National Training Requirements

SWEDEN

Specialty
Clinical Pharmacology
(Klinisk farmakologi)

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Supplied by (name):	J. Holm, S. Rosenborg
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Doctors' specialist medical training

Regulations and general guidelines

Descriptions of objectives

2008

Socialstyrelsen

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Regulations and general guidelines for doctors' specialist medical training

adopted 24 June 2008.

The National Board of Health and Welfare (Socialstyrelsen) prescribes the following under the provisions of Chapter 4, Sections 1 and 3 of the Ordinance (1998:1513) on Professional Activities in the Health and Medical Care System, and adopts the following general guidelines.

Under the provisions of the Statutes Ordinance (1976:725), Appendix 2, the regulations on which knowledge, skills, and approaches are to apply for each specialist competence (descriptions of objectives) will be published by other means in a special publication. Descriptions of objectives listed under the heading 'Training Structure' constitute general guidelines, as do the teaching methods under the heading 'Partial Objectives' where the follow-up method is not indicated.

Chapter 1 Area of application and explanation of terms

Section 1. These regulations are to apply to the further training of licensed doctors in order to achieve specialist competence according to Chapter 3, Section 9 of the Law (1998:531) on Professional Activities in the Health and Medical Care System.

Section 2. The following concepts and terms are used in these regulations and general guidelines:

Intended specialist competence	the specialist competence that the licensed doctor undergoing specialist medical training (the ST doctor) intends to obtain with the planned training
Tutor	a person who continuously, and in dialogue form, supports and guides as well as evaluates a staffer regarding his or her professional development
instruction	assignment from a staffer to an ST doctor on work-specific techniques or procedures, while not being responsible for the ST doctor's professional development
instructor	staffer who gives the ST doctor assignments on work-specific techniques or procedures, while not being responsible for the ST doctor's professional

	development
director of studies	doctor with specialist competence who provides an organisational support function for a clinical manager, tutor, and ST doctor. The director's area of responsibility can relate to one or several training units, all or part of a county council, region, or corresponding unit
clinical manager	holder of the position responsible for operations
health care provider	natural person or legal entity that practices health care professionally

Chapter 2 The basis for specialist medical training

Section 1. In accordance with Chapter 4, Section 1, first paragraph of the Ordinance (1998:1513) on Professional Activities in the Health and Medical Care System, the licensed doctor wishing to obtain specialist competence must undergo further education for at least five years in order to acquire the knowledge, skills, and approaches prescribed for the specialist competence being sought. These must be acquired through service as a doctor under tutoring and through participation in supplementary training (specialist medical training).

Section 2. Vacations and on-call compensation may be credited in specialist medical training.

Section 3. If the specialist medical training is completed on part time, the specialist medical training must be extended so that the service time corresponds to at least five years of full time service.

Chapter 3 Quality aspects in specialist medical training

Section 1. The health care provider is to provide directives and see to it that there are documented routines, so that the specialist medical training can be carried out and regularly evaluated, in order to ensure consistently high quality in the specialist training.

Service and training programmes

Section 2. The health care provider is responsible for access to a director of studies, who must be a doctor with specialist competence, and who has undergone tutor training.

Section 3. The clinical manager is responsible for

1. assigning a tutor for the licensed doctor undergoing specialist medical training (the ST doctor),

2. establishing and finalising an individual training programme in accordance with the requirements in the description of objectives, in consultation with the tutor and the ST doctor,

3. scheduling theoretical training elements and courses into the training programme in accordance with the requirements in the description of objectives, and

4. auditing the training programme regularly, and additionally as needed, in consultation with the tutor and the ST doctor.

General guidelines

Courses during specialist medical training should be audited for quality.

An example of this is the courses announced by IPULS, the Institute for Professional Development of Doctors in Sweden, and which are quality audited according to a clear standard.

The tasks of the director of studies should include providing an organisational support function for clinical managers, tutors, and ST doctors. The director of studies should, among other things, participate in establishing training programmes, drawing up orientation programmes, and see to it that the tutors have the relevant qualifications for the field.

The need for necessary tutor and instructor contributions should be met by access to doctors with the relevant specialist competence and other staffers in the operation with specialist medical training.

Operations where specialist medical training is practised should be comprehensive enough to meet the requirements for competence in the description of objectives. There should be premises and equipment to the extent and standard needed to achieve the requirements of the description of objectives.

All ST doctors should have access to regular, planned internal and external training, as well as the opportunity for time regularly set aside for self-study. The operation should also offer ST doctors the opportunity to participate in research and quality development work.

Tutoring and instruction

Section 4. In accordance with Chapter 4, Section 1 of the Ordinance (1998:1513) on Professional Activities in the Health and Medical Care System, the specialist medical training must be carried out under tutoring.

General guidelines

Tutoring should be provided regularly, with the greatest continuity possible, and should be in agreement with and based on the individual training programme.

Outside of tutoring, the ST doctor should be continuously provided with the necessary instructions in the service, with feedback from operations staff.

Section 5. The tutor must have specialist competence in the intended speciality, and must have undergone tutor training.

General guidelines

Tutor training should include tutoring, pedagogy, communication, and ethics.

Documentation, evaluation, and assessment

Section 6. The clinical manager is responsible for the continuous, regular evaluation of the ST doctor's professional development, based on the description of objectives and the training programme, during the entire specialist medical training.

Section 7. ST doctors, with the support of their tutors, must continuously document skills achieved and knowledge acquired.

General guidelines

The tutor should continuously support, guide, and evaluate the ST doctor's professional development.

The continuous evaluation of the ST doctor's professional development should

- encompass all aspects of the specialist medical training and all the objectives covered in the description of objectives,
- be carried out using methods known and agreed on in advance, and
- as a rule, be carried out internally within the operation.

If there are deficiencies in ST doctors' competence, it should lead to improvements in their training programmes, in the training efforts of the operation, or, where appropriate, through more explicit demands on the ST doctors' efforts.

The clinical manager, or the doctor with the intended specialist competence to whom the clinical manager has given the assignment, should hold regular professional development interviews, which should be documented. Tutors should document their interviews with the ST doctors. ST doctors should also document tutor and professional development interviews.

Section 8. The health care provider must give directives and ensure that there are documented routines for how operations with specialist medical training are to be regularly reviewed through external inspections.

The inspecting unit and the operation inspected must not have economic, administrative, or organisational connections with each other.

The review must relate to the requirements set down in Sections 1 through 7, as well as those pertaining to general guidelines.

General guidelines

A review according to Section 8 may be done in accordance with the SPUR inspection model (a model for external review developed by the training quality foundation of the Swedish Medical Association and the Swedish Society of Medicine).

Chapter 4 Combined specialities, etc.

Section 1. There must be two responsible clinical managers and two responsible tutors for the specialist competences in clinical immunology and transfusion medicine, clinical bacteriology and virology, and industrial and environmental medicine.

The provisions of this chapter regarding the clinical manager are also intended for the doctor with the intended specialist competence to whom the clinical manager has given the assignment.

Exceptions from the requirement for dual clinical managers may be made if the clinical manager has dual specialist competences in accordance with the above, or specialist competence in accordance with the speciality listing indicated in Chapter 4, Section 1 of the Ordinance (1998:1513) on Professional Activities in the Health and Medical Care System. The same exception also applies to the requirement for the tutors.

Section 2. The clinical managers indicated in Section 1, first paragraph, must both have the indicated specialist competence for the combined speciality in question. The same requirement applies to the tutors.

This means that the clinical manager and the tutors must have specialist competence in

1. clinical immunology and transfusion medicine respectively for the speciality in clinical immunology and transfusion medicine,
2. bacteriology and virology respectively for the speciality in clinical bacteriology and virology, and
3. occupational health care and occupational and environmental medicine respectively for the speciality in industrial and environmental medicine.

Section 3. One of the clinical managers and one of the tutors must have chief responsibility for the specialist medical training.

The clinical managers must select which of them will bear chief responsibility through an agreement. The same applies to the tutors.

