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ACADEMIC BACKGROUND OF THE PROFESSIONS ELIGIBLE FOR VOCATIONAL TRAINING IN MEDICAL BIOCHEMISTRY IN THE REPUBLIC OF NORTH MACEDONIA

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Abstract

Laboratory profession across Europe differs in academic background of the specialists in clinical chemistry. In our country, specialists in medical biochemistry/clinical chemistry hold basic education in general medicine (medical doctors MDs) or pharmacy (Masters of pharmacy).

The length of the graduate studies in general medicine is six years with 360 ECTS, and the length for general pharmacy is five years with 300 European Credit Transfer and Accumulation System (ECTS). Few common subjects are studied during graduate studies for both profiles that differ in the ECTS, such as: Chemistry, Anatomy, Physiology, Biochemistry, Biophysics, Molecular and Cell Biology and Genetics, Microbiology, Pathophysiology, Pharmacology.

The postgraduate training in medical biochemistry, as a monovalent specialization, for both profiles, ranges 4 years. Although the graduate syllabus in Masters of pharmacy doesn't have any clinical subject, the specialization program for both graduate profiles is the same, as well as the title. Presently, the total length of basic education for both profiles is 10.5 for MDs and 9.5 years respectively, and both profiles are registered in the European Register of Specialists in Laboratory Medicine.

The main question arising for the perspective vocational training in medical biochemistry for medical doctors and pharmacists is: do we need different specialization programs for these profiles, bearing in mind different academic background and the need of our health care system?

Keywords: Master of Pharmacy Syllabus, Integrated studies for medical doctor Syllabus, obligatory and elective subjects for graduate studies.

Introduction

The specialization in medical biochemistry, as a monovalent specialization in the Republic of North Macedonia is regulated by the Law on Health Protection and by the Regulations of specialisations and subspecialisations of the Republic of North Macedonia [1].

The eligible profiles to take the specialisation are medical doctors and pharmacists and the specialization program lasts 4 years for both MDs and Masters of pharmacy. The official name of the profile is specialist in medical biochemistry that is equivalent to the specialist in clinical chemistry or specialist in clinical biochemistry in the EU countries.

The specialization training is the same for both profiles, and both profiles are eligible to enrol it after they successfully pass the obligatory professional exam at the Ministry of Health.

As it is in the European Union, the background education of the specialists in medical biochemistry profiles in our Republic also differs.

Our country is a small one, with less than 2 000000 inhabitants, and the healthcare system has been established on the grounds of the previous one, and the demands of the health care providers and users [1].

The different healthcare profiles are providers of the services with different backgrounds of undergraduate education according to the requirements of the Bologna declaration [2].

The specialisation programs for all branches, including the specialisation in medical biochemistry, as a monovalent specialisation, have been revised several times (after the succession of the former country) and have been created to fulfil the needs of the healthcare system and to meet the minimum standards of the EU Syllabus for postgraduate training in clinical chemistry and laboratory medicine with the last revision in 2021 [3].

Profession of specialist in medical biochemistry is defined as a branch of specialisation for medical doctors and master of pharmacy profiles and the responsible institution for postgraduate education of both profiles are Medical Faculties in our country.
In our previous paper we have been discussing the duration of different vocational training for both profiles. The aim of this paper is to analyse the background qualifications, competences and skills of Medical doctors and Masters of pharmacy for vocational training in Medical Biochemistry.

Integrated studies of Medical doctors and masters of pharmacy in the Republic of North Macedonia

Graduate education for MDs according to Bologna declaration in the Republic of North Macedonia, is 6 year with total 360 ECTS, and for the Maters of pharmacy is 5 years of study with total 300 credits respectively [4, 5].

Both profiles have similar subjects during integrated studies, which are presented in Table 1. Table 1 also presents the subjects that are not studied at all in one or another syllabus.

As we can see from the Table 1, one of the main subjects in the syllabus for master of pharmacy is chemistry that is studied in several subjects such as: nonorganic, organic and analytical chemistry applied in pharmacy, physical chemistry for pharmacists, bioorganic chemistry and pharmaceutical chemistry with total number of theoretical lectures of 140 hours.

