National Training Requirements

SPAIN

Specialty

Clinical Pharmacology

(Farmacología Clínica)

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Supplied by :	Cristina Avendaño Solá
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Order SCO / 3129/2006, of September 20, which approves and publishes the training program of the specialty of Clinical Pharmacology

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MINISTRY OF HEALTH

17872 ORDER SCO/3129/2006, of September 20, which approves and publishes the training program of the Clinical Pharmacology specialty.

Article 21 of Law 44/2003, of November 21, on the organization of health professions, establishes the procedure to approve the training programs of health specialties in health sciences, foreseeing their publication in the Official State Gazette for general awareness. The National Commission of the Specialty of Clinical Pharmacology has elaborated the training program of this specialty that has been verified by the National Council of Medical Specialties, an advisory body in the field of specialised health training to which, in accordance with the provisions of the sixth transitory provision of Law 44/2003, cited above, corresponds to exercise the powers of the not yet constituted National Council of Specialties in Health Sciences. Likewise, said training program has been studied, analysed and reported by the Human Resources Commission of the National Health System referred to in Royal Decree 182/2004, of January 30, by which said collegiate body was created, which includes, among others, the health advisers of the various autonomous communities and the General Director of Universities of the Ministry of Education and Science. By virtue of this, in accordance with the provisions of article 21 of Law 44/2003, previous favourable reports from the Human Resources Commission of the National Health System and the Ministry of Education and Science, I have:

First – To approve the training program of the Specialty of Clinical Pharmacology, whose content is published as an annex to this Order.

Second – This training program will be applicable to the residents of the Specialty of Clinical Pharmacology who obtain a place in training in Teaching Units of that specialty, based on the Order of the Ministry of Health and Consumption by which the 2006 national call for selective tests is for access in 2007 to places of specialised health training is approved.

Sole transitory provision.

Residents who have begun their training in the specialty of Clinical Pharmacology for having obtained a place in training in calls earlier to which is mentioned in the second section of this Order will be applied the previous program of that specialty, approved by Resolution of April 25, 1996, from the Secretary of State for Universities and Research of the Ministry of Education and Science.

Notwithstanding the foregoing, the Teaching Commission of the Teaching Unit in which a position has been obtained may adapt, on the proposal of the head of the Unit and with the consent of the resident, the individual training plans provided in section 2.c) of the Order of June 22, 1995, to the new training program insofar as, in the opinion of said Commission, it is compatible with the general organization of the Unit and with the specific situation of each resident.

Final disposition.

This Order will enter into force on the day following its publication in the “Official State Gazette”.

Madrid, September 20, 2006.-The Minister of Health and Consumer Affairs. Elena Salgado Méndez.

ANNEX

Official Programme for Specialist in Clinical Pharmacology

I. Official name of the specialty and qualification requirements

Clinical Pharmacology

Duration: Four years

Previous degree: Medicine

II. Definition of the specialty and its competences

Clinical Pharmacology is the medical specialty that evaluates the effects of drugs in the human species in general, but also in specific subgroups and in specific patients. This evaluation focuses on the relationship between the therapeutic effects (benefits), the undesirable effects (risks) and the costs of therapeutic interventions, including efficacy, safety, effectiveness and efficiency.

Academically, Clinical Pharmacology is defined as a medical discipline that, on a scientific basis, combines pharmacological experience and clinical experience with the fundamental objective of improving efficacy and safety in the management of medicines. A WHO study group, in the year 1970, recommended the development of the specialty as an integrated discipline in health systems, and noted among its functions "to improve the care of patients by promoting a more effective and safe use of medicines, increase knowledge through research, transmit this knowledge through teaching and promote services such as information about medicines, drug analysis, monitoring of drug abuse and advice in the design of studies".

This specialty integrates the knowledge of the pharmacological properties of the drugs with the particular characteristics of each patient, in order to assess the variability in the response and individualise the treatment. For the development of its activities, medical knowledge is required that allows collaborating, together with other specialists, in therapeutic decisions about a specific patient or in the identification and diagnosis of complex clinical conditions related to the use of medications.