Section 4. The clinical manager with chief responsibility is responsible for

1. establishing a training programme for the ST doctor,
2. designating a tutor with the relevant specialist competence,
3. providing the ST doctor with tutoring, and
4. co-ordinating the certification procedure in consultation with the tutor with chief responsibility when the ST doctor has achieved all the requirements in the description of objectives.

Section 5. The tutor with chief responsibility must

1. establish a training programme for the ST doctor in consultation with the clinical manager with chief responsibility,
2. provide the ST doctor with tutoring, and
3. co-ordinate the certification procedure in consultation with the clinical manager with chief responsibility when the ST doctor has achieved all the requirements in the description of objectives.

Section 6. The clinical managers and tutors are responsible within their respective medical fields for certifying that the ST doctor has achieved the requirements of the description of objectives in their parts.

Section 7. In the speciality of radiology, a specialist in medical radiology must tutor and approve ST doctors being trained in the speciality.

Chapter 5 Branch and additional specialities

Section 1. In Chapter 4, Section 1 of the Ordinance (1998:1513) on Professional Activities in the Health and Medical Care System, the conditions under which a licensed doctor can obtain a certificate in a branch speciality and an additional speciality respectively are indicated.

General guidelines

A licensed doctor who wishes to obtain a qualification in a branch or additional speciality can, to a limited extent, begin specializing in the intended branch or additional speciality within the specialist medical training for the base speciality.

Section 2. Obtaining a certificate of specialist competence in emergency medical care requires possession of specialist competence in a base speciality belonging to any of

1. the surgical specialities,
2. the internal medicine specialities,
3. the paediatrics specialities,
4. the psychiatry specialities,
5. the neurological specialities (except clinical neurophysiology), or
6. the individual base specialities (except social medicine and clinical genetics).

Section 3. For those licensed as a doctor prior to 1 July 2006 who are applying for specialist competence in emergency medical care and who wish to include specialist competence in accordance with older regulations, the following shall apply.

Obtaining a certificate of specialist competence in emergency medical care requires a certificate of specialist competence in a speciality belonging to any of

1. the operating specialities,
2. the internal medicine specialities,
3. the paediatric specialities,
4. the psychiatric specialities, or
5. the individual specialities in general practice, occupational health care, school health care, skin and sexually transmitted diseases, neurology, infectious diseases, rehabilitation medicine, oncology, and pain relief.

Section 4. Obtaining a certificate of specialist competence in pain relief requires possession of a specialist competence certificate in a base speciality belonging to any of

1. the surgical specialities,
2. the internal medicine specialities,
3. the paediatric specialities,
4. the psychiatric specialities,
5. the neurological specialities (except clinical neurophysiology), or
6. the individual base specialities (except social medicine and clinical genetics).

Section 5. For those licensed as a doctor prior to 1 July 2006 who are applying for specialist competence in pain relief and who wish to include specialist competence in accordance with older regulations, the following shall apply.

Obtaining a certificate of specialist competence in pain relief requires possession of a certificate of specialist competence in a speciality belonging to any of

1. the operating specialities,
2. the internal medicine specialities,
3. the paediatric specialities,
4. the psychiatric specialities, or
5. any of the individual specialities in general practice, occupational health care, school health care, skin and sexually transmitted diseases, neurology, infectious diseases, rehabilitation medicine, and oncology.

Chapter 6 Crediting qualifications from doctoral studies and service abroad

Section 1. In accordance with Chapter 4, Section 1, first paragraph of the Ordinance (1998:1513) on Professional Activities in the Health and Medical Care System, qualifications from doctoral studies may be credited towards specialist medical training.

On condition that the requirements in the description of objectives in question are fulfilled, The National Board of Health and Welfare (Socialstyrelsen) shall issue a specialist competence certificate after at least four and a half years of service if the ST doctor has

1. a Swedish doctorate, or
2. a foreign doctorate that is judged to correspond to a Swedish doctorate by a Swedish university or college, or where applicable by the Swedish National Agency for Higher Education.

Section 2. Service in a clinic or corresponding facility in a country other than Sweden (service abroad) may be credited towards specialist medical training, if it

1. was included as part of an individual training programme,
2. was carried out under tutoring,
3. can be confirmed with a certificate issued by the institution's clinical manager or corresponding person, and
4. has led to the fulfilment of planned partial objective competence according to the clinical manager who will certify that the requirements of the description of objectives is fulfilled in its entirety.

The certificate under Point 3 must contain a short description of the operations managed at the institution.

Section 3. For doctors with licenses from a third country (a state outside the European Union and the European Economic Area), service may be credited in accordance with Section 2 from the moment the license was issued.

Chapter 7 Application and approval procedures

Section 1. In accordance with Chapter 3, Section 10 of the Law (1998:531) on Professional Activities in the Health and Medical Care System, issues of specialist competence will be examined by The National Board of Health and Welfare (Socialstyrelsen).

Section 2. The clinical manager, or the doctor with the intended specialist competence to whom the clinical manager has given the assignment, and the tutor are responsible for achieving the indicated training objective in the unit where operations within the intended speciality are managed.

Application

Section 3. An application for specialist competence in accordance with Chapter 3, Section 9 of the Law (1998:531) on Professional Activities in the Health and Medical Care System must be made on Form SoSB 45000 (***Appendix 1***). The application must be sent to The National Board of Health and Welfare (Socialstyrelsen).

Section 4. The clinical manager, or the doctor with the intended specialist competence to whom the clinical manager has given the assignment, and the tutor are to issue a certificate on form SoSB 45001 (***Appendix 2***) showing that the ST doctor has

1. acquired the knowledge, skills, and approaches indicated in the finalised description of objectives for the speciality being sought,
2. completed at least five years of service under tutoring, and
3. made use of the teaching methods in the description of objectives to the extent they indicate teaching methods as indicated in Section 7.

If any service abroad was relevant to fulfilling an objective or partial objective in the description of objectives, this shall also be indicated on the certificate.

The certificate must be attached to the application to The National Board of Health and Welfare (Socialstyrelsen).

Section 5. In the event the clinical manager has assigned a doctor with the intended specialist competence to issue the certificate in accordance with Section 4, this shall be verified by the clinical manager (***Appendix 2***).

In the event the clinical manager has been the tutor for the ST doctor, the clinical manager must designate a doctor with the intended specialist competence who, alongside the clinical manager him- or herself, is to certify the competence achieved (***Appendix 2***).

Section 6. If the ST doctor has served in several units, the clinical manager, or the doctor with the intended specialist competence to whom the clinical manager has given the assignment, in the unit within the speciality being sought where the ST doctor last served for the certificate are responsible.

The clinical manager must then consult with the clinical managers, or the doctor with the intended specialist competence to whom the clinical manager has given the assignment, in the units where the ST doctor served previously (***Appendix 2***).

Section 7. The following teaching methods in the description of objectives is to be used and shown via certificate on forms SoSB 45002, SoSB 45003, SoSB 45004, SoSB 45005 and SoSB 45006 (***Appendices 3–7***), which are to be sent to The National Board of Health and Welfare (Socialstyrelsen) in connection with applications for specialist competence in:

1. clinical service,
2. auscultations – only when the teaching method is indicated in the description of objectives as an alternative to clinical service,
3. courses,
4. written individual work in accordance with scientific principles, and
5. quality and development work.

General guidelines

The following may be used as supplementary teaching methods to those indicated in Section 7:

- instructing under supervision;
- tutoring under supervision;
- health care team work under supervision;
- seminar;
- large professional assembly;
- diagnostics and treatment symposia;
- training in a simulated environment;
- sit-ins;
- intraprofessional group reflection; and
- theoretical studies.

Approval

Section 8. The National Board of Health and Welfare (Socialstyrelsen) will, on the basis of the application, examine whether the requirement for service time according to Chapter 4, Section 1 of the Ordinance (1998:1513) on Professional Activities in the Health and Medical Care System, as well as the requirements in the description of objectives, have been fulfilled.

Section 9. The National Board of Health and Welfare (Socialstyrelsen) will collect statements from two external assessors for the review.