On the contrary, nonorganic and organic chemistry for medical doctors is studied in one subject (medical chemistry) with total 90 hours of lectures and 7 ECTS, that is in 35% less extend, than chemistry subjects studied according to the master of pharmacy syllabus (4,5).

Table 1. List of some mandatory subjects for integrated studies for medical doctors and for masters of pharmacy.

Subjects	Integrated studies for medical doctors Number of class room theoretical hours	Integrated studies for medical doctors Credits	Integrated studies for master of pharmacy Number of class room theoretical hours	Integrated studies for master of pharmacy Credits
Biophysics	30	2	30	6
Medical chemistry	90	7	n.a.	n.a.
Inorganic chemistry applied in pharmacy	n.a.	n.a.	30	8
Organic chemistry applied in pharmacy	n.a.	n.a.	40	7
Physical chemistry for pharmacists	n.a.	n.a.	30	6.5
Analytical chemistry, applied in pharmacy	n.a.	n.a.	30	8
Bioorganic chemistry	n.a.	n.a.	80	10
Introduction in human genetics	60	5	n.a.	n.a.

Morphology and physiology of the cell	60	5	n.a.	n.a.
Molecular and cell biology and genetics	n.a.	n.a.	45	6
Biochemistry	80	12.5	30	6
Anatomy and physiology	n.a.	n.a.	39	10
Anatomy	270	22	n.a.	n.a.
Physiology	240	17		
Introduction to immunology	45	3	30	3
Medical statistics and informatics	45	3	15+30	3.5
Microbiology and parasitology	135	10	35	7
Pathophysiology	165	11.5	40	6
Pathology	255	17	n.a.	n.a.
Nuclear medicine	30	1.5	n.a.	n.a.
Pharmacology	105	7	45	6
Clinical pharmacology/ Introduction to clinical pharmacology	30	1.5	30	4
Internal medicine	355	20.5	n.a.	n.a.
Toxicology	n.a.	n.a.	40	9
Emergency Medicine	30	1.5	n.a.	n.a.
Forensic Medicine	30	1.5	n.a.	n.a.
Transfusiology	30	2	n.a.	n.a.
Clinical Biochemistry	15	1.5	30	7

n.a.-not applicable.

As presented in Table 1, common subjects such as, human genetics morphology of the cell, anatomy and physiology also differ in the number of classes and ECTSs in between integrated studies in general medicine and integrated studies in master of pharmacy.

Introduction in human genetics and morphology and physiology of the cell in the integrated syllabus for MDs are represented with total number of 120 hours of classes and 10 ECTS Human genetics and morphology of the cell in the Master of pharmacy syllabus are studied as a part of the subject

Molecular and cell biology and genetics with 45 hours of classes and 6 ECTS.

In integrated syllabus for MDs, anatomy is studied in 270 hours of classes and 22 ECTS and Physiology in 240 of classes and 17 ECTS. These two subjects are part of a common subject Anatomy and physiology in the syllabus for master of pharmacy, with total number of 39 hours of classes and 10 ECTS that is a huge difference in comparison to the MDs syllabus (it is just 7% of extend and volume of lectures in comparison to MDs).

Biochemistry is a common subject for both profiles and, as we can see from the Table 1 it is also studied in the less extend according to Master of Pharmacy studies (60% less hours of classes, and 50% less achieved credits in comparison to integrated studies in general medicine).

Similar observations can refer to Microbiology and parasitology, Pathophysiology and Pharmacology, as common subjects, in the both syllabuses. Microbiology and parasitology is studied in the extent of only 26% hours and the extent of 70% in ECTS according to Master of pharmacy syllabus in comparison to integrated studies in general medicine syllabus.

In the integrated studies of master of pharmacy Pathophysiology is studied in an extend of 24% in regard to classes and 32% in regard to achieved credits in comparison to the number of hours and credits achieved according to the syllabus for integrated studies in general medicine.

Pharmacology, as a common subject, is studied in the extent of 43% of classes in Master of pharmacists program in comparison to MDs syllabus with similar number of credits (6 and 7 ECTS respectively).

