

www.epar.org



THE FEDERATION OF EUROPEAN
PHARMACOLOGICAL SOCIETIES

Projet EuCP European Certified Pharmacologists™



Utrecht 27-28 mars



Société Française de
Pharmacologie et de Thérapeutique

Background

- « In many countries world-wide, pharmacologists have raised concerns that pharmacology as a discipline is under threats of disappearing. In not few universities, departments of pharmacology have been abolished or merged with other units to form larger entities ... the visibility of our science has clearly been diminished. This also could easily result in a much weaker position of us pharmacologists when talking to policy-makers, governments and the like when attempting to secure the public support of pharmacological research and the public awareness of the importance of our science for giving expert advice. ”
- “Many pharmacologists have rightfully warned that the only possibility left for them to identify themselves as pharmacologists’ is membership in our societies of pharmacology. “

Objectif

- The European Certification of Pharmacologists is a system of The Federation of European Pharmacological Societies (EPHAR) for individual pharmacologists or scientists **working in the field of pharmacology** who **excel in standards** of education, skills, experience and professional standing. Individuals such qualified can apply to be certified as EUROPEAN CERTIFIED PHARMACOLOGIST (EuCP).

Exemples



- Le plus connu et le plus avancé: EUROTOX (Federation of European Toxicologists and European Societies of Toxicology, 7000 membres)
- EUROTOX a créé le « European Registered Toxicologist (ERT) » dès 1994 mise en place dans 17 des 31 sociétés nationales de EUROTOX
- Environ 1500 toxicologues certifiés, soit >20% des membres
- <http://www.eurotox.com/ert/>