To apply their knowledge, the clinical pharmacologist uses methods and techniques of a clinical, epidemiological and laboratory type, simultaneously developing training and information activities.

The Law 14/1986, of April 5, General Law of Health, and the Law 25/1990, of December 20, Law of the Drug, have defined the framework of action of Clinical Pharmacology, both in hospitals and primary care centres. Therefore, clinical pharmacologists can develop their activity in the hospital environment, primary care centres, university, administration, pharmaceutical industry and other institutions.

These are the competences of the specialist in Clinical Pharmacology:

1. Assistance

1.1 Therapeutic consultations.
1.2 Monitoring of drug levels for therapeutic purposes.
1.3 Monitoring of the adverse effects of drugs.
1.4 Information on drugs.
1.5 Evaluation and selection of medicines.

1.6 Realisation of technical reports, especially of the new active principles, for all Clinical Commissions in which pharmacotherapeutic decisions are made (Pharmacy, Rational Use of Medicine, Infections and Antibiotics Policy, among others), Technological Evaluation Agencies and health managers.

1.7 Training and information activities: therapeutic bulletins, clinical-therapeutic sessions, training courses.

1.8 Preparation and evaluation of clinical guidelines and therapeutic protocols.

1.9 Coordination and methodological, ethical and legal support to research projects with medicines.

2. Researchers: clinical and epidemiological evaluation of medicines:

2.1 Design and evaluation of the clinical development of medicines.

2.1[1] Evaluation of the pharmacokinetic and pharmacodynamic properties of medicines in man.

2.2 Evaluation of efficacy: clinical trials.

2.3 Evaluation of adverse effects: development of pharmacovigilance programs.

2.4 Evaluation of suitability, quality of use and effectiveness: studies on the use of medicines and health outcomes.

2.5 Evaluation of efficiency: pharmacoeconomic studies.

3. Teachers:

3.1 Undergraduate: Clinical Pharmacology in the Bachelor of Medicine and other degrees in Health Sciences.

3.2 Postgraduate: specialist training program, doctorate and master's degree programs.

3.3 Continuous training aimed at Primary Care physicians, other medical specialties and other Health Sciences degrees.

Fields of action of the specialty:

The activities of Clinical Pharmacology described above may be carried out in:

Specialised Care Centres of the National Health System or not belonging to the same.
Universities and other Research Centers.
Primary Care Centers.
Spanish or European Medicines Agency.
Health Technology Assessment Agencies regarding the human use of medicines.
Spanish Pharmacovigilance System.
Pharmaceutical companies.
Suppliers and planners of Sanitary Services.

III. Training objectives

General objective: Acquire a solid formation in semiological, etiopathogenic, pharmacological knowledge and evaluation of clinical response that enables the solution of pharmacological-clinical and therapeutic problems of patients. At the same time it should allow to create knowledge and promote the best use of medicines.

[1] *Translator's note: Error in consecutive numbering in the original.*

For this, the specialist in Clinical Pharmacology must:

Know the pharmacokinetic and pharmacodynamic characteristics, as well as other determinants of the use of the main pharmacological groups, for its application for therapeutic, prophylactic or diagnostic purposes.

Know and apply the clinical procedures and the scientific methodology that allows to evaluate the beneficial and harmful effects of the drugs, integrating them in the therapeutic decision making.

Carry out the communication actions of the information on medicines aimed at optimizing the prescription habits and promoting the good use of the medication.

Evaluate the health, economic, sociological or anthropological implications related to the consumption of medications.

Design, conduct and evaluate research studies.

Assess the economic cost of using the drug in relation to existing health resources.

IV. Development of research in the specialty

The resident must receive training on the scientific method and its application to Clinical Pharmacology.