Clinical pharmacology and Clinical chemistry are studied with the same number of classes, but the ECTS scale differs: 4 ECTS for Clinical pharmacology in the Master of pharmacist syllabus versus 1.5 in the integrated studies in general medicine syllabus and for Clinical biochemistry 7 ECTS versus 1.5 respectively. Few subjects such as: Pathology, Nuclear medicine, Internal medicine, Forensic medicine and Transfusion medicine are not studied at all during the integrated studies in master of pharmacy.

Graduate education at the Faculty of pharmacy-Medical Biochemistry in Croatia and Serbia

Traditionally, Medical Biochemistry has been studied for more than 50 years at the Faculty of Pharmacy-Medical Biochemistry, University in Zagreb, Croatia and at the Faculty of Pharmacy-Medical Biochemistry, Belgrade University Republic of Serbia. Both countries have been a part of a common state with the similar to ours healthcare needs and system. The aim of these studies is to build graduate professionals, who afterword enter one year program of supervised practical training in laboratory that leads to a state exam and issuing the license for practice in the profession (5, 6).

The knowledge and skills of Medical Biochemists are accomplished first, trough integrated studies in Medical Biochemistry at the faculties of Pharmacy/Medical Biochemistry in Croatia and Serbia, presented in Table 2.

Table 2 also compares the mandatory courses at the Faculty of Pharmacy in North Macedonia and Faculty of Pharmacy-Medical Biochemistry in Croatia and in the Republic of Serbia, as examples of the syllabuses for the graduate studies in pharmacy-medical biochemistry for the needs of the health care system, similar to ours.

Table 2. Mandatory subjects for integrated studies in master of pharmacy in the Republic of North Macedonia and integrated graduate studies in medical biochemistry in Croatia and Republic of Serbia**.**

Year	Mandatory courses in the Republic of North Macedonia (ECTS)	Mandatory courses in Croatia (ECTS)	Mandatory courses in the Republic of Serbia (ECTS)
First year of studies	Introduction to pharmacy (2)	Introduction in the medical biochemistry studies (1.5)	Introduction to medical biochemistry (4)
		Mathematics (7.5)	
		Cell biology with genetics (7.5)	
		Physics (7.5)	
	Inorganic chemistry applied in pharmacy (8)	General chemistry with stoichiometry (11)	General inorganic chemistry (6)

		Cytology and histology (5.5)	
		Sociology and healthcare (2.5)	
	Organic Chemistry applied in pharmacy (7)	Analytical chemistry 1 (7.5)	Organic chemistry (7)
	Physical chemistry for pharmacists (6.5)	Physical chemistry 1 (7.5)	Physical chemistry (5)
		Bioethics (2)	
	Analytical chemistry applied in pharmacy (8)		Analytical chemistry 1 (4)
	Bioorganic chemistry (10)		Bioorganic chemistry (5)
	pplied statistics (3.5)		Mathematics (4)
	Biophysics (6)		Physics (3)
	Literature survey (2)		Biostatistics (4)
	Evaluation of the pharmacopeia substances (2)		Biology and human genetics (5)
			Human morphology (5)
			Pharmaceutical physiology 1(5)
Total ECTS in the first year of studies from mandatory subjects	55	60	57
Second year of studies	Instrumental analysis in pharmacy (7)	Analytical chemistry 2 (6)	Instrumental methods (7)
	Pharmaceutical chemistry (7)	Physical chemistry 2 (6)	Analytical chemistry 2 (7)
	Principles in pharmaceutical biology (4)	Organic chemistry (11)	Pharmaceutical chemistry (6)
	Molecular and cell biology and genetics (6)	Biological chemistry (6)	
	Anatomy and physiology (10)	Human physiology and anatomy (9)	
	Microbiology (7)	Microbiology and parasitology (8)	Microbiology (7)
	Biochemistry (6)	Biochemistry (10.5)	Pharmaceutical physiology 2 (5)
	Principles in immunology (3)	Medical chemistry (3.5)	Immunology with immunochemistry

