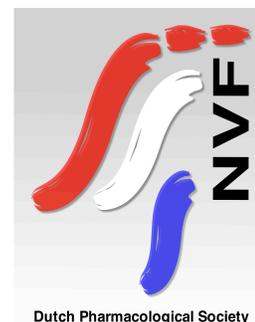


NEDERLANDSE VERENIGING VOOR FARMACOLOGIE

DUTCH PHARMACOLOGICAL SOCIETY



Conditions for Accreditation as (Basic) Pharmacologist

1. Introduction

The Dutch Pharmacological Society (DPS) is the organization of professional (basic) pharmacologists in The Netherlands. The DPS organizes scientific activities for its members and aims to advance of the pharmacological profession in the biomedical field. To achieve this goal, the DPS has defined a number of qualifications to which scientists should comply in order to obtain their accreditation as a (basic) pharmacologist registered with the DPS. This accreditation is comprised of elements of scientific knowledge and practical skills. The conditions for accreditation as an acknowledged, professional pharmacologist including the procedure for application, examination and evaluation are described in this document.

2. Profile of a Professional Pharmacologist

A professional pharmacologist is an expert with appropriate scientific and theoretical knowledge and practical skills in experimentation and evaluation regarding pharmacodynamics and pharmacokinetics of medicinal compounds. Meeting with the criteria to become a pharmacologist means that he/she will be able to design/criticize experiments aimed at identification of ligand-target-interaction. Moreover, he/she will be able to develop and/or use pharmacodynamic and pharmacokinetic parameters to allow proper evaluation of medicinal compounds. The area of expertise of a pharmacologist ranges from molecular receptor pharmacology in cell-lines and laboratory animals up to drug effects in humans. Pharmacologists will apply state of the art technology such as “pharmacogenomics”, “functional genomics” and “proteomics” in combination with more classical experimental techniques in isolated organs or *in vivo* models.

This allows the pharmacologist to participate in a multidisciplinary environment with other professional biomedical investigators in projects to assess or evaluate the mode of action of potential medicinal compounds, as well as in the (pre)clinical development and assessment of drugs. Examples of positions where a professional pharmacologist can be employed include laboratories for drug discovery and development, education and evaluation as well as institutes

for drug action in academic hospitals, pharmaceutical companies, hospitals and government institutes.

3. Basis for Professional Training of the Professional Pharmacologist

The profession of pharmacologist is subject to continuous change, both internally (as a discipline) and externally (the environment in which pharmacology plays a role). This is caused by the increased multidisciplinary in drug research regarding discovery as well as development processes (process instead of discipline oriented). In addition, the use of a wide variety of technologies derived from other fields such as molecular biology and cellular biology (pharmacogenomics, functional genomics, proteomics) together with the possibilities to apply new imaging technologies and bioinformatics are at the basis of perpetual alterations. The current training program for accreditation as a professional pharmacologist has been approved in extended consultation between the Board of the DPS and the Professors of Pharmacology at the Academic Pharmacology Institutes at the Universities of Amsterdam, Groningen, Leiden, Maastricht, Nijmegen, Rotterdam and Utrecht. The program is designed to meet the needs of society and the practical consequences of the above stated.

The curriculum is based on the following:

- The curriculum consists of modules that can be attended partly as courses and partly on an individual basis. These modules can be attended at the participating universities and graduate schools, while certain skills can be obtained at non-academic institutes (e.g. pharmaceutical companies, governmental institutes).
- The minimum requirements can be met within the time frame of the appointment as a PhD-student (or AIO-position) at one of the Universities mentioned. Alternatively, the qualification can also be obtained during a post-doc position.
- The curriculum will be drawn up individually and evaluated.

4. Accreditation Procedure

Roadmap to qualify as a professional pharmacologist:

1. The candidate (AIO/PhD-student) has to complete the standard application form¹ and submit it to the (secretary of the) Accreditation Committee (CTB), signed by the principal supervisor. This form should contain:
 - a. *The CV of the candidate + copy of master diploma academic education (the candidate needs to meet with the criteria for admittance).*
 - b. *Name of the intended tutor(s) + description of the pharmacological characteristics of the intended training environment (tutor and environment need to meet with the training criteria).*
 - c. *The completed list of described end-terms (see training criteria below), which describes the present knowledge and expertise and how possible gaps in the knowledge will be filled (aim is to allocate general pharmacological qualifications per individual that are recognizable and acknowledged).*

¹ Form "Aanmelding Farmacologenopleiding"

2. The CTB evaluates the submitted plan based on the qualities of the candidate, the tutor and institute (acknowledged supervisor and training environment), the intended PhD project (clear pharmacological content) and the quality and quantity of the proposed course plan. Evaluation of the training programme is performed according to the below mentioned accreditation terms (section 5).
3. After completion of the training programme a final report is drawn up by both the candidate and the supervisor and submitted to the CTB. This report describes (in the same structure as the training plan) the success (and possible limitations) of the various aspects of the training programme. Changes in the original plan (as submitted under 1.) should be reported immediately using an updated training plan.
4. Upon evaluation of the report, the CTB may wish to discuss it with the candidate or the supervisor. Possible gaps may be evaluated in an interview.
5. Accreditation is finalized by a diploma issued by the DPS and due from the date of issue up to seven (7) years thereafter.

5. Accreditation Terms

5.1. Admittance Criteria

Masters' Degree in Pharmacy, (Bio) Pharmaceutical Sciences, Medicine, Medicinal Biology, or comparable (in consultation with the CTB).