Clinical Pharmacology must carry out research work in any of the activities that are specific to it, indicated in section II, and that should cover the following areas:

a) Studies on the variability of the response to drugs (pharmacokinetic and pharmacodynamic studies): influence of age, sex, pathological situations, genotypic characteristics and environmental factors. This requires knowledge of the tools that allow the individualisation of pharmacological treatments (monitoring, genotyping, analysis of risk factors, among others).

b) Research and development of drugs for the resolution of relevant therapeutic problems (clinical trials), of socio-sanitary interest and especially of those whose objectives are not covered by other means, including:

   New uses and indications of already known drugs (studies on the use of medicines and health outcomes).

   Analysis aimed at determining the risks of the drugs (pharmacovigilance studies).

   Uses in groups of special populations.

   Uses in orphan indications.

c) Research on the social, health and economic impact of the use of drugs (pharmacoeconomic studies).

V. Specific contents

To achieve the stated objectives, the resident of Clinical Pharmacology must receive training in all areas that are the specialty of the Specialty:

V.1 Training in clinical medicine

During the clinical rotation the resident must acquire knowledge of diagnostic and therapeutic skills, and of evaluation of the patient and the response to therapy. Special attention and concern should be given to the selection and control of the pharmacological treatment of the patients and the adverse reactions that may arise. This will allow an adequate approach for the subsequent decision-

making of individual therapeutic decisions for the evaluation of the response to drugs in medical practice, for selection processes and for research activity.

V.2 Therapeutic consultations

Therapeutic consultation is the specific support application of the training and information on medicines to the therapeutic problem of the patients. The development of this activity requires a solid clinical training. The origin of the consultation may be related to the treatment of patients in special situations in which the standard guidelines may not be adequate.

A hallmark of clinical pharmacology is the knowledge of the variability in the response and the need to individualise pharmacological treatment according to the characteristics of each patient. The clinical pharmacologist must be able to evaluate the clinical context of the patient of his disease and its treatment, critically evaluate the therapeutic options and recommend the best option. The therapeutic consultation, unlike the mere report on drugs, has two important nuances: the clinical evaluation of the case and the need for a precise response and to the specific case.

V.3 Selection and information of medicines

The resident must actively participate in the preparation of therapeutic guidelines, bulletins and other materials made with the aim of improving pharmacological prescription.

Among the functions of Clinical Pharmacology is particularly important the preparation of scientific information, objectively and independently, on recently marketed drugs and, in particular, its comparison with other drugs with similar therapeutic properties. This information must be considered in order to make decisions in relation to the drug policy at all levels of the health field: Pharmacy and Therapeutic Commissions, rational use of medication, infections and antibiotic policy, preparation of bulletins, protocols or therapeutic guidelines, reports on specific drugs (pharmacokinetic aspects, interactions, physiopathological limitations for their use, etc.) requested by the Health System and by clinical specialists.

V.4 Clinical trials

The clinical pharmacologist must be able to establish the objectives, perform the design, supervise the execution and interpret the results of the clinical trials.

Likewise, the clinical pharmacologist must be able to act as technical support to the Ethics and Clinical Research Committee (CEIC) on methodological, ethical and legal aspects of drug research. This activity is related to the requirement that a clinical pharmacologist appear as a member in all the CEICs that are established in the law of medicine and development legislation.

V.5 Pharmacoepiemology

a) Drug use studies: In general, the EUMs are developed with the purpose of obtaining information on the usual therapeutic practice. They not only consist of a description of the actual use of the medicines and their practical consequences, but also have as their ultimate goal to achieve an optimal therapeutic practice. From the EUM it is possible to: a) obtain a description of the use of the medications and their consequences; b) make a qualitative assessment of the data obtained to identify possible problems; c) actively intervene in the identified problems.

b) Evaluation of the effectiveness: The differences between the conditions of performance of the clinical trials and the usual clinical practice demand the realization of clinical studies of pragmatic orientation that evaluate the effectiveness of the medicines in the general population. The clinical pharmacologist must be trained to:

Orient correctly the objectives of these studies from the perspective of Health Systems and the interest of patients

Develop strategies for the implementation of these studies within the Health Systems.