Section 10. The external assessors must

1. be selected by The National Board of Health and Welfare (Socialstyrelsen) for a period of three years, which can be renewed once,
2. be appointed according to proposals from the speciality association in the Swedish Medical Association or the section in the Swedish Society of Medicine, and
3. have specialist competence in the intended speciality.

Section 11. The external assessment must include an examination of whether

1. services and certified teaching methods for the various partial objectives in the description of objectives as regards its contents were relevant to fulfilling all of the competence requirements and partial objective requirements,
2. the certified persons had the relevant competence for the task, and
3. any service abroad has been certified by persons with the relevant competence.

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1. This statute enters into force, with reference to the requirement for tutor training in Chapter 3,
Sections 2 and 5, on 1 September 2010, and otherwise on 1 September 2008.

2. With this statute, the following are repealed:
– The National Board of Health and Welfare (Socialstyrelsen) regulations (SOSFS 1996:26) Description of objectives for specialities within specialist medical training for doctors,
– The National Board of Health and Welfare (Socialstyrelsen) regulations and general guidelines (SOSFS 1996:27) Specialist medical training for doctors, etc.

3. For doctors who received a licence prior to 1 July 2006, however, the old statutes may apply if applications regarding a certificate of specialist competence are submitted no later than 31 Dec 2013.

Description of objectives for the respective specialties

Clinical pharmacology

Introduction
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Competence requirements
Competence requirements for medical competence
Competence requirements for communicative competence, leadership competence, and competence within medical science and quality work
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Medical competence
Communicative competence
Leadership competence
Competence within medical science and quality work

Introduction

On June 24, 2008, The National Board of Health and Welfare (Socialstyrelsen) decided to issue new regulations and general guidelines for doctors' specialist medical training (SOSFS 2008:17). The statute consists of a general part with common provisions for all specialties and a specific part with all the descriptions of objectives. The description of objectives for each specialty should be understood against the background of the provisions in the general part.

In each description of objectives, there is a section headed 'Training structure' which constitutes general guidelines. The teaching methods under the heading 'Intermediate objectives' where no follow-up is indicated also constitute general guidelines.

Explanation of terms

current mentor

a specialist doctor whose specialist competence corresponds to the area of competence indicated by the intermediate objective, and who is responsible for ST doctors's professional development during the teaching period or for the method of teaching indicated

the assignment as a mentor for an ST doctor generally encompasses the entire period of specialist training but can also encompass part or parts of it

auscultation

during mentoring, and in accordance with a pre-designed programme, to study the profession of a specialist doctor or other health care staff by following one or several professionals, as well as carrying out assignments in the relevant area to a certain extent

evaluate

to form a sound opinion of a patient or similar person as a basis for further management

master

being fully able to evaluate and handle the medical investigation, diagnostics, treatment, and follow-up of a patient or similar person, and being fully able to use the techniques relevant to the area

capability

personal capacity to execute or perform a task

have understanding

having acquired knowledge and insight into an area through theoretical studies and/or practical exercise of the profession

have knowledge

having acquired some knowledge in an area through theoretical studies and/or practical exercise of the profession

mentoring under supervision

as an ST doctor, mentor a co-worker while simultaneously being mentored by a doctor with specialist competence

mentor
continuously, and in dialogue form, supporting and guiding, as well as evaluating, a co-worker's professional development

mentoring
see mentor

handle
to actively carry out measures regarding investigation, diagnostics, treatment, and follow-up of a patient or similar person, and have overall responsibility for carrying out these measures

initially handle
as the primary physician in charge, to actively carry out measures regarding investigation, diagnostics, treatment, and follow-up of a patient or similar person, and have overall responsibility for carrying out these measures

initially evaluate
as the primary physician in charge, to form a sound opinion of a patient or similar person as a basis for further management

intraprofessional group reflection
reflection done in a group together with other doctors, chiefly for the purpose of further education and training

clinical service
health and medical care duties that ST doctors perform under their own professional liability and with the support of a mentor

course
teacher-led training with an established plan, given during a defined period of time

sitting-in
training activity involving an ST doctor observing when a specialist doctor or other health care staff holds a consultation

or

assessment activity involving a specialist doctor or other health care staff observing and evaluating ST doctors during a consultation

seminar
instruction in group form with active participation

training in a simulated environment
training carried out in an environment created to emulate reality

large professional assembly
conference, congress, symposium or similar event

health care centre
health care unit in primary care

health care team work

work where ST doctors, under supervision, participates in and sometimes leads a group of co-operating health care staff with various competencies charged with responsibility for care for an individual patient or group of patients

General definition of competence

Definition of area of competence

The specialty of clinical pharmacology encompasses the evaluation of the effects and safety of medicines at the individual, patient group and community levels. It further includes the provision of both objective medicinal information and the production of new knowledge about the effects and side effects of medicines. Clinical pharmacology thus represents expertise in medicine within health care, promoting evidence-based and rational medicinal treatments.

Competence requirements

Competence requirements for medical competence

Specialist competence in clinical pharmacology requires knowledge and skills enabling the independent practice of the profession. This involves expertise in critically evaluating medicine from the perspective of both effects and safety, which assumes fundamental pharmacological, medical, statistical and epidemiological knowledge. It also involves the ability to use this expertise in the choice of medicines for both individual patients and for patient or diagnosis groups. The choice and follow-up of medicines must further be based on pharmacokinetic principles and the results of medicinal and abuse analyses.

Specialist competence further requires knowledge in order to work for the rational and socially beneficial use of medicine, e.g. by means of objective, producer-independent medicinal information, orally and in writing. Knowledge about the development of medicines and about the national organisation for medicines is also essential.

Besides broad expertise in the field of clinical pharmacology, competence in a patient-oriented, medicine-intensive specialty is required.

Competence requirements for communicative competence, leadership competence and competence within medical science and quality work

Communicative competence

The equal and responsible patient

Doctors with specialist competence must be capable of dialogue and of maintaining open contact with patients and their next of kin. Contact should be characterised by empathy and trust, as well as respect for the patients' right to information, influence, and participation in decisions. It must also be characterised by cooperation and sensitivity to patients' needs, wishes and right to self-determination, and must stimulate patients' commitment to and responsibility for their own care.

Multicultural and gender aspects

Communication with patients and their next of kin should be characterised by understanding and respect for cross-cultural and multicultural aspects such as age, language, ethnicity, sexual orientation and religion, as well as gender.

Interprofessional relations

Doctors with specialist competence must be capable of communicating, both in writing and orally, with other doctors and co-workers showing respect for their professional knowledge and competencies. The same applies to contact with representatives of the public and various civil authorities.

Pedagogical skills

Doctors with specialist competence must have pedagogical capability in order to inform and instruct not only patients and their next of kin, but also other doctors and co-workers, as well as students.

Professional approach and ethics

Doctors with specialist competence must be capable of working continuously with their professional and medical ethical approaches, with the objective of being able to make independent decisions of a medical ethical nature.

Individual professional development

Doctors with specialist competence must be capable of continually examining and identifying their own needs for professional development, in addition to operational requirements, in order to be able to meet requirements for the best possible patient care.

Leadership competence

Collaboration

Doctors with specialist competence must have a developed capability for self-knowledge and an understanding of their own functions and roles in the organisation.

Mentoring skills

Doctors with specialist competence must be able to mentor other doctors and co-workers, as well as students.

Leadership

Doctors with specialist competence must have a capability for leadership characterised by collaboration, openness, and dialogue with co-workers. Leadership must further be characterised by participation and activity development aimed at improvement. The ability to lead work in a team is essential.

System knowledge

Doctors with specialist competence must have an understanding of the organisation, administration, financial and regulatory systems of health care, as well as its governance, in order to make the best use of resources.

Competence within medical science and quality work

Medical science

Doctors with specialist competence must be capable of adopting a medically scientific outlook and approach, and must have knowledge of research methodology, including basic epidemiological concepts, as well as of methods for evidence-based medicine and review of scientific information.

Improvement and quality work

Doctors with specialist competence must have understanding of, and competence in, evidence-based improvement and quality work. The objective is to be able to initiate, participate in, and be responsible for continuous systematic improvement work with emphasis on a holistic perspective, patient safety, patient benefit, measurability, and teaching management in order to be able to review and evaluate their own operations.