5.2. Training Duration

It should be possible to complete the program within a regular PhD project of 3-4 years, in which research is performed with a pharmacologically identifiable profile.

5.3. Requirements

Thesis

Registration as a pharmacologist is obtained upon completion of a PhD-thesis with a pharmacological subject or comparable documented peer-reviewed experimental pharmacological studies (in consultation with the CTB). The training is further comprised of several basic skills implemented in biomedical PhD programmes at Dutch Universities and Research Schools (such as courses in biostatistics, experimental study design as well as scientific publication and presentation).

5.3.1. Minimum requirements:

- Thesis with pharmacological profile
- At least two pharmacological publications as first author
- Courses in:
 - Pharmacokinetics
 - Pharmacodynamics
 - Animal experimentation

- Basics in Pharmacotherapy
 - Pharmacology of main drug classes
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- Minimum of two (2) presentations at the DPS Annual Meeting
 - Minimum of one (1) presentation at an international (preferably pharmacological) scientific meeting

5.4. Final Terms

5.4.1. General

When the pharmacology training program is integrated in a PhD program at one of the mentioned Dutch Universities or Research Schools, the final terms drawn up by these institutions apply (see for example: 1, 2, 3) and the specific final terms below. These specific final terms for the accreditation as a pharmacologist can often be integrated with the above mentioned PhD programs provided that the courses they consist of have an “advanced” level.

5.4.2. Knowledge²

- Broad knowledge of general pharmacodynamics and pharmacokinetics
- Broad knowledge of quantitative pharmacodynamic and pharmacokinetic analytical methods
- Broad knowledge of transmitter/hormonal systems, their respective receptors and intracellular signal transduction together with their merit in important pathophysiological mechanisms
- Knowledge of molecular biological technologies and pharmacogenetics

And additionally two of the following:

- Methods in drug discovery and drug development³
- Knowledge of design and conduct of studies under GLP⁴
- Knowledge of design and conduct of clinical studies⁵

5.4.3. Skills

- Application of knowledge mentioned in section 5.4.2 in experimental design, conducting and analysis of drug effects (for example in research proposal).
- Use of several experimental models
- Translation of a published method into an experimental protocol
- Assessment of druggability of potential biological targets

² At the level of: Human Pharmacology, 3rd Ed. Brody, Larner, Minneman (Eds), Mosby, St. Louis, 1998; of Goodman & Gilman's The Basis of Therapeutics, 9th Ed. Hardman, Limbird (Eds), McGraw-Hill, New York, 1996.

³ Level “Modern Drug Discovery” Course LACDR

⁴ Level GUIDE cursus : <http://www.nvkfb.nl/news/GUIDE%20Course%2020080208.pdf?>

⁵ Level GUIDE cursus: <http://www.trialcoordinationcenter.nl/KGO2007/index.htm>

5.4.4. Others

- Legal permission to conduct animal experiments (ex article 9 Dutch Law on Animal Experimentation), unless a specialized *ex vivo* pharmacological technique is mastered.

6. Scrutiny and quality of the training program

Regarding this, the following principles apply:

6.1. Accreditation Committee (CTB)

The DPS appoints an Accreditation Committee (Commissie Toetsing en Beoordeling: CTB) from its senior members. This Committee consists of DPS members elected based on their knowledge of the field. The CTB is endowed to evaluate the curriculum of candidates in light of the requirements set by the accreditation rules. Upon approval, the CTB acknowledges the candidate as a professional pharmacologist on behalf of the DPS.

The CTB performs an entrance- and exit check. When a PhD student indicates to be eligible for accreditation as a pharmacologist, he/she needs to comprise a training program according to the criteria mentioned below. This training program is submitted to the CTB for advice. After approval in advance, the CTB also evaluates whether the program has met the criteria upon completion.

6.2. Tutor and trainingcenters

The DPS assembles a register of tutors and trainingcenters. These registers can be found on the DPS website.

6.2.1. Trainer

Per University or Research School, there will be one principal tutor (pharmacologist) and co-tutors (professors in pharmacology). The principal tutor coordinates the activities regarding the training in contact with the CTB/DPS. He/she can assign his training responsibilities to a co-tutor, which will be stated in the training program.

6.2.2. Training centre

A University or Research School can serve as an accredited pharmacological training centre after acknowledgment by request to the CTB. In order to be able to evaluate the quality of the training, the training centres will be visited by the CTB, which in principle will take place every 7 years. Visitation criteria are focussed on the autonomy of a centre to perform the training of a candidate and/or the existence of workable agreements with other centres, institutes or companies.

6.3. Accreditation and renewal

The CTB maintains a register of accredited DPS members. This accreditation is due after 7 years and re-registration is needed for continuation of registration. Re-registration is linked to active DPS membership and professional use of the accreditation e.g. in a position in pharmacology (researcher, tutor, drug advisor, clinical specialist etc.) in academia, hospital, research and development, or government institute (e.g. Medicines Evaluation Board). The administration of

accreditations and renewal will be organized by the DPS. The board of the DPS has an annual meeting with the CTB and tutors to review/renew accreditations.

7. Conditions for Implementation

- CTB members are appointed by the board of the Dutch Pharmacological Society.
- These Rules will apply from 1 October 2008.
- The above-mentioned plan will be proposed to the SMBWO and upon approval, the registration will be carried out by this organization.