National Training Requirements

ITALY

Specialty

Clinical Pharmacology and Toxicology

(Farmacologia e tossicologia clinica)

Language:	English
Deposited:	03.01.2018
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ITALIA

Specialization in Clinical Pharmacology and Toxicology (BIO/14)

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1. Introduction

The specialization in Farmacologia e Tossicologia Clinica (BIO/14) (in English language: Clinical Pharmacology and Toxicology) is governed by the Italian legislation "Decreto Interministeriale 4 febbraio 2015 n. 68 Riordino scuole di specializzazione di area sanitaria" (in English language: Ministerial Decree February 4, 2015 n. 68 Reorganization of the health area specialization schools) and by "Decreto 13 giugno 2017 "Standard, requisiti e indicatori di attività formativa e assistenziale delle Scuole di specializzazione di area sanitaria" (in English language: Decree of 13 June 2017 "Standards, requirements and indicators of training and assistance activities of the health sector specialization schools).

In Italy, each University, according to the Italian Ministry of Education, Universities and Research directives, performs the nomination and the supervision of medical specialties. The Specialization in Clinical Pharmacology and Toxicology, which lasts 4 years, can be obtained at Universities of Medicine and Surgery allocated on the Italian territory.

2. Educational objectives of specialization in Clinical Pharmacology and Toxicology

The Specialization aims to the:

- Acquisition of advanced knowledge on the pharmacodynamic, pharmacokinetic and toxicological characteristics of drugs, in order to obtain data for their research and development as well as for their therapeutic use.
- Acquisition of specific biomedical skills that allow to interpret, predict and evaluate the effects of drugs in pathological conditions.
- Acquisition of cellular and molecular toxicology and pharmacology knowledge related to single organs and diseases.
- Acquisition of biomedical, pharmacological and toxicological skills for the management of most common acute and chronic diseases as well as for the interpretation and resolution of adverse events.

- Acquisition of toxicodynamic and toxicokinetic knowledge for the interpretation of adverse drug effects and for appropriately managing the clinical conditions associated with acute and chronic intoxications during emergencies.
- Acquisition of basic knowledge on pathophysiology and clinics to optimize therapeutic regimens.
- Acquisition of pharmacokinetic, pharmacodynamic, and pharmacogenetic skills to perform therapeutic drug monitoring (TDM) as part of the individualized drug therapy for patients.
- Acquisition of basic knowledge on the methodologies of regulatory disciplines at a national and international level and on the functioning of ethics committees.
- Acquisition of skills for comparative analyses, in terms of efficacy, tolerability and cost of pharmacological treatments.
- Acquisition of knowledge for the analysis and interpretation of pharmacovigilance data, with particular attention to the identification of the causal relationship between the drug intake and the occurrence of adverse drug reactions (ADRs).
- Optimization and individualization of therapeutic regimens;
- Acquisition of knowledge for the valuation of protocols of clinical studies.
- Acquisition of knowledge for the correct use of antidotal therapy and biomedical technologies that allow to accelerate detoxification (hemodialysis, blood transfusion, etc.) and to support patients in critical clinical conditions.

Thanks to the acquired training, the Specializing in Pharmacology and Clinical Toxicology will be able to deal with the main hospital emergency situations, to diagnose and treat diseases associated with drugs, alcohol and medication addiction, to gain in-depth knowledge on the clinical management, to take charge of addicted subjects, and to acquire technical skills necessary to deal with abstinence syndromes as well as to know the legislative measures that

regulate the diagnostic, therapeutic and rehabilitative interventions in case of drug abuse and addiction.

3. Training Content

According to the Italian Ministry of Education, Universities and Research directives for the Specialization in Clinical Pharmacology and Toxicology, during the 4 years of Specialization, the resident has to cover several practical activities for a total amount of 1,800 hours (38 hours per week).

The Specialization of Clinical Pharmacology and Toxicology aims to train specialists for the evaluation and prediction of drugs response in patients with normal and pathological conditions. The specialist in Clinical Pharmacology and Toxicology is a physician who is directly or indirectly involved in the medical treatment of patients and plays an indispensable role in assuring a rational and safe use of the drug.