Public health and prevention

Doctors with specialist competence must have an understanding of the factors determining health, other aspects of public health, and methods for promoting health and efforts aimed at preventing injury and illness, in order to be able to take this understanding into account in medical scientific work.

Training structure

It is important that most of the necessary competence is obtained at a clinical pharmacology unit. Specialist medical training should begin with an introduction to the various activities within clinical pharmacology, after which ST doctors will actively participate in the various activities. The individual elements of service can vary depending on the operational circumstances of the activity, but it is essential that ST doctors receive gradually increasing responsibility and become increasingly independent during their specialist medical training.

In order for ST doctors to obtain clinical experience in medicinal treatment of patients, it is important that service at a clinical pharmacological unit is supplemented with extended service within a patient oriented, drugs-intensive specialty for a lengthier period. In order to reap the greatest benefit from the supplementary service, ST doctors should perform service within clinical pharmacology, following supplementary training, in order to be able to use his or her clinical expertise in clinical pharmacological practice. Service at a drugs authority, drugs unit or in the drugs industry may also be considered.

During specialist medical training it is of great value that ST doctors are able to plan and carry out a research or development project within the field of clinical pharmacology, and that this project be presented at a scientific assembly or in a science periodical. The timing of this project will be determined by the conditions governing the activity.

Special recommendations

The specialty associations and sections of the medical organisations have formulated special recommendations for their own specialties. The recommendations concern such issues as how specialist medical training should be structured.

Intermediate objectives

Medical competence

Intermediate objective 1	Teaching methods	Follow-up
To master evaluation of the effects of medicines	Clinical service under supervision in a unit where such operations are practised	Certificate of successfully completed clinical service and competence achieved, issued by current mentor
	Course	Certificate of successfully completed course, issued by course leader
	Theoretical studies	

Intermediate objective 2	Teaching methods	Follow-up
To master evaluation of the safety of medicines	Clinical service under supervision in a unit that handles these issues	Certificate of successfully completed clinical service and competence achieved, issued by current mentor
	Course	Certificate of successfully completed course, issued by course leader
	Theoretical studies	

Intermediate objective 3	Teaching methods	Follow-up
To master fundamental statistical and epidemiological methods in the field of medicine	Clinical service under supervision in a unit that handles these issues	Certificate of successfully completed clinical service and competence achieved, issued by current mentor
	Theoretical studies	

Intermediate objective 4	Teaching methods	Follow-up
To master giving advice to individual patients regarding medicinal treatment	Clinical service under supervision in a unit that handles these issues	Certificate of successfully completed clinical service and competence achieved, issued by current mentor
	Theoretical studies	

Intermediate objective 5	Teaching methods	Follow-up
To master giving advice to patient or diagnosis groups regarding medicinal treatment	Clinical service under supervision in a unit that handles these issues	Certificate of successfully completed clinical service and competence achieved, issued by current mentor
	Theoretical studies	

Intermediate objective 6	Teaching methods	Follow-up
To have an understanding of pharmacokinetics, medicinal analyses, and abuse analyses	Clinical service under supervision in a unit that handles these issues or auscultation under supervision in a unit that handles these issues	Certificate of successfully completed clinical service and competence achieved, issued by current mentor or certificate of successfully completed auscultation and competence achieved, issued by current mentor
	Theoretical studies	

Intermediate objective 7	Teaching methods	Follow-up
To master promoting the rational and socially beneficial use of medicines	Clinical service under supervision in a unit that handles these issues	Certificate of successfully completed clinical service and competence achieved, issued by current mentor
	Theoretical studies	

Intermediate objective 8	Teaching methods	Follow-up
To master the provision of objective, producer-independent medicine information, orally and in writing	Clinical service under supervision in a unit that handles these issues	Certificate of successfully completed clinical service and competence achieved, issued by current mentor
	Instruction under supervision	
	Theoretical studies	

Intermediate objective 9	Teaching methods	Follow-up
To have an understanding of all phases of the clinical development of medicine	Clinical service under supervision in a unit that handles these issues or auscultation under supervision in a unit that handles these issues	Certificate of successfully completed clinical service and competence achieved, issued by current mentor or certificate of successfully completed auscultation and competence achieved, issued by current mentor
	Theoretical studies	

Intermediate objective 10	Teaching methods	Follow-up
To have an understanding of the national organisation for medicines	Clinical service under supervision in a unit that handles these issues	Certificate of successfully completed clinical service and competence achieved, issued by current mentor
	Theoretical studies	

Intermediate objective 11	Teaching methods	Follow-up
To have an in-depth understanding of at least one therapy area	Clinical service under supervision in a unit that handles these issues	Certificate of successfully completed clinical service and competence achieved, issued by current mentor
	Mentoring under supervision	
	Theoretical studies	

Intermediate objective 12	Teaching methods	Follow-up
To have an understanding of investigation, diagnostics and treatment within one specialty	Clinical service under supervision in a unit that handles such conditions	Certificate of successfully completed clinical service and competence achieved, issued by current mentor
	Theoretical studies	

Communicative competence

Intermediate objective 13	Teaching methods	Follow-up
To be capable of dialogue and open contact with patients and their next of kin, and with other doctors and co-workers	Clinical service under supervision in a unit where such operations are practised	Certificate of successfully completed clinical service and competence achieved, issued by current mentor

Intermediate objective 14	Teaching methods	Follow-up
To be capable of informing and instructing patients, next of kin, other doctors, and co-workers, as well as students	Clinical service under supervision in a unit where such operations are practised	Certificate of successfully completed clinical service and competence achieved, issued by current mentor
	Instruction under supervision	

Intermediate objective 15	Teaching methods	Follow-up
To be capable of a professional, medically ethical approach	Clinical service under supervision in a unit where such operations are practised	Certificate of successfully completed clinical service and competence achieved, issued by current mentor

Leadership competence

Intermediate objective 16	Teaching methods	Follow-up
To be capable of mentoring other doctors and co-workers, as well as students	Clinical service under supervision in a unit where such operations are practised	Certificate of successfully completed clinical service and competence achieved, issued by current mentor
	Course	Certificate of successfully completed course, issued by course leader
	Mentoring under supervision	

Intermediate objective 17	Teaching methods	Follow-up
To be capable of leading using collaboration and dialogue with co-workers as well as in a team	Clinical service under supervision in a unit where such operations are practised	Certificate of successfully completed clinical service and competence achieved, issued by current mentor
	Course	Certificate of successfully completed course, issued by course leader

Intermediate objective 18	Teaching methods	Follow-up
To have an understanding of the organisation, management, and regulatory systems of health care	Clinical service under supervision in a unit where such operations are practised	Certificate of successfully completed clinical service and competence achieved, issued by current mentor
	Course	Certificate of successfully completed course, issued by course leader

Competence within medical science and quality work

Intermediate objective 19	Teaching methods	Follow-up
To be capable of a medically scientific outlook and approach	Clinical service under supervision in a unit where such operations are practised	Certificate of successfully completed clinical service and competence achieved, issued by current mentor
	Written individual work under supervision according to scientific principles	Certificate of approved written individual work, issued by current mentor

Intermediate objective 20	Teaching methods	Follow-up
To have an understanding of, and competence in, evidence-based improvement and quality work	Quality and development work under supervision	Certificate of quality and development work, issued by current mentor

Swedish Medical Association

Swedish Society for Clinical Pharmacology

Training book for clinical pharmacology 2015

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I. Some words from the Swedish Society for Clinical Pharmacology

Welcome to clinical pharmacology which has important duties in healthcare, research and teaching. To get a broader perspective on our area, we recommend reading the publication "Clinical Pharmacology in Health Care, Teaching and Research" published by WHO, IUPHAR and CIOMS 2012.
http://apps.who.int/medicinedocs/documents/s19916en/s19916en.pdf

The clinical pharmacologist will "work for rational and safe drug use through consultative, laboratory and educational services to all other clinical specialties, as well as to other actors in society dealing with drug issues."