			(6)
	Phytochemistryy (7)		Pathological physiology 1 (5)
	Pharmaceutical botany (3)		General biochemistry (14)
Total ECTS in the second year from the mandatory subjects	60	60	57
Third year of studies	Pathophysiology (6)	Pathophysiology and pathology (7.5)	Pathophysiology 2 (5)
		General Clinical Biochemistry (13.5)	Medical biochemistry (20)
		Haematology 1 (5)	Laboratory haematology (5)
	Principles in pharmaceutical technology (6)	Physical Biochemistry (5)	
	Pharmaceutical technology (10)	Clinical biochemistry of organs and organic systems 1 (4)	
	Principles of pharmaceutical biotechnology (3)	Analytical biochemistry (5)	
	Pharmaceutical chemistry (2)	Haematology 2 (5)	Haematology (4)
		Immunology (4)	
		Molecular biology with genetic engineering (6)	
		Professional practice 1 (2)	Professional practice 1 (2)
	Pharmacognosy (9)		Bromatology (8)
	Principles of pharmacology (6)		Pharmacology1+2 (12)
	Principles of phytotherapy (4)		
	Social pharmacy and methodology (3)		
	Pharmaceutical legislative and ethics (3)		
Total ECTS in the third year of studies from the mandatory subjects	52	57	56

Fourth year of studies of studies		Human and population genetics (2.5)	
		Molecular diagnostics (5)	
		Coagulation (4)	
		Clinical biochemistry of organs and organ systems 2 (6)	
	Advanced pharmaceutical technology (8)	Pharmacology (8.5)	
	Pharmaceutical chemistry (10)	Immunochemistry (2.5)	Pharmacokinetics (7)
		Neurochemistry (1.5)	Laboratory statistics (4)
	Food and nutrition (5)	Nutritional Biochemistry (5)	Control of the food safety 1(5)
			Dietetics (4)
	Clinical biochemistry (7)	Special topics of clinical biochemistry (5)	Clinical enzymology (5)
	Analytics of drugs and legislative (7)	Drug metabolism (5)	Laboratory endocrinology (5)
	Introduction to clinical pharmacy (4)	Transfusiology and immunohaematology (2.5)	Clinical chemistry with molecular diagnosis 1 (10)
	Toxicology (9)	Toxicology (5)	Toxicology with analytics (7+8)
	Biopharmacy (7)	Professional practice 2 (3)	Professional practice 2 (2)
	Pharmacoinformatics (3)		
Total ECTS in the fourth year of studies from mandatory subjects	60	55,5	57
Fifth year of studies			
	Clinical pharmacy and therapeutics (10)	Biostatistics (2.5)	Laboratory hemostasis (5)
		Integrated course of laboratory diagnostics (2.5)	Clinical and toxicological analyses (6)
		Evaluation of instruments, procedures and reagents (2.5)	Clinical chemistry with molecular diagnostics 2 (8)
		Organization and management of	Control of the food safety 2 (5)

		medical biochemistry laboratory (3.5)	
		Health legislation in laboratory diagnostics(1.5)	Ethics and legislation (3)
	Diploma work (5)	Degree thesis (10)	Final work (15)
	Professional practice (30)	Professional training (30)	Professional practice 3 (15)
Total ECTS in the fifth year of studies from mandatory subjects	45	52.5	57
Total ECTS from the mandatory subjects	272	285	284

As we can see form the Table 2, the total number of achieved credits from mandatory and elective subjects is the same in our country, Croatia and Serbia (300 ECTS)

The first year of studies is mainly focused on physical, inorganic and organic chemistry in all three countries, with exception of the subjects: Human morphology and Pharmaceutical physiology studied in Serbia, but not in Croatia or in North Macedonia.

Most of the subjects of the second year of studies are focused on chemistry in our country, with the similar credits, as they are in Croatia and Serbia (Instrumental Analyses in Pharmacy, Analytical Chemistry, Pharmaceutical Chemistry, Microbiology and Biochemistry/General biochemistry). Anatomy and physiology is studied in North Macedonia and Croatia with similar ECTSs, but not in Serbia. Molecular and cell genetics in our country is studied in the second year of studies with 6 ECTS, and in Croatia and Serbia in the first year of studies with the similar ECTS. Pathophysiology is studied in Serbia with 5 credits in the second year and 5 credits in third year of studies and in our country and in Croatia in third year of studies.

