

Swiss Society of Pharmacology and Toxicology (SSPT)

Schweizerische Gesellschaft für Pharmakologie und Toxikologie Société Suisse de Pharmacologie et Toxicologie Società Svizzera di Farmacologia e Tossicologia

SCPR Swiss Certified Pharmacologist Register

Guidelines for the Certification as European Certified Pharmacologists (EuCP)

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1. Aims

The aims of the Swiss Certified Pharmacologist Register (SCPR), linked to the EuCP register of the EPHAR (Federation of European Pharmacological Societies) and the EACPT (European Association for Clinical Pharmacology and Therapeutics), are to

- a. Recognize expert scientists and clinicians engaged actively in the multidisciplinary field of pharmacology (by definition, the term "pharmacology" includes in this document experimental and clinical pharmacology);
- b. Ensure that SCPR and EuCP certified pharmacologists maintain high standards of professional expertise;
- c. Ensure that the "Certified Pharmacologist" designation is restricted to those who satisfy the SCPR and EuCP criteria for their professional expertise and competence, standards that are equal for all national societies adhering to EPHAR and/or EACPT;
- d. Stimulate pharmacologists to expand their personal skills with the aim of increasing their chances for obtaining high level positions in a 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 by the EuCP Committee of EPHAR and EACPT, upon notification by the SCPR Evaluation Committee.

2. Application

All candidates who wish to apply for inclusion in the register must use the application form, approved by the SCPR Evaluation Committee, which is available at the end of the document.

2.1. Pharmacologists having already a title in pharmacology

Pharmacologists having either the title "Clinical pharmacologist SSCPT" (SSCPT = Swiss Society for Clinical Pharmacology and Toxicology) for non-MDs, or the title of "Medical Specialist Physician in Clinical Pharmacology and Toxicology" as issued by the Swiss Institute for postgraduate and continuous medical education (SIWF / ISFM) or the Swiss Federal Authorities, or the title of "medical specialist for clinical pharmacology and toxicology" as acknowledged by mutual recognition following the Directive 2005/36/EG (in the currently valid version), who wish to apply for inclusion in the register

- a. must provide a written proof of their "SSCPT clinical pharmacologist" or "specialist for clinical pharmacology and toxicology" title, and
- b. document their activities related to pharmacology between the date on which they obtained the title, and the application date for the EuCP title.

2.2. All other candidates

- 2.2.1. All other candidates who wish to apply for inclusion in the register, have to fulfil all criteria cited below, in order to be eligible for inclusion in the register:
 - a. A university course degree of at least the master level or equivalent in a relevant subject (e.g. medicine, pharmacy, biology, environmental sciences, natural sciences, etc.).

- b. Knowledge of the major areas of pharmacology and toxicology. This has to be proven by the submitted documentation in the application form.
- c. Have proven professional experience and scientific qualifications.
- d. Meet the criteria for admission, as specified by the Certification Commission of EPHAR and EACPT (https://www.eucp-certification.org/).

2.3. All candidates

- 2.3.1. All candidates have to provide proof that they fulfil the following additional criteria:
 - a. Employment in the field of pharmacology, or actively seeking such a position.
 - b. At least 5 years of relevant activity in the field of pharmacology under the guidance of a qualified pharmacologist or at a department/institute of pharmacology or toxicology, or at least 5 years of relevant professional development in pharmacology (experimental, clinical, theoretical or regulatory). This period may be interrupted by periods of complementary training, career breaks, or similar.
 - c. Active membership in the national society of pharmacology (SSPT, SSEP, SKTP; candidates who are not members of one of these societies, but are members of national societies affiliated with EPHAR or EACPT, can also be accepted. Members of other pharmacological societies can only be accepted if there exists a formal agreement between the guest society and the Swiss Society of Pharmacology, which has been approved by the EuCP committee.)
- 2.3.2. Applications have to be submitted before August 31 of each year. The suitability of the candidate for the SCPR must be evaluated by the SCPR Evaluation Committee before November, 30th of the same year. The applicant has to be notified, in writing, within the same year, both in case of positive or negative result.
- 2.3.3. When a candidate has passed the assessment by the SCPR Evaluation Committee, and has paid the registration fee (the amount of which is fixed by the SCPR Evaluation Committee), the SCPR evaluation committee notifies the EuCP committee of her/his inclusion in the SCPR. Once the EuCP Committee has acknowledged the nomination by the SCPR Committee and has issued the EuCP Certificate, the applicant will be included in the SCPR.
- 2.3.4. In the event that the SCPR Evaluation Committee does not approve the application by the candidate, the evaluation committee will issue a list of missing qualifications according to the lists in 2.1–2.3 to the candidate, and the candidate will be entitled to additional opportunities for admission to the register until she/he has fulfilled the admission criteria that are specified in in 2.1–2.3.
- 2.3.5. Before August 31 of the fifth year of having the EuCP title, the concerned SCPR member must resubmit the application form, and document in this form the continuous practice of pharmacology, and a continuous professional development during these 5 years, as required by the EuCP guidelines
- 2.3.6. Members of the SCPR are "Certified Pharmacologists".
- 2.3.7. Members of the SCPR may use the title "EuCP" or "European Certified Pharmacologist".