The subject area includes basic pharmacology (pharmacodynamics, pharmacokinetics, drug metabolism), drug analysis and therapy control, evaluation of drug side effects, drug abuse epidemiology, clinical drug evaluation and clinical drug testing. Research and development work aimed at achieving better drug treatment is an integral part of the work in clinical pharmacology. Future duties for specialist in clinical pharmacology are in the field of healthcare, government agencies such as the Medical Products Agency, the SBU and the National Board of Health and Welfare, as well as the pharmaceutical industry.

The specialist association, the Swedish Society for Clinical Pharmacology, has in this paper summarised education programs with specified interim goals for specialist competence in clinical pharmacology. The publication complements the National Board of Health and Welfare's objective description and intends to provide a basis for local and individual education programs. It will also provide support in discussions with the director of studies, supervisors and representatives at clinics where training takes place.

Stockholm, 5 April 2016

Carl-Olav Stiller for the Board of the Swedish Society for Clinical Pharmacology

II. About specialization in clinical pharmacology

National Board of Health

From 01/05/2015, new regulations and general recommendations from the National Board of Health and Welfare regarding the Specialisation of Doctors (SOSFS 2015:8) apply. As before, it consists of a common part with common rules for all specialties, and a specific part with target descriptions for each specialty. The target description is available at www.socialstyrelsen.se. Based on the target objectives, the Swedish Clinical Pharmacology Association has developed a comprehensive training program and detailed interim goals, which together provide recommendations for how the goal description can be met.

Profile and field of activity

The specialty of clinical pharmacology includes in-depth knowledge and skills in the safe and efficient use of drugs. The specialty provides consultative, laboratory and educational services in pharmaceutical matters in health care and society. This service applies to individual patient cases and partly to general issues such as comparisons between drugs used for a particular disease state. It is important for the clinical foundation of the specialty that consultative services can be offered both remotely and in direct clinical contacts. In support of this service, laboratory methods, such as drug-concentration measurements and genotyping, are used for individualisation of drug treatment, as well as concentration determinations for substances of abuse and for issues of poisoning. Development of new methods for safer and more efficient diagnostics and treatments is an essential part of the activities. Clinical pharmacologists participate to a great extent in the production and dissemination of producer-related drug information and continuing training. Representatives of the specialty are usually included in the county council's drug committees, whose task is to promote rational and cost-effective drug use. An important task for clinical pharmacologists in drug committees and in pharmaceutical authorities (both nationally and internationally) is the compilation and evaluation of scientific documentation of drugs, their effects and safety. Other important tasks include contributing to health-economic valuations of drugs, as well as studying the use of drugs and the occurrence of side effects, interactions and addiction.

Collaboration within and outside the healthcare system

Clinical pharmacology touches all forms of closed and open care, acute as well as chronic disease states, and all patient categories and ages. As far as the laboratory is concerned, it is closely related to several laboratory medicine specialties and to clinical genetics. In addition, clinical pharmacologists cooperate with national and international authorities such as the Swedish Medicines Agency, the SBU[1], the TLV[2], the National Board of Health and Welfare and EMA (the European Medicines Agency). Clinical pharmacologists are also included in the regional ethics committee. Many clinical pharmacologists work in the pharmaceutical industry.

Knowledge, skills and attitudes

Specialist training will lead to in-depth knowledge of basic pharmacology, pharmaco-dynamics, clinical pharmacokinetics and drug metabolism, drug interactions, drug analysis and therapy control, pharmacology of adverse drug reactions, clinical drug testing, drug treatment in risk conditions, drug abuse, critical drug evaluation, drug epidemiology, biostatistics and data processing and knowledge in various fields of pharmacotherapy. The goal of the clinical supplementary training is to acquire a deeper insight into at least one therapy area and to place pharmacotherapy in relation to non-pharmacological interventions.

The ST[3] doctor will develop a good ability to handle patient-related drug problems, to act as an expert in drug committees, to compile and evaluate drug documentation, to provide training on pharmaceuticals and to convey producer-related drug information, as well as to participate in planning and conducting drug trials. The ST doctor will also

[1] *Translator's note:* Statens beredning för medicinsk och social utvärdering – State Process for Medical and Social Evaluation
[2] *Translator's note:* Tandvårds- och läkemedelsförmånsverket – Dental and Pharmaceutical Benefits Agency
[3] *Translator's note:* Specialiseringstjänstgöring – Specialist training

acquire the ability to respond to follow-up of drug use with assessment of benefits, risks and health-economic consequences. In addition, the ST doctor will acquire skills to be able to answer for laboratory activities in drug analysis services for therapy control, toxicological diagnostics and drug abuse investigations, and also provide healthcare new drug analyses, genetic analyses and functional tests regarding drug effects or metabolism.

In the course of the specialisation tasks, the future specialist will also:

– exercise his/her ability to make independent and well-founded decisions in matters of medical ethical nature

– acquire knowledge of overall health policy goals and priorities

– be prepared to participate in business planning and financial follow-up as well as in production control and quality development work

– acquire knowledge and insights into the doctor's supervisor role

– be encouraged to participate in research and development work, as well as develop his/her ability to critically review the results

– deepen his/her knowledge of the possibilities for preventing disease and injury, as well as participating in individual and general preventive work

– train his/her educational ability by participating in teaching and supervision of different student and/or staff categories

Supplementary training

In order to meet the requirements of the target description, supplementary training in a patient-care specialty is required, where pharmacotherapy is a dominant form of treatment and drug-related problems often occur. The supplementary training should provide in-depth knowledge of symptomatology, diagnostics and treatment within the current clinical field. The ST^3 doctor will also gain knowledge about the clinical use and management of drugs in closed and open care and insight into the clinical decision-making process.

Theoretical training

In parallel with the clinical tasks, the ST doctor should be given room for theoretical studies. Participation in supplementary education in the form of courses, conferences etc. must thus be included. The ST doctor will, in consultation with the supervisor, design literature studies and course participation that can promote the development of skills and provide such skills and skills, which may be difficult to acquire within the framework of the regular tasks.

Quality assurance

The National Board of Health and Welfare's objective description describes the skills required for specialist competence in the subject area. It shall furthermore form the basis for an individual training and duty program, to be developed in consultation with ST doctor and supervisor as soon as possible after the employment.

The specialisation service is under supervision and it is the responsibility of the operations manager and the supervisor to plan with the ST doctor to perform service and

training so that specialist competence can be achieved within the time specified in the constitution. It is also the responsibility of the head of operations that the ST doctor receives the supplementary training prescribed by the goal description and that supplementary training/service is provided in cases where the knowledge need cannot be met in the institution's own activities. The supervisor shall ensure that the supplementary training is designed to meet the requirements of the targeting and to establish good and regular contact with the supervisor of the supplementary training unit and with the ST study director. The ST doctor's competence development shall be continuously monitored and attuned to the individual training program. An appropriate form of this reconciliation is regular supervision.

Individual training and tasks program

The objective description presents the knowledge and skills required for specialist skills in clinical pharmacology. The overall training program and the specified targets constitute the specialty recommendations for how the goal description can be met. These documents form the basis of the individual training and tasks program, which is planned jointly by the ST doctor, the supervisor and the activity manager. When the training starts, an overall training plan should be established. Detailed planning can, however, be performed for shorter periods of time.

III. General training program for clinical pharmacology

Specialty's recommendations on how to meet the target description

Genreal recommendations

Introduction

When a doctor is admitted to specialist clinical training in clinical pharmacology, or initiates a specialist training with the stated desire to achieve specialist competence, a specialist and supervisor-qualified physician at the clinic should be appointed as supervisor. The head of operations is responsible for this. The supervisor and the prospective specialist will jointly design an individual training and duty program. The implementation of the training is continuously documented and followed up by regular interviews, partly with the supervisor and partly with the immediate manager.

Duty time

In total, the training covers at least five years. It is important that most of the necessary skills are obtained from a clinical pharmacological unit. In order to gain clinical experience in drug treatment of patients, it is important that duty in clinical pharmacological units be supplemented with duty in patient-care and drug-intensive specialties for a longer period of time. In order to get the most out of the page service, the ST doctor should, after posting, serve in clinical pharmacology to use his clinical skills in clinical pharmacological work. The service consists of approximately 4 years in clinical pharmacology and approximately one year in patient-close, drug-intensive, clinical activities. Service at the medicines authority, drug unit or pharmaceutical industry may also be relevant.