The number of achieved credits from this subject in Serbia is similar with the number of credits achieved during the study of general medicine in our country (Table 1). Immunology is studied in different years and number of credits (in the Republic of North Macedonia and Serbia in second year of studies with 3 and 6 ECTS respectively and in Croatia the third year of studies with 4 ECTS). Some subjects, such as: Phytochemistry, Pharmaceutical Botany, Principles of Pharmaceutical Technology, Pharmaceutical Technology, Principles of Pharmaceutical Biotechnology, Pharmaceutical Chemistry, Pharmacognosy, Principles of Phytotherapy, Social Pharmacy and Methodology, which comprise of 4,5 ECTS in the syllabus of Master of pharmacy in the Republic of North Macedonia are not studied at all in Croatia and Serbia. 5 ECTS in the syllabus of the medical biochemistry studies in Croatia in the third year are gained from the subjects: Physical biochemistry (5 ECTS), Clinical Biochemistry of Organs and Organic systems 1 (4 ECTS), Molecular biology with genetic engineering (6 ECTS), Haematology 1and 2 (5 and 5 ECTS respectively) that is almost the same as it is in Serbia (Laboratory Haematology and Haematology with 5 ECTS and 4 ECTS respectively), General Clinical Biochemistry studied in Croatia with 13.5 ECTS is equivalent to Medical Biochemistry in Serbia (20 ECTS respectively).

In the fourth year of studies subjects such as Toxicology, Clinical Biochemistry, Food and Food Nutrition/Biochemistry of Food and Food Safety and Analytics of Drugs Legislative are almost the same in all three syllabuses. What lacks in the syllabus of master of pharmacy in the Republic of

Macedonia, are the subjects: Clinical biochemistry of organs and organ systems, Clinical Enzymology, Laboratory Endocrinology, Neurochemistry, Coagulation, Transfusiology and Immunohematology, which are present either in the syllabus in Croatia or in the syllabus in Serbia.

The fifth year of studies in the Republic of North Macedonia is mainly focused on Diploma work and practice (35ECTS from total 45 ECTS). In the syllabus of Medical biochemistry studies in Croatia in addition to Professional training and Diploma work (40 ECTS) there are a few subjects closely connected to laboratory organization and diagnostics such as: Integrated course of laboratory diagnostics-assessment of findings (2.5 ECTS), Evaluation of instruments, procedures and reagents (2,5 ECTS), Organisation and management of the medical-biochemical laboratory (3,5 ECTS) and Health legislation in laboratory medicine (1,5 ECTS).

According to the syllabus for integrated studies in Medical Biochemistry in Serbia, in addition to diploma work and practice (15 ECTS plus 15 ECTS respectively) there are subjects focused on ethics and legislative (3 ECTS), Laboratory Haemostasis (5 ECTS), Clinical Toxicology and Control of Food safety (6 ECTS, 6 ECTS and 5 ECTS respectively). The differences in the syllabuses in between countries with the similar healthcare systems might be due to the main aim of integrated studies in master of pharmacy in our country that is to produce pharmacists that are highly educated and skilled for the economical needs having:

- a knowledge about the drugs and the substances that are used in drug production;
- a knowledge about the pharmaceutical technology and about the physical, chemical, biological and microbiological research on drugs;
- a knowledge about the use and metabolism and the effects of the drugs, as well as about their toxicity;
- a knowledge about the evaluation of the scientific data about drugs and
- a knowledge about the legislative and other requirements associated with the profession.

On the other hand, the aim of the Medical Biochemistry programs according to the Syllabuses in Croatia and Serbia is to produce personnel who can:

- independently work in biochemical, toxicological and sanitary laboratories;
- develop and apply different methods and techniques for determination of different biochemical parameters in biological samples;
- explain the biochemical parameters and their changes in regard to illnesses, drugs, toxicological substances and food;
- control the quality and safety of food and dietetic products, air and environment;
- perform qualitative and quantitative analyses and toxicological risk assessment of environment;
- prevent the risk of intoxication, diagnose the type of intoxication in collaboration with other health profession profiles;
- take part in regulatory bodies in legislate and their application in order of permanent improving of the health system and public health;
- work on development and application of the relevant analytical methods and techniques in the scientific, developmental and control laboratories and centres in different pharmaceutical and biomedical fields;
- take part in continues education during their professional work.

The main goal of the integrated studies for medical doctors in the Republic of North Macedonia, who are eligible for the vocational training in Medical biochemistry, is to obtain the knowledge and skills for the independent medical practice through specific skills in diagnosis, prevention and curing the illnesses.