Insertion Européenne

IMI LifeTrain EMTrain

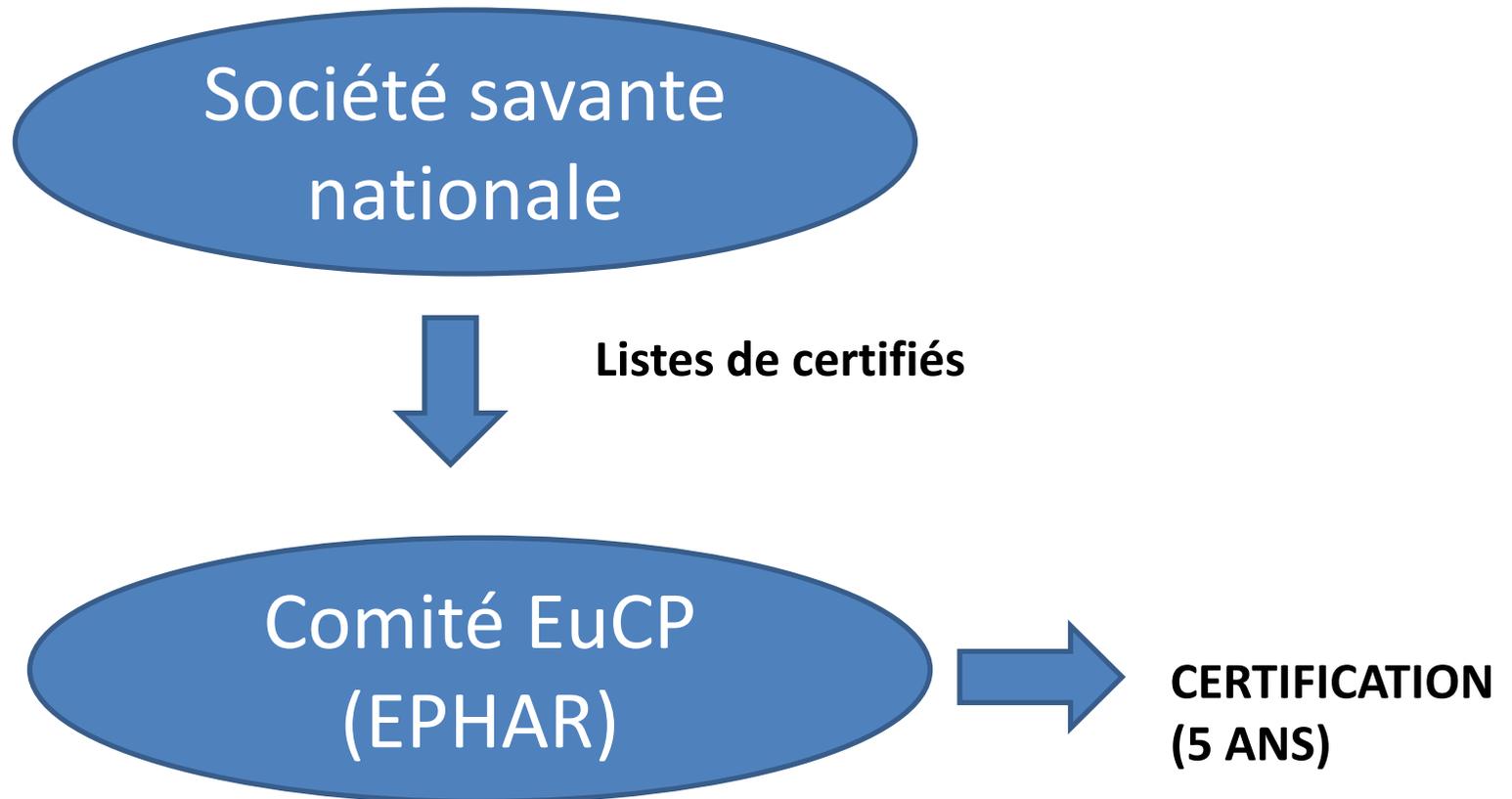


Charter for Professional/Scientific Bodies

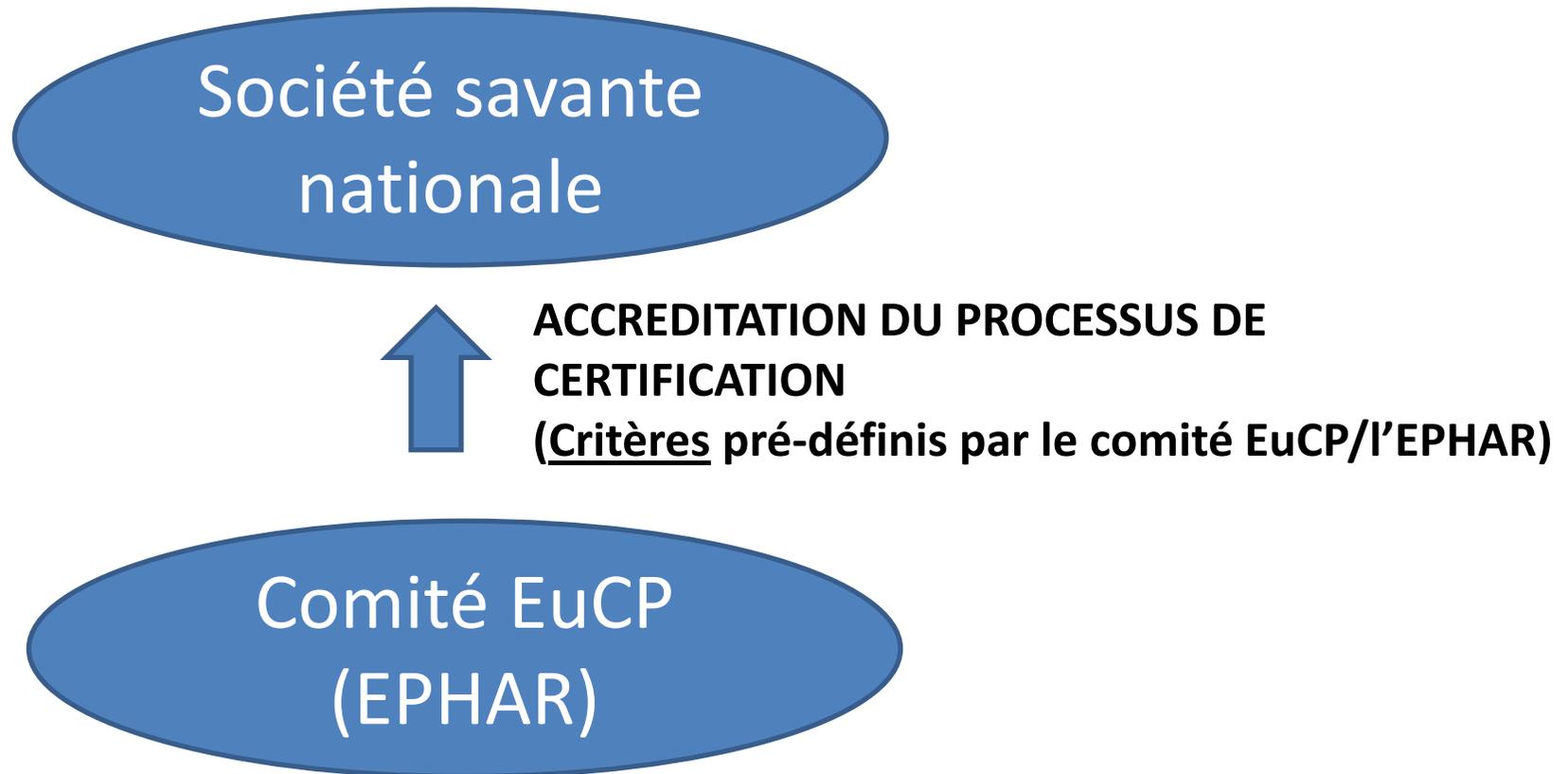
1. Encourage maintenance of professional competency as a pre-requisite for continuing membership, including continuing certification/re-registration*
2. Support members to develop and maintain a competency portfolio
3. Recognise the importance of trans-disciplinary and generic competences
4. Mutually recognise competences from all partner professional/scientific bodies
5. Implement the shared IMI Education and Training standards for course quality and certify courses that fulfil the appropriate criteria
6. Monitor compliance