The ST^3 doctor should also be able to account for up to 12 months of service in a clinical laboratory specialty relevant for clinical pharmacology. If part of or whole/full interim goals have been met by prior employment, the time to specialist evidence in clinical

pharmacology may be shortened by a maximum of 6 months after individual assessment. Such work may, for example, consist of participation in regional therapy groups or clinical trials. However, in order to achieve specialist competence, at least three years of service are required in a clinical pharmacological unit. An ST doctor who has a Swedish or comparable foreign doctoral degree can receive specialist qualifications after four and a half years of employment. The above timeframes are to be considered as guidelines. Crucial for the assessment of specialist competence is how well the target description of the specialty is met. Formal requirements are regulated in the Patient Safety Ordinance (2010:1369), Chapter 4, Section 1, where it is stated that the licenced physician who wishes to achieve specialist competence must undergo further training for at least five years in order to acquire the knowledge, skills and experiences prescribed for the specialist competence sought.

Specialist competencies are to be acquired through service as a doctor under supervision and through participation in supplementary training. Qualifications from training at the research level may be credited.

Examples of specialties for clinical supplementary training

All drug-intensive, patient-care specialties, such as internal medicine, geriatrics, child and adolescent medicine, general medicine, anaesthesiology and intensive care, psychiatry, neurology, infectiology and oncology.

Service in clinical pharmacology

A. Introduction (ca. 4–6 weeks)

The ST doctor should prepare time to rotate between different activities and follow the work of experienced colleagues, and work in parallel with experienced colleagues at, for example, the Drug Information Centre and the Drug Analytical Laboratory. The ST doctor should also get a first introduction in drug analytical methodology.

B. Basal training (ca. 4 years)

The ST doctor participates in the daily work at the department, comprising:

– drug analysis activities – assessment of individual analytical responses (e.g. drug concentrations, drug tests in occupational health and occupational healthcare and drug metabolism tests) and documentation about them, follow-up of new analyses, development and evaluation of analytical methods, contact with remitting clinics

– drug information – to seek and evaluate literature on clinical drug issues, as well as to communicate this information to other healthcare institutions orally and in writing

– questions about drug side effects

– rational use of drugs

– clinical trials – to plan and conduct clinical trials

The ST doctor should also be given an opportunity to participate in work in drug committees, therapy groups or the equivalent, clinical consultation in pharmaceutical matters, teaching of especially physiotherapists, but also students in other health care programs and further training of doctors in other specialties and other healthcare professionals.

Courses

At least 1–2 weeks per year should be allocated for SK courses or equivalent. The National Board of Health and Welfare is responsible for the overall planning and administration of SK courses. However, the range of SK courses directed directly to prospective clinical pharmacologists is small, so supplementation should be made with other types of national or international courses in subjects such as drug evaluation, pharmacokinetics, pharmacoepidemiology, pharmacogenetics, drug testing and drug safety. The ST doctor should as far as possible be prepared to participate in annual recurring national education and information meetings, such as the "Clin Pharm Days" (Swedish Society for Clinical Pharmacology), "Pharmacovigilance Day" (Medicines Agency) and the Section for Pharmaceutical Sciences activities.

The ST doctor should also participate actively at one or more international congresses in the field of clinical pharmacology.

Medical science and quality work

The ST doctor must carry out work according to scientific principles, as well as quality and development work. Work according to scientific principles and quality and development work can also be combined in one and the same work. Individual scientific work should correspond to at least 10 weeks full-time work throughout the ST period, including planning, implementation, theoretical course and written report. The quality work, which may be considered to be an obvious part of the ongoing improvement work within an activity, is not included in time, but the course and subject area may be common.

The supervisor for the scientific work shall have specialist competence and supervisor training. The supervisor with scientific competence (equivalent to a doctorate) shall participate in the planning and design of the work, as well as in examination of the same. If the regular supervisor lacks scientific competence, scientific guidance should be linked to the work in another way to ensure quality. The research or development project may be presented at a scientific gathering or in a scientific journal. The timing of this is determined by the conditions of the business.

If the ST doctor has previously obtained a medical doctorate, it may be reasonable to assume that this has attained the goal of a medical scientific viewpoint and approach, but it is the task of the task manager and supervisor to assess and certify this. However, for ST doctors who have a doctorate in another field, it may be an advantage to be prepared for a scientific project in the field of clinical pharmacology.

Complementary training

Service at a clinical pharmacology department elsewhere, at the Medical Products Agency, national forensic centre or in laboratory specialties may be relevant for achieving competence in defined areas, where the activities of the department are not comprehensive. Examples of such areas may be drug analysis, clinical trials or side effects.

Literature

Literature studies are planned in consultation with the supervisor and include familiarity with clinical pharmacological reference works, regular follow-up of clinical pharmacological, pharmacological and broader medical journals, and selected literature in various specialist areas.

IV. Precise interim goals – recommendations for how the National Board of Health and Welfare's target description for specialization services 2015 can be met

Qualification description from the National Board of Health

The specialty of clinical pharmacology is characterised by the evaluation of drug effects and safety at individual, patient and community level. Furthermore, it includes the transmission of producer-based drug information and the generation of new knowledge about the effects of drugs and side effects. Clinical pharmacology is the medical expertise of the healthcare professional, which works for evidence-based and rational drug treatment.

Usually, several different recommended learning methods are suggested. A combination of several of these may in some cases be desirable, while in other cases it may be sufficient to choose one or a few methods for achieving the target. Thus, all methods need not be applicable to each individual. The methods that, according to the National Board of Health and Welfare, are to be included in bold design. Other methods are to be considered recommendations and thus are not obligatory.

Target a1 Teamwork, leadership and didactics

Target a1	**Recommended methods of learning**	**Evaluation**
–can take responsibility for continuous learning at the workplace –can practice leadership in the daily work, including leading a care team –can take responsibility for the development of multi-professional cooperation –can take responsibility for cooperation with patients and close relatives –can cooperate in networking around the patient –can cooperate with non-health professionals, such as social boards, activities in social services, school and social security –can present and explain medical information in a manner that is understandable to the recipient, both verbally and in writing –can plan and carry out teaching –can tutor and instruct employees and students	**Clinical service under supervision** at units where such activities are conducted **Course** in e.g. didactics Active participation in the unit's planning and development work Clinical service under supervision at unit where such activities are conducted Tutor under supervision Teach clinical pharmacology at undergraduate level Lead clinical pharmacological training for different occupational categories in health care	Certificate of approved clinical service and obtained competence issued by the current supervisor Certificate of approved course Documentation of planning and development work Certificate of approved clinical service and obtained competence issued by the current supervisor Documentation regarding tutor assignment Documentation of clinical pharmacological teaching at the undergraduate level Documentation of clinical pharmacological training for different occupational categories in health care

Target a2 Ethics, diversity and equality

Target a2	Recommended methods of learning	Evaluation
–demonstrates knowledge of the meaning of medical ethical principles as well as identify ethical problems and analyse them in a structured manner –can handle conflicts of value in daily work –can consciously treat people as individuals and with respect regardless of sex, gender identity or expression, ethnicity, religion or other beliefs, disability, sexual orientation and age	**Clinical service under supervision** **Participation in one or more courses** Participation in group or inter-professional reflection, e.g. in the form of conversations with the supervisor and the other ST doctors	Certificate of completed training activities and required competency requirements issued by supervisor Certificate of completed training activities and required competence requirements issued by course supervisor or tutor Regular, documented tutorial conversations

Target a3 Hospital hygiene and infection protection

Target a3	Recommended methods of learning	Evaluation
–can take responsibility for preventing health-related infections and spread of infection	**Clinical service under supervision**, especially in connection with site care and in the laboratory	Certificate of completed training activities and the required competence requirements issued by supervisors