3. Maintenance of certification

3.1. Maintenance conditions

On a 5-year basis, the EuCPs (SCPR members) 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 (before August 31 of year 5 of the certification):

- a. an updated CV containing relevant information such as details of posts 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, presentations, teaching activities, publication activities in expert committees and/or similar. Regarding educational courses and meetings, official proofs of participation and a detailed program have to be provided, and an equivalent of 250 credit points from certified events has to be obtained during the most recent 5-year period. Scientific meetings on topics related to pharmacology and/or potential drug targets may be considered, based on a provided detailed program.

3.2. Revocation or termination of certification

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

At the end of the 5 years, the members who do not renew their certification, will be removed from the register.

4. Registration/Membership fee

A five-year fee (amount fixed by the SCPR Evaluation Committee) must be paid by each member to SCPR to access and to maintain the register, within 30 days from the receipt of the payment request.

5. SCPR Evaluation Committee

5.1. Members

- a. <u>Appointment of SCPR Evaluation Committee members</u>: The members of the SCPR Evaluation Committee shall be appointed by the board of the SSPT and must be registered as European Certified Pharmacologists. During the initial period of the SSPT 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 this becomes available.
- b. Functions of the SCPR Evaluation Committee:
 - 1) The evaluation of candidates for inclusion in the register and for the renewal of certification.
 - 2) Exclude and remove members from the register.
- c. <u>Composition of the SCPR Evaluation Committee</u>: The SCPR Evaluation Committee is composed of five members, appointed by the SSPT, and holds office for four years. At least one member has to be actively working in pharmacology, one in clinical pharmacology and one in toxicology. These representatives of their specialties have to be members of the respective Swiss societies (SSEP, SSCPT, and SST). A member of the administrative office will participate in meetings with the only function of secretary.
- d. <u>SCPR Evaluation Committee chair</u>: The members of the SCPR Evaluation Committee shall elect a chair(wo)man from within the SCPR Evaluation Committee, and a secretary.
- e. <u>Duration of Assignment</u>:
 - 1) SCPR Evaluation Committee members may not hold office consecutively for more than eight years
 - 2) The members of the SCPR Evaluation Committee may be renewed once after four years.

3) In the event of resignation or retirement of a member or members of the SCPR Evaluation Committee, they will be replaced in accordance with paragraph 5a-iii of this article.

5.2. Meetings

- a. The SCPR Evaluation Committee shall meet at least once a year. It will be possible to hold these meetings as video conferences.
- b. The meeting is valid if three members are participating.
- c. Observers or experts, without the right to vote, can be invited to the meetings at the discretion of the chair(wo)man.
- d. The chair(wo)man formulates the agenda and presides over the SCPR Evaluation Committee. In her/his absence the members present at the meeting design an acting president that shall act as chair(wo)man only for the specific meeting. In each case, a meeting is considered valid in the presence of at least three members. The SCPR Evaluation Committee may be convened at the request of an absolute majority of the committee.
- e. SCPR Evaluation Committee decisions are valid by a simple majority of the committee members participating. In case of dissent, a minority report has to be established.
- f. The secretary, at the request of the chair(wo)man or an absolute majority of the SCPR Evaluation Committee, convenes generally via e-mail a meeting of the committee with reasonable notice of at least 15 days, indicating the agenda. The application documents of the EuCP candidates have to be made available to the members together with the agenda.
- g. The SCPR Evaluation Committee must elaborate operational rules. These include for example to document each meeting by a protocol.