During the 4 years of Specialization, the resident will cover a series of activities strictly related to the pharmacology field. These activities include:

- analysis and interpretation of pharmacovigilance data (these activities may include: collection of individual case safety reports, causality assessment of ADRs, and evaluation of safety signals);
- pharmacodynamics, pharmacokinetics and toxicological properties of drugs (the achievement of this knowledge is aimed to the interpretation, prediction and evaluation of drug effects in pathological conditions as well as to the identification of the most appropriate therapeutic regimens);
- pharmacogenetics, in order to assess how polymorphisms can affect the efficacy/safety profile of a drug as well as to identify the most appropriate therapeutic regimens;

- toxicodynamic and toxicokinetic properties, in order to interpret the toxicological effects of drugs and to appropriately deal the management of drug addiction/abuse;
- regulatory framework regarding the activities of ethics committees;
- pharmacoeconomics.

Residents in the specialty of Pharmacology will perform the following activities:

- Setting and design of pharmaco-toxicological tests and preclinical trials;

- Participation in the evaluation of the efficacy and safety of drugs;

- Participation in laboratory activities of Clinical Pharmacology Services: monitoring of pharmacological treatments, monitoring of drug abuse and pharmacogenetic analyses;

- Participation in the clinical management of medication (100 hours of activities);

- Participation in courses, seminars, lectures and conferences related to Clinical Pharmacology and Toxicology (at least 200 hours);

- Participation in diagnostic and therapeutic activities both at units of general medicine and specialized medicine (cardiology, endocrinology, geriatrics, gynecology, internal medicine, infectious diseases, emergency department, pediatrics, pulmonology, nephrology, neurology, pulmonology, psychiatry and rheumatology, and intensive care for at least 100 hours);

- Participation in diagnostic, therapeutic, preventive, and monitoring activities in healthcare services (100 hours);

- Participation in pharmaco-toxicological consultancy activities (100 hours of activities);

- Evaluation of individual case safety reports;

- Participation in the evaluation of drug treatments, therapeutic monitoring, pharmacogenetics, and individualization of pharmacological therapies at hospitals;

- Participation in diagnostic and therapeutic activities at hospitals and specialized medicine units.

- Participation in activities at poison control centers and perinatal toxicology services.

4. Examination

4.1 Objective and content

The resident in the Specialty of Clinical Pharmacology and Toxicology has to pass one pharmacology exam per year (which is mandatory for the registration to the successive year), and at the end of the course (after 4 years) he has to pass a final exam and to discuss the thesis.

The exam in Pharmacology (one per year) covers the following topics:

- General principles of pharmacology;
- Pharmacokinetics (the dynamics of drug absorption, distribution, metabolism, and elimination), pharmacodynamics (molecular mechanisms of drug action), drug toxicity and poisoning, membrane transporters, and drug response;
- Pharmacogenetics;
- Neurotransmission (muscarinic receptor agonists and antagonists, anticholinesterase agents, agents acting at the neuromuscular junction and autonomic ganglia, adrenergic agonists and antagonists, 5-hydroxytryptamine and dopamine);
- Neurotransmission and the Central Nervous System (drug therapy of depression and anxiety disorders, psychosis and mania, hypnotics and sedatives, opioids, analgesia, and pain management, general anesthetics and therapeutic gases, local anesthetics, treatment of epilepsies, central nervous system degenerative disorders, drug addiction);
- Regulation of renal and vascular volume (renin-angiotensin-aldosterone system, treatment of myocardial ischemia and hypertension, pharmacotherapy of congestive heart failure, anti-arrhythmic drugs, blood coagulation and anticoagulant, fibrinolytic, and antiplatelet drugs, therapy for hypercholesterolemia and dyslipidemia);

- Inflammation, immunomodulation, and hematopoiesis (histamine, bradykinin, and their antagonists, eicosanoids and platelet-activating factor, anti-inflammatory, antipyretic, and analgesic agents; pharmacotherapy of gout, immunosuppressants, and immunostimulants, pulmonary pharmacology, and hematopoietic agents like growth factors, minerals, and vitamins);
- Hormones and hormone antagonists (the hypothalamic-pituitary axis, thyroid and anti-thyroid drugs, estrogens and progestins, androgens, endocrine pancreas and pharmacotherapy of diabetes mellitus and hypoglycemia);
- Drugs affecting gastrointestinal function (pharmacotherapy of gastric acidity, peptic ulcers, and gastroesophageal reflux disease, treatment of disorders of bowel motility and water flux; anti-emetics; agents used in biliary and pancreatic disease, pharmacotherapy of inflammatory bowel disease);
- Chemotherapy of microbial diseases;
- Chemotherapy of neoplastic diseases;
- Special systems pharmacology.

