6 años/Grados de 300 o más créditos (Medicina y Cirugía, Odontología, Farmacia y Veterinaria)…….. 20

1.1.2. Otras Licenciaturas/Grados de 240 créditos relacionados con la Farmacología (Enfermería, Química, Biología, Biotecnología, Biomedicina,….) 10

1.1.3. Másteres relacionados con la Farmacología…….. 10

1.1.3. Título de especialista (Real decreto 639/2014) relacionado con la Farmacología…….. 10

1.1.4. Doctorado (Programa de doctorado relacionado con la Farmacología)…… 10

1.2. Cursos de formación continuada (actualización /perfeccionamiento/innovación/ etc.) relacionados con la farmacología (dependiendo del número de créditos) .....hasta…… 5

Puntuación máxima..... 30

Parte 3. Actividad profesional en el campo de la Farmacología

2.1. Categoría profesional actual y categorías anteriores…… 25

2.2. Experiencia profesional desarrollada (mínimo 10 puntos equivalente a un mínimo de experiencia profesional de 5 años, de los cuales como máximo 4 podrán corresponder a un programa de doctorado)…… 25

Puntuación máxima…….. 40

Parte 4. Reconocimientos profesionales en el campo de la farmacología

3.1. Contribuciones a la actividad farmacológica 20

3.1.1. Actividades de colaboración a nivel nacional e internacional (grupos de investigación, proyectos de investigación, acciones concertadas...)

3.1.2. Pertenencia a Comités científicos y Sociedades científicas nacionales e internacionales

3.1.3. Pertenencia a Comisiones técnico-científicas en el campo de la Farmacología

3.1.4. Reconocimiento de la actividad docente, investigadora y profesional

3.2. Cursos y seminarios impartidos relacionados con la farmacología (cursos de formación, seminarios, ponencias en congresos)… 5

3.3. Actividad editorial (Publicaciones) 14

3.3.1. Artículos en revistas/informes-evaluaciones de experto (mínimo 3 equivalentes a 6 puntos)

3.3.2. Comunicaciones a congresos

3.3.3. Libros

3.3.4. Otra actividad editorial

3.4. Premios Científicos y Títulos Honoríficos..... 1

Puntuación máxima..... 30

Parte	Puntos	Máximo
Parte 2. Formación académica en Farmacología (mínimo 20)		30
Parte 3. Actividad profesional en el campo de la Farmacología (mínimo 10)		40
Parte 4. Reconocimientos profesionales en el campo de la farmacología (mínimo 6)		30
		100

Para obtener la certificación es necesario superar la Parte 1 de acuerdo a los criterios descritos en el Artículo 2.2. y obtener un mínimo de 50 puntos en la suma de las puntuaciones de las Partes 2, 3 y 4.

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[1] Remitir la documentación a través del portal de la SEF www.socesfar.com en formato pdf

[2] Obligatorio incluir copia en el documento pdf de la solicitud

[3] Obligatorio incluir copia título aportado pdf de la solicitud

[4] Firmado y acompañado de declaración jurada del solicitante certificando la veracidad del contenido.

[5] Toda la documentación a evaluar deberá estar debidamente justificada y firmada por el personal autorizado o en su defecto poder ser comprobada por la comisión por ser pública. En todos los casos debe ser tal que permita reconocer de forma inequívoca el mérito y poder asignarle la puntuación que le corresponda. La documentación se presentará en formato electrónico y deberá ser enviada a través del portal de la SEF www.socesfar.com. Una vez finalizado el proceso de evaluación la comisión podrá solicitar los documentos originales o una copia compulsada