Analyse and draw valid conclusions about the use in the population.

c) Evaluation of adverse effects, pharmacovigilance: The main objective of pharmacovigilance is the identification of previously undescribed adverse reactions of drugs and the generation of hypotheses about the causal relationship between the administration of a drug and the appearance of a certain undesired effect (signals). These signals can come from descriptions of isolated patients, from observational studies or from experimental studies (clinical trials). Currently, the spontaneous notification of adverse reactions by health professionals play a predominant role in their identification.

   The clinical pharmacologist, in collaboration with other primary care health professionals, specialised care centres and other institutions, should be responsible for the development of pharmacovigilance programs, since the adverse reactions are clinical episodes that require a differential clinical diagnosis and the probability of introducing therapeutic changes.

d) Evaluation of efficiency, pharmacoeconomics:

   The limitation of resources and the need to establish priorities in health spending, have made the economic evaluation of medicines is being imposed as a need to contribute to a more rational use of these. Pharmacoeconomic studies are essential at present to carry out a correct critical analysis, on the theoretically exaggerated use of a certain high-cost medication.

   The clinical pharmacologist who, as a physician, is empowered to prescribe, must play a fundamental role in this type of analysis.

V.6 Individualization of the treatment

The significant variability in the response to drugs requires the individualization of treatments in order to optimise the benefit–risk ratio of the drugs. Knowledge of the pharmacokinetic, pharmacodynamic and pharmacogenetic factors that determine this variability allows us to adapt the administration of a specific drug to a specific patient or to groups of patients that share certain characteristics: newborns, children, the elderly, pregnant women, obese patients with kidney disease, hepatic, cardiovascular etc.

The greater knowledge of these factors that the clinical pharmacist has in front of other medical specialists, should lead to individualised treatment and significantly improve the quality of the prescription.

a) Clinical pharmacokinetics and monitoring of drug levels in biological fluids: It is a special type of therapeutic consultation that requires the determination, through different analytical techniques, of the concentration of a particular drug in serum or plasma, although it can also be performed in blood total, urine, CSF etc. This method allows to adjust the dose to a specific patient, in order to obtain greater efficacy with less toxicity and is of special interest when drugs with narrow therapeutic margin are used. In addition, monitoring has an unquestionable value to check therapeutic compliance, especially in chronic treatments, or detect possible drug interactions.

b) Pharmacogenetics: Differences in genetic load are a relevant source in the interindividual variability of the response to drugs, both in pharmacokinetic and pharmacodynamic aspects. The recent development of pharmacogenetic and pharmacogenomic techniques facilitate

genotypic determinations that allow us to predict the response in different subpopulations and improve the individualization of the therapeutic regimen.

The clinical pharmacologist must know, select and use pharmacogenetic analytical techniques and therapeutic monitoring as a complement to allow the selection of the best pharmacotherapeutic regimen and with the best benefit–cost ratio. Likewise, it must identify the subpopulations of patients and the groups of drugs that can benefit the most from this type of technique.

The clinical pharmacologist, together with other professionals, will advise on the modification of the individual treatment that may arise.

VI. Knowledge and skills to be acquired by the resident

VI.1 Knowledge

Clinical Pharmacology of the main therapeutic groups.

Internal Medicine and other medical specialties performing the same activities as the residents of said specialties.

The sources of information available (textbooks, medical journals, reports from regulatory agencies, bibliographic databases).

The methods for assessing the scientific quality of the information available (reliability of the information and data sources).

The grades and classification of the available tests in therapy and the degree or strength of the recommendations.

The criteria for the selection of medicines (efficacy, safety, convenience and cost) and their comparison with available therapeutic alternatives.

Clinical pharmacokinetics: dosing criteria and medication administration.

Analytical techniques most frequently used in Clinical Pharmacology.

Investigation methodology.

Basic principles of bioethics. Functions, organization, competences of the Clinical Research Ethics Committees (CEICs). Basic principles of pharmacoeconomics and health management.

Functions, organization and competences of the regulatory bodies for the use of medicines: Spanish Agency for Medicines and Health Products, European Medicines Agency and others.