The pharmacologist uses knowledge in various scientific fields - especially those of physiology, biochemistry, cell biology and molecular biology - to solve problems associated with drugs. Therefore, the pharmacologist optimizes drug therapies, improves the appropriateness of prescribing, provides information on the pharmacogenetic markers that can predict the effectiveness or toxicity of a drug, participates in pharmacovigilance activities in both pre- and post-marketing phases, and in pharmacoeconomics activities to enhance a safe and cost-effective use of medicines. The pharmacologist is also involved in the management of several aspects of clinical research, playing a key role in the evaluation of the ethical, methodological and scientific appropriateness of any clinical trial.

4.2 Exam method and procedures

The exam committee, which consists of 3-5 Professors of Pharmacology, is responsible for the selection of exam questions.

5. Essential requirements

Essential requirements	**Minimum performance for the entire educational path of one resident to distribute based on the training plan (N)**	**Minimum annual care activity of the training network for each year (a)**	**Minimum annual care activity of the training network for the activation of the medical specialty (b)**	**Minimum annual care activity of the training network for the activation of the medical specialty (b)**
Planning of experimental projects in pharmacology, toxicology, and preclinical research for the evaluation of medicines, chemotherapies, and xenobiotic substances.	25	125	375	n. **1000**
Participation in the evaluation of efficacy and safety of substances in the field of research and development of new medicines.	50	250	750	n. **3000**

Execution of at least 50 clinical interventions in acute intoxications and 30 clinical interventions in chronic intoxications with regards to the laboratory diagnostic.	80	400	1200	n. **2000**
Participation in laboratory activities of Clinical Pharmacology Services: monitoring of madical treatment (100 determinations of medicine levels in biologic fluids), monitoring of abuse substances and pharmacogenetics analyses (10 clinical cases).	110	550	1650	n. **3300**
Collaboration in the preparation of the Pharmaceutical Codex, planning of protocols for the evaluation of the drug use, and elaboration of guidelines for the prevention of adverse drug events.				n. **250**
Installation of databases and other sources of data to get information on pharmacological treatments.				n. **1500**
Conduction of therapeutic-diagnostic pathways for	50	250	750	n. **1500**

addicted patients to abuse substances, with regards to the application of protocols and psychiatric comorbidities in dedicated facilities, including regional addiction treatment services.				
Participation in clinical-toxicological interventions to manage emergencies at Intensive Care Unit or in other dedicated facilities, including poison control centers.	30	150	450	n. **750**
Participation in the elaboration and management of protocols for the treatment of abuse and/or misuse of medicines.	10	50	150	n. **600**
Training period at an emergency room, in other territorial dedicated facilities, and poison control centers for interventions and consulting in the field of clinical-toxicology.	50	250	750	n. **1250**
Participation in Pharmacovigilance activities with	10	50	750	n. **4000**

regards to the phase 4 of post-marketing surveillance.				
Participation in protocols of phase 1, 2, and 3 of clinical research, with regards to the activities performed by ethics committees.	20	100	300	n. **1000**
Collaboration in the updating of the Hospital Pharmaceutical Codex.				n. **75**
Discussion with medical specialists for the integrate conduction of complex toxicological cases.	10	50	150	n. **300**
Management of patients in ambulant treatment for complex toxicological diseases.	50	250	750	n. **1250**
Execution of phone consulting and visits for toxicological perinatal problems.	10	50	150	n. **250**
Participation in the management of the use of medical devices in acute and chronic diseases.				n. **50**
Participation in the clinical government of medicines and medical devices at hospitals.				n. **500**

Participation in biomolecular and pharmacogenetic diagnostic-therapeutic activities to define drug therapy appropriateness.				n. **200**
Participation in training courses, seminars, and conferences on Clinical Pharmacology and Toxicology.				n. **30**
Participation in the design and execution of a comparative evaluation of the efficacy, safety, and cost of pharmacological treatments. For example a) participation in the protocol of 5 pharmacoutilization, pharmacoeconomic, and pharmacoepidemiological studies. b) Participation in the protocol of 5 studies on medical devices.	10	50	150	n. **250**
Specific activities for students with a degree in medicine and surgery: **Participation in diagnostic and therapeutic activities**				n. **300**

at an unit of general medicine or specialized medicine (cardiology, endocrinology, geriatrics, gynecology, internal medicine, infectious disease, emergency medicine, pediatrics, oncology, pneumology, psychiatry, rheumatology, intensive care, and toxicology).				
Specific activities for students with a degree in medicine and surgery: **Collection and interpretation of anamnestic, diagnostic, and instrumental data for therapeutic decision processes in the field of cardiology, endocrinology, gastroenterology, geriatrics, infectious disease, internal medicine, nephrology, neuro-psychiatry, pneumology, psychiatry, oncology, and rheumatology.**	50 clinical cases	250 clinical cases	750 clinical cases	n. **1300**
Specific activities for students with a degree in				n. **1200**