5.3. Functions of the SCPR Evaluation Committee

- a. <u>Review of applications</u>: Applications are evaluated by the SCPR Evaluation Committee that ensures that they comply with the criteria for certification of EPHAR. Initial evaluations of applications are done by 2 independent reviewers.
- b. <u>Responsibilities</u>: The SCPR Evaluation Committee is responsible for:
 - 1) Preparing an annual report and defining the amount of the fee, in consultation with the SSPT board;
 - 2) Managing the SCPR registry and budgets;
 - 3) Including, excluding or removing members from the register;
 - 4) Informing and contributing to the SCPR development in Switzerland;
 - 5) Choosing experts to be convened if necessary;
 - 6) Establishing internal regulations that define situations of conflict of interest, in which a committee member will not participate in the evaluation of a given applicant (e.g. close collaboration, competition, etc.);
 - 7) Proposing updates to the present guidelines and forms to the SSPT board if necessary.

6. Administrative office

6.1. The board of the SSPT

The board of the SSPT ensures the organization of the administrative office.

6.2. Functions of the administrative office

The administrative office is responsible for:

- a. Keeping all the documents and SCPR register and keeping a SCPR member register, preparing detailed minutes of all meetings and archiving SCPR Evaluation Committee documents;
- b. Informing interested applicants on the requirements for the applications;
- c. Notifying and informing applicants of SCPR Evaluation Committee decisions, as quickly as possible;
- d. Preparing the certificates once the candidates have been approved and the fees have been paid:
- e. Communicating periodically to EuCP the new SCPR members, including dates of certification and certification renewal;
- f. Issuing an annual report with the SCPR Evaluation Committee analysis and results for submission to the SSPT assembly, specifying at least:
 - 1) The number of applicants, the outcome of requests, and the percentage approved;
 - 2) The names of those who have been removed from the register for any reason;
 - 3) An analysis of the financial status of the register;
 - 4) The composition of the SCPR Evaluation Committee and any changes that occurred in the period of the committee appointment.

7. Appeals against decisions of the SCPR Evaluation Committee

- 7.1. If a candidate disagrees with the committee's decision, the application must be reconsidered. In the event that the candidate does not agree after the re-evaluation made by the committee, she/he will be able to ask for an appeal by the independent appeal committee.
- 7.2. The appeal committee consists of three members, a past president of SSPT (or sub-organization of the SSPT) and two members of the SSPT board. The members of the appeal committee must not be members of the SCPR Evaluation Committee.
- 7.3. The decision of the appeal committee will be binding on all parties.

8. Reporting

Every year, an annual report of the SCPR activities is presented at the general assembly of one of the four SSPT member societies. This rotation is organized in a way that in each society, the annual report presentation is held every fourth year.

9. Expulsion

The SCPR Evaluation Committee may expel from SCPR every member whose misconduct is, in the opinion of the committee, adversely affecting the SCPR. This includes also non-payment of the membership fee. Neither SCPR, its officers, employees nor representatives, nor the SCPR Evaluation Committee nor any member shall have any obligation to the person who has been expelled. An expelled member has the opportunity to lodge an appeal against the decision (section 7).

10. Changes of the regulation

- 10.1. These regulations may be changed only when the SCPR Evaluation Committee, unanimously, and the SSPT board with three-fourths majority of the members present, approve the amendment.
- 10.2. The notification of the request to change the existing regulation, must be sent to the administrative office in writing by the SCPR Evaluation Committee.
- 10.3. Changes to the guidelines need the final approval of the EuCP Committee in order to come into effect.

11. 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 ruled by the SCPR Evaluation Committee, in agreement with the SSPT board, whose decision shall be final and binding upon all members.

12. Terms and abbreviations

SCPR: Swiss Certified Pharmacologist Register

SCPR Evaluation Committee: the committee for the evaluation of candidates and approval for

inclusion in the SCPR

Register: The Swiss Register of Certified Pharmacologists

SSPT: Swiss Society of Pharmacology and Toxicology

SSEP: Swiss Society of Experimental Pharmacology

SSCPT: Swiss Society for Clinical Pharmacology and Toxicology

SST: Swiss Society of Toxicology

EPHAR: The Federation of European Pharmacological Societies

EACPT: The European Association for Clinical Pharmacology and Therapeutics



Appendix - Application Form

Application form for certification as European certified Pharmacologist (EuCP) according to the guidelines of the SSPT