Although the subjects studied during the undergraduate studies are different between master of pharmacy and medical doctors, the specialisation program is the same, leading to the same title, specialist in medical biochemistry, and the same competences and responsibilities for both profiles.

The objectives of the training program of specialisation in medical biochemistry in our country are defined on the grounds of the European federation of clinical chemistry and laboratory medicine syllabus for postgraduate education and training for specialists in Laboratory medicine: version 5-2018 as follow:

"Throughout training, the objective is to develop the knowledge, skills, competence, attitudes and behaviours consistent with specialist level clinical, scientific and professional practise. Clinically, the specialist assesses the appropriate clinical investigations for his/her local population; evaluates how those investigations relate to diagnosis, management and prognosis; and provides the expertise to ensure appropriate application. Scientifically, he/she is able to assess the scope of service need, plan and implement its delivery and ensure a safe and effective working environment. Professionally, the specialists assess, plan, conduct, report, diffuse and adopt their research, development and innovation output. Their clinical leadership training contributes to the evolution of health and health services" [7].

According to the present Law on Health Protection in the Republic of North Macedonia eligible to assess the 48 months of vocational training in Medical biochemistry specialisation program are medical doctors and masters of pharmacy [1].

The vocational training is the same for both profiles and consists of following courses: Medical biochemistry with specialised laboratories 31 months; Haematology 2 months; Transfusion medicine 2 months; Medical microbiology 1 month; Genetics 1 month; Biochemical aspects of pathology and oncology 1 month; Pharmacology/Pharmacotoxicology 2 months; Management and insurance of the quality in laboratory process, 2 months and Scientific work and paper work 6 months [3].

As presented in this paper, there is a huge difference in the total number of credits and in the obligatory and elective subjects of integrated studies between medical doctors and master of pharmacy in our country. This is not a situation in the surrounding countries, such as Croatia and republic of Serbia, where traditionally, the Masters of Medical Biochemistry are educated at the faculties of pharmacy achieving competences to be employed in the medical biochemistry laboratories.

On the other hand, undergraduate study in Master of Pharmacy in the Republic of Macedonia is mostly focused in producing the professionals highly educated and skilled for the economical needs of the pharmaceutical industry. In addition, in our country there is a special profile with 240 ECTS with the degree in Analytical Chemistry and undergraduate studies with 180 ECTS for Engineers of Medical Laboratory Diagnoses. Both profiles are educated and have skills in analytical chemistry and are part of the medical biochemistry laboratory staff and according to the present legislative these two profiles do not have permission for unsupervised work in medical biochemistry laboratories.

Conclusions and future perspectives

From the data presented we may conclude that in our country eligible for specialization in Medical Biochemistry are medical doctors and masters of pharmacy with the 4 years specialization program that is the same for both profiles. There is a serious gap of basic knowledge in anatomy, physiology, pathology, pathophysiology, haematology, transfusion medicine and some parts of internal medicine in the master of pharmacists' profile, while medical doctors lack more analytical chemistry subjects. Bearing in mind the objectives of training in specialisation in medical biochemistry and in the era of modernisation of the laboratory medicine, facing with the new global challenges in the health care system, one of the main goals of the national health care system should be promoting highly skilled professionals not only in medical biochemistry, but in all the specialisation and subspecialisation branches. Although the formal education of both profiles lasts for 10 years, there is a serious gap in clinical medical knowledge of master of pharmacists. According to our opinion there are two ways in improving the medical biochemistry profession in the Republic of North Macedonia:

1. First approach could be revision of the integrated syllabus for Master of Pharmacy-introducing a new study program, similar to that in our surrounding, that will produce highly trained Medical biochemists who can continue their further training for in the Medical Biochemistry profession trough the common or different revised specialization programs;
2. Second approach could be proposing and preparing two different specialization programs for graduate students in integrated studies in Master of Pharmacy (Master of Pharmacy/Master of pharmacy-Medical Biochemists) and for integrated studies in general medicine (Medical Doctors) which will lead to two different specialization titles, Specialists in Medical

Biochemistry and Specialists in Clinical Chemistry respectively, and could overcome the gaps in the background academic education of both profiles.

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