medicine and surgery: **Participation in diagnostic, therapeutic, preventive, and monitoring activities at addiction treatment services.**				
Specific activities for students with a degree in medicine and surgery: **Participation in pharmacological and toxicological clinical trials for the evaluation of medicines, chemotherapies, and xenobiotic substances with reference also to the duties of ethics committees.**	10	50	150	n. **350**
Specific activities for students with a degree in medicine and surgery: **Participation in consulting activities for pharmacology and toxicology (100 hours). – Evaluation of spontaneous individual case safety reports of ADRs in the post-marketing surveillance**	10	50	150	n. **9000**

(phase 4).				
Specific activities for students with a degree in medicine and surgery: **Participation in activities for the evaluation of pharmacological treatment, therapeutic monitoring, pharmacogenetic analyses, and identification of therapies at hospitals or clinical pharmacology and toxicology services.**	50	250	750	n. **1500**
Specific activities for students with a degree in medicine and surgery: **Participation in diagnostic and therapeutic activities at an unit of general medicine and specialized medicine to follow patients during their pharmacological treatment.**	20	100	300	n. **500**
Specific activities for students with a degree in medicine and surgery:	10	50	150	n. **5000**

Participation in the pharmacological and toxicological monitoring.				
Use of test machine for an emergency simulation and cardiopulmonary reanimation, participation in first aid activities outside the hospital and in the transport of patients in-hospital or between hospitals.				n. **10**
Educational paths for graduates in medicine and surgery will be structured to educate specialists in the monitoring and evaluation of the clinical response to medicines.				n. **800**
Educational paths for graduates in medicine and surgery will be structured to educate specialists in the identification of adverse drug events.				n. **4000**
Educational paths for graduates in medicine and surgery will be structured to educate specialists in the choice of pharmacological treatments for acute or				n. **100**

chronic diseases.				
Educational paths for graduates in medicine and surgery will be structured to educate specialists about the evaluation of new medicines in clinical trials.				n. **5**
Educational paths for graduates in medicine and surgery will be structured to educate specialists about the activities to perform in poison control centers and in toxicology and perinatal services.				n. **300**
Educational paths for graduates in medicine and surgery will be structured to educate specialists in the consulting of healthcare emergencies.				n. **50**
Educational paths for graduates in medicine and surgery will be structured to educate specialists to operate in addiction treatment services.				n. **300**
Other activities that will be acquired by students include the advanced knowledge on the risk of				n. **1000**

chemical agents and the management of healthcare emergency. This knowledge will be acquired through activities at services and laboratories of pharmacology, pharmacogenetics, clinical toxicology, and pharmacoeconomics.				

6. Requirements for the training institution

Typology		**General description**
Equipment and laboratories		*Residents carry out their experimental work in laboratories related to the relevant departments of each specialization. Each laboratory is equipped with modern tools to ensure the performance of scientific and industrial research activities.*
Book heritage	Consistency in volume and coverage of the themes of the course	*Libraries are placed in each department in order to support facilities for teaching and research carried out during the 4-year period. Each library has a bibliographic heritage and provides for document delivery services as part of the national and international library cooperation.*
	Magazine Subscriptions	*Acta Paediatrica; American Journal Of Physiology ; Heart And Circulatory Physiology; British Journal Of Surgery; Cancer Research; Cancer Reviews;Circulation Research; Clinical Cancer Research; Diabets Care; Endocrine Reviews Investigative Ophtthalmology & Visual Science Nature New England Journal Of Medicine; Pediatrics Pharmacological Reviews; Proceedings Of The National Academy Of Sciences Of The Usa; Radiology; Science*
E-resources	**Databases (access to the content of sets of magazines and/or book series)**	*Several databases (SciFinder Scholar, Scopus and Web of Science, and is free to PubMed, TOXNET) are available in the University network for residents in Specialization.*

Typology		General description
	Software specifically related to the research areas foreseen	*The equipment for residents in Specialization includes computers with scanners and printers, many updated programs designed self-study, software for data processing and statistical evaluations, copiers, projectors multimedia educational activities, internet connection.*
	Space and resources for graduate students and for the electronic computing	*Multimedia classrooms with internet connection are available for students.*

Annex 1 - SCHOOL OF SPECIALIZATION IN CLINICAL PHARMACOLOGY AND TOXICOLOGY - Teaching plan