NAME, first name		
Birth date and location	Dat	te: Country:
Academic title		
Institution		
Position		
e-mail address		
Indicate here whether		Clinical pharmacologist SSCPT
you have one of the		Medical Specialist Physician in Clinical Pharmacology and
following, pharmacology-		Toxicology
related titles	Dat	:e
	obt	rained:

Requirements:

- 1. An academic degree (MD, PhD or MSc or equivalent) in a relevant subject such as medicine, pharmaceutical sciences, biomedical sciences, biology or chemistry;
- 2. Knowledge of the major areas of Pharmacology. These can be obtained either by attending appropriate courses, by practical experience or on job training;
- 3. Documentation of training with respect to knowledge, skills and competencies acquired, obtained during the last 5 years
- 4. Active membership in a national society of pharmacology which is member of EPHAR: Swiss Society of Pharmacology and Toxicology (SSPT) or one of its member societies Swiss Society of Experimental Pharmacology (SSEP), Swiss Society of Clinical Pharmacology and Toxicology (SSCPT), Swiss Society of Pharmaceutical Medicine (SGPM).
- 5. 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;
- 6. Current professional engagement in the practice of Pharmacology;
- 7. Proven significant contribution in at least 3 original publications in peer-reviewed scientific journals (excluding review articles), confidential reports, or assessments (suitable for submission to regulatory agencies or for regulatory decision-making), as first or last author. In case of confidential reports and assessments, the significant contribution has to be proven in the accompanying documents.

Checklist for documents to include

(these documents need to be provided in electronic form)

Check	Document	Description
	Master or equivalent title	Copy of the official document
	Other academic titles (MD, PhD, etc)	Copy of the official document
	Diploma as medical specialist	Copy of the official document
	Diploma of "Clinical pharmacologist SSCPT" or "Medical Specialist Physician in Clinical Pharmacology and Toxicology" if applicable	Copy of the official document
	Documentation of training and professional activities during preceding 5 years *	Reference letter(s) of an established pharmacologist who knows you well, confirming: - Training in pharmacology - Professional activity related to pharmacology (these reference letters have to cover the last 5 years)
	Documentation of ≥ 5 years of relevant pharmacological experience	Confirmation by the employer
	Documentation of current activity/employment	Confirmation by the employer
	Current CV **	
	List of publications	
	Ethical code of conduct	Signed EPHAR document of code of conduct
	SSPT or related society membership	Indicate the starting year of your membership, and the name of the society.

Additional documents (optional)

- *, This reference letter should describe the type of activity in pharmacology the applicant has carried out, it should also describe the extent of his/her knowledge in pharmacology. Several reference letters can be provided; together they should cover at least the preceding 5 years. See section "Indications regarding the application", below.
- **, The CV needs to contain the following elements: Complete address, higher education, employment history, list of funded research projects, teaching activities, membership in panels & scientific review activities, membership in scientific / professional societies, organization of conferences, prizes and awards.

Indications regarding the application

The assessment is based on the SSPT Guidelines for Certification of the EuCP program from EPHAR and EACPT and the Guidelines for Certification of Medical Specialists in Pharmacology and Toxicology as European Certified Pharmacologists (both available at...(to complete))

A.	Theoretical knowledge of pharmacology
	The EuCP Guidelines for Certification require theoretical knowledge in all of the following areas:
	principles of basic and clinical pharmacology (pharmacodynamics, pharmacokinetics;
	 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.
	Please describe here how you fulfil these criteria. Indicate also if you are expert in other, more specialized topics of pharmacology.

В.	Practical knowledge and skills
	A candidate for EuCP has to possess practical awareness (not necessarily experience) in five of the following topics and in-depth knowledge and experience of at least two of the following topics:
	preclinical experiment design, biometrical and statistical methods, data retrieval and derivation and performance of in-
	vitro and ex-vivo studies;
	 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;
	biometrical and biostatistical methods used in clinical research;
	pharmacogenetics and -genomics, epigenetics and other - omics;
	 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.);
	10. teaching and education in pharmacology;
	11. pharmacoeconomics and/or regulatory affairs.
	Check the topics of those mentioned above in which you have practical awareness, and discuss topics on which you have in-depth knowledge:

	With reference to "B10. Teaching and education in pharmacology", describe your involvement in activities such as academic teaching, internal teaching (in an industrial setting), and in continuous education. Provide confirmation of such activities, such as for example a current teaching register if you teach at a university.
C.	Other indications (optional)