*only applies to professional bodies

Principe général



Principe général



Pré-requis généraux pour la certification

- An academic **degree** (MD, PhD or MSc or equivalent) in a relevant subject such as medicine, pharmaceutical sciences, biomedical sciences, biology or chemistry;
- **Knowledge of the major areas of Pharmacology**. These can be obtained either by attending appropriate **courses**, by **practical experience** or on **job training**;
- **Active membership in a national society of pharmacology** which is member of EPHAR;
- At least **5 years of relevant pharmacological experience** (in laboratory, clinical, theoretical or regulatory work
- **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).



Introduction
The European Register of Pharmacologists is a service of the Federation of European Pharmacological Societies (EPHAR) for individual pharmacologists or scientists working in the field of pharmacology who meet in standards of education, skills, experience and professional standing, individuals such qualified can apply to be certified as EUROPEAN REGISTERED PHARMACOLOGIST (ERP).

The Guidelines for Registration describe the formal requirements and procedures for Registration and its recognition as well as fields of theoretical and practical knowledge and experience that are required for eligibility for registration. In order to cope with the large extent of specialisation in the field of pharmacology today, the Guidelines attempt to identify core competencies, which should be required by all applicants, as well as specific topics or fields, which may constitute additional elements of training. Finally, the tasks and responsibilities of the national registering bodies as well as of EPHAR are set out in these Guidelines.

The Guidelines for Registration shall be reviewed and updated as regular intervals (approximately 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 with the European context. The EPHAR ERP Committee shall do this in close cooperation and consensus with those national societies of pharmacology or professional bodies that are responsible for the primary registration procedure. Significant changes of these Guidelines are subject to approval by the EPHAR Executive Committee and validation by the EPHAR Council.

General Principles of the Registration Procedure
In a first step, a national registering board (the respective national pharmacological society) evaluates applications of candidates according to a consensus process and admit success candidates to their national register. In a second step, upon request by a candidate and endorsement by the national registering board or national pharmacological society, EPHAR will apply these individuals as ERP without further evaluation. The national registering body is fully responsible to ensure that the candidate has fulfilled all requirements to be eligible for registration as ERP.

Pré-requis spécifiques: formation théorique

- **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 and should embrace at least the following topics:**
 - ✓ principles of basic and clinical pharmacology (pharmacodynamics, pharmacokinetics);
 - ✓ cellular, biochemical and molecular bases of drug action (therapeutic and toxic);
 - ✓ drug interactions;
 - ✓ experimental design, biometry and biostatistics;
 - ✓ principles of organ pharmacology;
 - ✓ R & D processes;
 - ✓ ethical aspects of preclinical (including the 3R principle) and clinical research;
- **In addition, elective topics, such as listed below, should be recognised:**
 - ✓ specific aspects of pharmacology such as gender, age, ethnicity;
 - ✓ systems pharmacology
 - ✓ pharmacogenetics and -genomics;
 - ✓ procedures and rules that govern marketing authorization and market access;
 - ✓ pharmacovigilance;
 - ✓ pharmacoepidemiology;
 - ✓ pharmacoconomics;
 - ✓ regulatory sciences and affairs;
 - ✓ safety pharmacology.

Pré-requis spécifiques: formation pratique

- 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 science, or can be obtained in specific courses meeting EuCP quality criteria.
- 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 practical awareness (not necessarily experience) in half 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;
 - ✓ biochemical and molecular techniques and diagnostics;
 - ✓ clinical trial design and management;
 - ✓ 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);
 - ✓ pharmacoepidemiology, pharmaco-utilisation and/or treatment optimization and individualization (through expertise in pharmacodynamics, pharmacokinetics, pharmacogenetics, therapeutic drug monitoring etc.);
 - ✓ teaching and education in pharmacology;
 - ✓ pharmacoconomics and/or regulatory affairs.

Pré-requis spécifiques: formation pratique

- 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 science, **or can be obtained in specific courses meeting EuCP quality criteria.**
- 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 practical awareness (not necessarily experience) in half 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;
 - ✓ biochemical and molecular techniques and diagnostics;
 - ✓ clinical trial design and management;
 - ✓ 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);
 - ✓ pharmacoepidemiology, pharmaco-utilisation and/or treatment optimization and individualization (through expertise in pharmacodynamics, pharmacokinetics, pharmacogenetics, therapeutic drug monitoring etc.);
 - ✓ teaching and education in pharmacology;
 - ✓ pharmaco-economics and/or regulatory affairs.

- Avis favorable pour la participation de la SFPT au dispositif donné par le CA en date du 9 Avril 2014
- Avis transmis à l'EPHAR