Legislation that regulates clinical trials, post-marketing studies and pharmacovigilance in Spain and the European Union.

Operation of the Spanish Pharmacovigilance System and the WHO International Program.

Organization of the National Health System in both Specialised Care and Primary Care.

Basic training in epidemiology, biostatistics and information technology.

VI.2 Skills

Realisation of a complete clinical history.

Assessment and reasoning of the therapeutic place of the different alternatives. The differential diagnosis of adverse effects is especially important.

Management of information sources. Making bibliographical searches.

Identification and selection of relevant information about medications or therapeutic problems.

Selection of medications: making reports for clinical committees and therapeutic guidelines.

Evaluation and coding of adverse reactions.

Critical interpretation of clinical trial protocols and any type of study related to the use of medications.

Evaluation of the most useful analytical techniques for drug monitoring and reporting.

Oral and written communication of the information developed.

VII. Rotations

The resident must receive sufficient training in all the activities of the specialty mentioned above. To do this, he/she must make mandatory rotation periods for:

a) Internal Medicine Services and other specialties: Resident training in these areas should begin in the first or second year of the training period. During this phase, the resident of Clinical Pharmacology will perform the same activities as the residents of the medical specialties for which he is rotating, including guards.

   Also, in this period a rotation could be included for the services of Hospital Pharmacy or medication management centres.

   Duration: 18 months.

b) Clinical Pharmacology Service: The rotary service by the Clinical Pharmacology Service may be initiated at the beginning of the training, for a period of 6 months to a year, in order for the resident to begin to know about the Specialty. The establishment of this period at the beginning of the training will be optional.

   The rest of the training period by the Clinical Pharmacology Service, or the entire time established, will be done during the third or fourth year.

   During this period, the resident must continue his training on all the clinical activities of the specialty indicated above. It is recommended that, in order to ensure training in all of these activities, if necessary, the resident moves to other Centres.

   Duration: 20 months.

c) Primary Care: The importance of performing activities specific to Clinical Pharmacology in Primary Care, aimed primarily at enhancing the rational use of medicines (studies on the use of medicines, preparation of protocols, detection and reporting of adverse reactions, testing clinical, among others) requires that this revolving be performed once the resident of Clinical Pharmacology has received virtually all of its training, so it is established in the last year.

   Although this training period is considered highly recommendable, it is necessary to consider the peculiarities of each Autonomous Community and the differences in the availability of the corresponding health authorities necessary to make it possible.

   Duration: 4 months.

d) Other Centres: Taking into account that the Clinical Pharmacology includes activities not developed in the Hospital Services, and with the aim of completing the training in those areas in which the new specialist will most likely develop his professional activity, the resident's training can be completed with stays in Centres such as the Spanish or European Medicines Agency, Regional Pharmacovigilance Centres, Pharmaceutical Industry and others.

   Duration: 6 months

Diagram that proposes the organization of the different phases of the Rotation:

	Rotations		
First year	Internal medicine (6 mo)	Optional specialty (3 mo) *	Optional specialty (3 mo) *
Second year	Optional specialty (3 mo) *	Optional specialty (3 mo) *	Monitoring / Consultation T/EUM[2] (6 mo) **
Third year	Monitoring / Consultation T/EUM (3 mo) **	Pharmacovigilance (3 mo)	Clinical trials (6 mo)
Fourth year	Primary care (4 mo)	External rotation (6 mo) ***	Clinical Pharmacology (2 mo)

* Specialties recommended. Each Service can choose freely. It is advisable to include: Infectious Diseases, Anaesthesia and Resuscitation. Pain unit, Paediatrics and Oncology.

** It can also be done at the beginning of the Rotation.

*** Optional.

**** Optional: Spanish Agency for Medicines and Health Products, European Medicines Agency and other Centres. This rotation, if deemed necessary, can be established at any other time during the third or fourth year of training.

[2] *T/EUM: Terapéutica/Estudios de Utilización de Medicamentos (Therapeutics / Drug Use Studies)*