Target a4 Systematic quality work and patient safety work

Target a4	Recommended methods of learning	Evaluation
–can critically review own activities and can conduct a risk and event analysis –can take responsibility for the systematic implementa-tion of improvement measures, processes and routines for patient benefit –can take responsibility for the integration of new technologies and methods in daily health care work	**Clinical service under supervision** **Quality and development work** under supervision Independent written work under supervision according to scientific principles Participation in a seminar Participation in a larger professional gathering Course	Certificate of approved clinical service and required competence requirements issued by the current supervisor Certificate of approved quality and development work issued by the current supervisor Certificate of approved written individual work issued by the current supervisor Certificate of participation in a seminar Certificate of participation in a larger professional gathering Certificate of approved course and required competence requirements issued by course leader

Target a5 Medical Science

Target a5	Recommended methods of learning	Evaluation
–demonstrates in-depth knowledge of medical scientific methods and ethical principles	**Clinical service under supervision**	Certificate of approved clinical service and required competence requirements issued by supervisor
–can critically review and evaluate medical scientific information	**Independent written work under supervision according to scientific principles**	Certificate of approved written individual work issued by the current supervisor
–demonstrates a medical scientific approach to routines and working methods in daily work	**Participation in one or more courses**	Certificate of approved course and required competence requirements issued by course supervisor or supervisor
	Participation in so-called “Journal Clubs”, seminars or equivalent	Documented active participation in so-called “Journal Clubs”, seminars or equivalent
	Participation in a larger occupational gathering	Certificate of participation in a larger professional gathering

Target a6 Laws and other regulations as well as the organization of healthcare

Target a6	Recommended methods of learning	Evaluation
–demonstrates knowledge of laws and other regulations in the field of health care and for its personnel	**Participation in one or more courses**	Certificate of approved clinical service and required competence requirements issued by supervisor
–demonstrates knowledge of the healthcare organisation and administration	Clinical service under supervision	Certificate of approved course and required competence requirements issued by course leader
–demonstrates knowledge of the various healthcare systems and their importance for priorities and balances in daily work		

Target b3 Medicines

Target b3	Recommended methods of learning	Evaluation
–can adjust drug treatment according to age, gender, weight, kidney and liver function of the patient, and potential comorbidity and other medication –can assess the risks of interactions and side effects in drug treatment –can cooperate with patients and relatives to achieve compliance with drug treatment –can interact with other actors in the care chain regarding patient drug treatment –can critically review and evaluate drug information –demonstrates knowledge of the effects of drugs on the environment –demonstrates knowledge of health-economic aspects of drug treatment	**Clinical service under supervision** **Participation in one or more courses**	Certificate of approved clinical service and required competence requirements issued by supervisor Certificate of approved course and required competence requirements issued by course leader

Target c

From the National Board of Health:

The specialist doctor should have basic knowledge in pharmacology, medicine, statistics and epidemiology, and be able to use this competence in drug selection for both individual and patient or diagnostic groups. The choice and follow-up of the drugs should be based on scientific documentation, pharmacodynamic and pharmacokinetic principles as well as results of assessments of drugs and drug abuse.

The specialist doctor should further

- be able to critically evaluate drugs from both the efficacy and the safety perspective,
- be able to promote rational and beneficial use of drugs, including through providing producer-related drug information orally and in writing,
- have knowledge of drug development and national and international medicines organisations,
- have knowledge of the distribution of responsibilities in drug use throughout the care chain, and
- be able to advise on drug treatment to individual patients as well as patient or diagnosis groups.

Target c	Recommended methods of learning	Evaluation
c1 masters the evaluation of drug effects	**Clinical service** Answer therapy questions received for clinical pharmacological unit Participation in the evaluation and monitoring of new drugs Participation in so-called "Journal Clubs" or the equivalent Course, e.g. within statistics and epidemiology Participation in the implementation of clinical trials Theoretical studies	Documentation of responses from clinical pharmacology Written report/summary of evaluation and/or follow-up study Documented active participation in so-called "Journal Clubs" or the equivalent Certificate of approved course issued by course leader. Documented participation in the implementation of clinical trials
c2 masters the valuation of drug safety	**Clinical service** Response to clinical pharmacological unit adverse reactions Evaluate information about drug side effects under supervision. Participation in the implementation of clinical trials Participation in so-called “Journal Clubs” or the equivalent Participation in the Medicines Agency’s Pharmacovigilance Days Course, e.g. within statistics and epidemiology. theoretical studies	Documentation of response to adverse drug reactions received into clinical pharmacology Service on unit carrying out clinical trials. Documented active participation in so-called “Journal Clubs” or the equivalent Documented participation in the Medicines Agency’s Pharmacovigilance Days Certificate of approved course issued by course leader
c3 masters basic statistical and epidemiological methods in the field of pharmaceuticals	**Clinical service** under supervision at clinical pharmacological unit, regional drug centre or similar. Course Theoretical studies Written individual work under supervision according to scientific principles	Certificate of approved clinical service and required competences issued by the current supervisor. Certificate of approved course issued by course leader. Certificate of approved written individual work issued by the current supervisor

c4 manages advice on drug treatment to individual patients	Answer pharmacodynamics, kinetics, genetics and interaction questions received in clinical pharmacology Answer TDM-related questions **Clinical service** under supervision in drug-intensive specialty Theoretical studies	Documentation of responses from clinical pharmacology Documentation of answered TDM questions Certificate of approved clinical service and required competence requirements issued by the current supervisor
c5 manages advice on drug treatment to patient or diagnosis groups	**Clinical service** Answer therapy questions received in clinical pharmacology Participation in expert councils, therapy group and/or pharmaceutical committee Contribution to design and maintenance of decision support for rational drug treatment Theoretical studies	Documentation of responses from clinical pharmacology Documented participation in expert councils, therapy group and/or pharmaceutical committee Documented involvement in the design and maintenance of decision support for rational drug treatment
c6 has knowledge of pharmacodynamics, pharmacokinetics, drug analyses and analysis of drug abuse	**Clinical service** under supervision or attending a course under supervision of one or more entities carrying out such activities or handling such cases Theoretical studies	Certificate of completed training activities and the required competence requirements issued by supervisors
c7 manages to work for a rational and beneficial drug use	**Clinical service** under supervision at a clinical pharmacological unit, drug committee or in expert groups, or a drug authority such as LV and/or EMA. Participation in meetings or work of regional and local drug agencies, e.g. drug committee, regional drug units Theoretical studies	Certificate of approved clinical service and required competence requirements issued by the current supervisor. Documented participation in meetings and work of regional and local drug agencies
c8 masters the dissemination of producer-related drug information, orally and in writing	**Clinical service** Teach, under supervision, in clinical pharmacology at undergraduate level Teach, under supervision, in clinical pharmacological training for different occupational categories in the healthcare sector Theoretical studies	Documentation of clinical pharmacological education at the undergraduate level Documentation of clinical pharmacological training for different occupational categories in health care

c9 has knowledge of all phases of clinical drug development, including the approval process for pharmaceuticals	**Clinical service** Participation in the planning and implementation of clinical trials Work/observation at a regulatory authority Observation at the regional ethics committee (EPN[4]) Course in clinical trial methodology, research ethics and GCP Theoretical studies Participate in written application to the EPN	Documented involvement in the planning of clinical drug testing Documented involvement in the conduct of clinical trials Documentation of work/observation at a regulatory authority Documentation of observation at a regional ethics committee Certificate of approved course issued by course leader
c10 has knowledge of national and international medicines organisations has knowledge of the distribution of responsibility for drug use throughout the care chain including care transfers	**Clinical service** under supervision at a clinical pharmacological unit, drug authority, National Board of Health, TLV and/or SBU. Observation at national drug agencies, such as Medical Products Agency, TLV, SoS, SBU Observation at regional and local drug agencies, e.g. drug committee, regional drug units Theoretical studies	Certificate of approved clinical service and required competence requirements issued by the current supervisor. Documentation of observation at national drug agencies. Documentation of auscultation at regional and local drug agencies
c11 has in-depth knowledge in at least one therapy area	Participation in expert or therapy groups or in the work of such groups Clinical service under supervision in at least one therapy area. Be lecturer, under supervision, in clinical pharmacological education at the undergraduate level Be lecturer in clinical pharmacological training for other occupational categories in health care Theoretical studies	Documented involvement in expert or therapy group or work of such group. Certificate of approved clinical service and required competence requirements issued by the current supervisor. Documentation of clinical pharmacological education at the undergraduate level Documentation of clinical pharmacological training for other occupational categories in health care
c12 has knowledge about investigation, diagnostics and treatment within a field of specialisation	**Clinical service** under supervision of one or more units carrying out such activities or handling such cases. Theoretical studies	Certificate of completed training activities and the required competence requirements issued by the current supervisor