I° year of specialization courses

BASIC ACTIVITIES	
SCIENTIFIC FIELD – teaching	**University Credits/HOURS**
BIO/09 Physiology	1/25
BIO/10 Biochemical	1/25
MED/05 General Pathology	1/25
BIO/14 General Pharmacology I	1/25
SCIENTIFIC FIELD - teaching	**University Credits/HOURS**
BIO/12 Clinical Biochemistry	2/60
BIO/14 Pharmacology	1/30
MED/05 Clinical Pathology I	1/30
SPECIFIC ACTIVITIES	
SCIENTIFIC FIELD - teaching	**University Credits/HOURS**
BIO/14 Pharmacology:	15/375
General Pharmacology II	1/25
Pharmacokinetics	1/25
Cellular and Molecular Pharmacology I	4/100
Preclinical research	1/25
Special Pharmacology I	4/100
Toxicology I	4/100
SPECIFIC ACTIVITIES	
SCIENTIFIC FIELD - teaching	**University Credits/HOURS**
BIO/14 Pharmacology	35/1050

OTHER ACTIVITIES	
SCIENTIFIC FIELD - teaching	**University Credits/HOURS**
L – LIN/12 English	1/25

II° year of specialization courses

BASIC ACTIVITIES	
SCIENTIFIC FIELD - teaching	**University Credits/HOURS**
MED/01 Medical Statistics	1/25
SCIENTIFIC FIELD - teaching	**University Credits/HOURS**
BIO/14 Pharmacology	2/30
MED/03 Medical Genetics	1/30
MED/05 Clinical Pathology II	1/30
SCIENTIFIC FIELD - teaching	**University Credits/HOURS**
BIO/14 Pharmacology:	15/375
Molecular Pharmacology II	4/100
Special Pharmacology II	4/100
Toxicology II	4/100
Chemotherapy I	3/75
SCIENTIFIC FIELD -	**University Credits/HOURS**

teaching	
BIO/14 Pharmacology	35/1050
INTEGRATIVE ACTIVITIES	
SCIENTIFIC FIELD - teaching	**University Credits/HOURS**
MED/09 Internal Medicine	1/30
MED/25 Psychiatry	1/30
INTEGRATIVE ACTIVITIES	
MED/07 Microbiology	1/25
OTHER ACTIVITIES	
SCIENTIFIC FIELD - teaching	**University Credits/HOURS**
L-LIN/12 English	1/25
INF/01 Informatics	1/25

III° year of specialization courses

SPECIFIC ACTIVITIES	
Scientific field - teaching	**University Credits/HOURS**
BIO/14 Pharmacology:	15/375
Special Pharmacology III	4/100
Chemotherapy II	2/50
Clinical Toxicology I	3/75
Pharmacogenetics	1/25
Pharmacovigilance	1/25
Clinical Research	4/100

Clinical Pharmacology I	3/75
SPECIFIC ACTIVITIES	
Scientific field - teaching	**University Credits/HOURS**
BIO/14 Pharmacology	35/1050
INTEGRATIVE ACTIVITIES	
Scientific field - teaching	**University Credits/HOURS**
MED/43 Legal Medicine	1/30
SCIENTIFIC FIELD - teaching	**University Credits/HOURS**
MED/06 Oncology	2/60
MED/09 Internal Medicine	2/60
OTHER ACTIVITIES	
SCIENTIFIC FIELD - teaching	**University Credits/HOURS**
L-LIN/12 English	1/25
INF/01 Informatics	1/25
ACTIVITIES RELATED TO THE FINAL EXAM/THESIS	
Thesis preparation	**University Credits/HOURS**
	3/90

IV° year of specialization courses

SPECIFIC ACTIVITIES	
SCIENTIFIC FIELD - teaching	**University Credits/HOURS**

BIO/14 Pharmacology:	15/375
Special Pharmacology IV	4/100
Cancer chemotherapy	2/50
Epidemiological Pharmacology	1/25
Economic Pharmacology	1/25
Clinical Pharmacology II	3/75
Drug utilization	1/25
Clinical Toxicology II	3/75
SPECIFIC ACTIVITIES	
SCIENTIFIC FIELD - teaching	**University Credits/HOURS**
BIO/14 Pharmacology	30/900
SCIENTIFIC FIELD - teaching	**University Credits/HOURS**
MED/38 Paediatrics	2/60
MED/40 Genecology	1/30
INTEGRATIVE ACTIVITIES	
SCIENTIFIC FIELD - teaching	**University Credits/HOURS**
MED/41 Anaesthesiology	1/25
ACTIVITIES RELATED TO THE FINAL EXAM/THESIS	
Thesis preparation	**University Credits/HOURS**
	12/360