[4] *Translator's note:* etikprövningsnämnd – ethics board

c13 can apply laws and regulations that apply to the specialty, including knowledge of prescription beyond approved indication	**Clinical service under supervision** **Participation in one or more courses**	Certificate of completed training activities and the required competence requirements issued by supervisors and course leaders

V. Speciality recommendations for supervision

The head of department is responsible for the fact that every physician during the specialisation service has a personal supervisor. A trustworthy relationship between supervisor and the trainee is a prerequisite for the optimal functioning of the supervision. The supervisor must possess specialist competence in clinical pharmacology and have an interest in teaching and didactic knowledge and have undergone supervisor training. The supervisor is appointed in consultation with the head of operation and the ST[3] doctor, where the ST doctor's personal preferences must be carefully taken into account in view of the long and close cooperation that the training entails. Change of supervisor should be possible, but continuity is important for a good end result.

The supervisor and the ST doctor, in cooperation with the ST studies director and head of department, create a training and task program based on the different parts and requirements of the target descriptions and the education book, as well as the conditions of the department. If training cannot be met by the department, the supervisor, in cooperation with other departments, shall ensure that they are implemented. This may mean service elsewhere with a supervisor.

The training takes place at different stages with an introductory period (approximately 4–6 weeks), where the ST doctor gets a general view of the department's working methods. During the continuing training, close contact between the ST doctor and the supervisor is important and it is important that open communication exists where both parties can provide feedback and advice on how improvements in the education can take place. The supervisor should be in contact with other doctors and other staff members participating in the ST doctor's education, and to follow up their comments. The intention is that the supervisor should support the ST doctor in his/her competence development and make sure that the physician manually acquires the knowledge, skills and attitudes stated in the target description. If special efforts are needed to promote skills development, it is the supervisor's responsibility to work for appropriate measures, such as changes in the doctor's service, arrangements for service at another unit, instructions for literature or project work.

The supervisor is in charge, together with the head of department, for an appropriate workplace with an own computer, and that literature and other study material is available. The ST doctor must participate in SK courses or equivalent, and the choice of courses and the timing of these should be determined in cooperation with the supervisor to get a good adjustment to the completed study plan. The ST doctor will, with the assistance of his/her supervisor, continuously document the acquired skills and acquired knowledge. In addition to the head of department, the supervisor is also responsible for issuing certificates of competence according to the course description for specialization.

VI. Quality development

External quality review of ST education (SPUR review)

In order to maintain a high quality specialist training, training units must have the resources needed to provide the doctors with the guidance and support required by the training during the service. Historically, such inspections have been carried out by the Medical Association and the Medical Association Foundation for Educational Quality (SPUR Foundation), IPULS and LIPUS[5]. The inspections are carried out using the specialist associations. First, a questionnaire is sent to the head of department and authorised physician at the clinics concerned. These include questions about the nature of the activities, the composition of the doctoral staff, training programs, supervision, courses, premises, libraries and technical equipment. The information is then supplemented by inspectors appointed by the respective specialty association. The inspectors are experienced doctors with high clinical and scientific expertise in the specialty. They are also well-educated in further education. The results of inspections performed are reported in the Medical Journal and on the LIPUS website (http://www.lipus.se).

External quality review of ST training in clinical pharmacology

The head of department is responsible for an external quality review at least every five years at a clinic offering specialist training. The Swedish Society for Clinical Pharmacology has initiated the organisation of external inspections of ST training by proposing that two persons at each clinic let train to be SPUR inspectors, so that all the country's clinics can carry out inspections and themselves be inspected. The first inspections by the Society were conducted in autumn 2011. The experience is good. The inspectors' visits are usually appreciated by both clinics and doctors in training.

The role of inspectors is to act as experienced consultants, and inspections must provide a basis for discussions regarding the training situation at the clinic. The purpose of the inspections is to be a continuous quality-enhancing operation.

VII. Further education in clinical pharmacology

Continuing education refers to education after specialist qualification.

Continuing education can be organised on four levels:

– locally within the own hospital, own clinic, own reception

– regionally, e.g. within the county council or in regional cooperation

– nationally, e.g. within the universities, the SFKF society meetings, individual initiatives

– internationally, mainly in the form of conferences and congresses

The emphasis on continuing education in clinical pharmacology should be at national and international level. Annually, "Clin Pharm days" are organised by the Swedish Society for Clinical Pharmacology, the "Pharmacovigilance Day" by the Medical

[5] *Translator's note:* Läkarnas institut för professionell utveckling – Medical Institute for Professional Development

Products Agency and symposiums of the Department of Pharmaceutical Sciences. The Department of Pharmaceutical Sciences in the Swedish Medical Association has been active at least since 1907 and still seems to promote research, development and education in the field of theoretical and practiced pharmacology.

Training of ST doctors in the subject of clinical pharmacology takes place at university clinics where research is an important part of the activities. In view of this, it is natural to undergo postgraduate studies in parallel with specialist training. Participating actively in research work is a good way to train a critical approach and to express and present collected knowledge material. Although there are no formal requirements for postgraduate education, the Swedish Society for Clinical Pharmacology recommends and encourages future specialists to participate in research work.

VIII. Information from the Swedish Society for Clinical Pharmacology

Join the Swedish Society for Clinical Pharmacology!

The Swedish Society for Clinical Pharmacology is a specialty association within the Swedish Medical Association and is a group of doctors who have or have been active in the field of clinical pharmacology. According to the statutes, the society's task is to "promote the effective development of healthcare within the members' special disciplines and to safeguard members' union and scientific interests". The Swedish Society for Clinical Pharmacology wants to promote clinical pharmacologists' education and training and support clinical pharmacological activities wherever they occur – in healthcare, academy, in government or in the pharmaceutical industry. The association is responsible for the development of the target description for specialist education and this training book, as well as organising training of inspectors and clinic inspections within the framework of the SPUR activities. An important part of the association's activities is also to answer referrals from ministries, authorities and associations regarding legislative proposals, investigations, etc.

The society is a member of the European Association of Clinical Pharmacology and Therapeutics (EACPT) and is in collaboration with The International Union of Pharmacology (IUPHAR).

EACPT organises a European conference every two years and IUPHAR a World Congress every four years. IUPHAR also has cooperation with the WHO.

Membership in the society means joining the majority of clinical pharmacologists in their endeavour to develop their own profession. The activities are funded through membership fees. The association's activities also offer opportunities for creating and maintaining a professional identity through the contacts that are linked to the association's meetings and other activities. The association meetings also provide estimated opportunities for social co-operation with other colleagues. You do not have to be a member of the Medical Association to be considered as a member of SFKF.

For current information and application for membership, please refer to the SFKF website, which is found via the Medical Association's specialist list; http://www.slf.se/Foreningarnas- startsidor/Specialitetsforening/Svensk-Forening-for-Klinisk-Farmakologi/

IX. Information from the Section of Pharmacology

The Section of Pharmacology[6] is one of the sections of the Swedish Medical Association and is an association of persons interested in pharmacology, clinical pharmacology and related subjects. The purpose of the section is to promote the development of pharmacology, primarily through the organization of meetings with scientific lectures and discussions, as well as to promote pharmacology as a teaching subject. The section interacts internationally with scientific issues and education issues in the field of pharmacology.

The application for membership is via the section's website, which can be accessed via the Swedish Medical Association's website (www.sls.se).

[6] *Translator's note:* Sektionen för Läkemedelslära (Svenska Läkaresällskapet) – Section of Pharmacology (Swedish Medical Society)