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MEDICAL BIOCHEMISTRY AS A MONOVALENT SPECIALIZATION IN THE REPUBLIC OD MACEDONIA - PRESENT SITUATION

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Abstract

Clinical Chemistry (Medical Biochemistry) practice as a subdiscipline of laboratory medicine in the Republic of Macedonia is regulated by the Ministry of Health according to the Law on Health Protection of the Republic of Macedonia, and was established for the first time in 1960.The four year Specialization Syllabus according to the EU4 Directive was introduced in 2008 and is still in force. Eligible to enter the specialization program are medical doctors and pharmacists. Completing the specialization program and the final exam are requirements for issuing the license for independent clinical chemistry practice by the Macedonian Doctor's Chamber.The common training meets the requirements for the perspective professional movements across EU borders for the medical doctors and pharmacists (the length of total education is 10 years). In the era of the new analytical techniques, use of statistics, it will be of a great importance to update the present syllabus according to the fifth version of the European Syllabus for post graduate training for specialists in Laboratory Medicine and the needs of our country. The revised training program should call attention towards the structure of the program, as well as towards the expected responsibilities of trainees and trainers and the strategies of our country. The Medical Faculties providing the training in medical biochemistry in the Republic of Macedonia, as well as the professional societies should be included in updating the syllabus in order to have equally trained professionals who can face the new requirements in laboratory medicine in the Republic, but also qualified specialists prepared for the free movement across the European Union borders in the future.

Key words: medical biochemistry, specialization syllabus, vocational training, examination, registration, continues medical education, accreditation.

Introduction

The field of specialization in medical biochemistry in the Republic of Macedonia is the usual name for clinical chemistry or clinical biochemistry specialization within European Union. The official specialization in the field of medical biochemistry in the Republic of Macedonia was first established in 1960 (1). Till 1984 eligible to enroll the specialization in Medical Biochemistry were medical doctors, pharmacists, biologists, technologists and chemists. From 1984 only medical doctors and pharmacists can enroll the specialization program (1). Till 2008 the specialization program lasted for 3 years vocational training after the first cycle of studies (or in total from 7 till 8 years education), which was extended to four years vocational training after introducing the new syllabus based on EC4 curriculum in 2012, which is still in power (2). The Medical Faculties (Departments of Biochemistry) are proposing the specialization syllabuses to the Educational and Scientific Board of the faculties for acceptation and for further action to the Minister of Health of the Republic of Macedonia. According to the Law on Health Protection of the Republic of Macedonia (the Law), Article 138 and Bylaw (3, 4) the minister legislates the Syllabuses of specialization proposed by Medical Faculties (that is to say by the Departments). Presently there are three Schools of Medicine in the Republic of Macedonia (as a part of the three Universities: in Skopje, Stip and Tetovo), two of them conducting the Specialization in Medical Biochemistry according to the same Syllabus proposed by Department of Biochemistry Medical Faculty

Skopje. Eligible to enroll the specialization are Medical doctors and Pharmacists realizing the same specialization program receiving the same title - Specialist in Medical Biochemistry (3, 4).

Definition of the specialty

Many different names are used for the specialty field at National level in the EU countries such as: Klinisk Biokemi , Medizinische und Chemische Labordiagnostik , Biochimica Clinica etc. listed in the Table 1, with different combination of the words clinical, medical, laboratory, bio(chemistry), which accurately define the profession of clinical chemistry and laboratory medicine (5). In 2010 EFCC (now named EFLM) has adopted the name of the profession "specialist in laboratory medicine "as it encompasses all specialists working in the field from whatever academic background and whatever polyvalent or sub-specialized (6).

Table 1. Names of the specialties in EU and in the Republic of Macedonia

Austria	Medizinische und Chemische Labordiagnostik
Belgium	Biologie Clinique, Klinische Biologie
Bulgaria	Клинична лаборатория (Clinical Laboratory)
Croatia	Specijalist medicinske biohemije I laboratoriske medicine (Specialist in Medical biochemistry and Laboratory Medicine)
Cyprus	Clinical Chemistry
Czech Republic	Clinical Biochemistry
Denmark	Klinisk Biokemi
Estonia	Laborimeditsiin
Finland	Kllininen Kemia Saiaalakemisti
France	Biologie Medicale
Germany	Laboratoriumsmedizin
Greece	κλινική χημεία- κλινική βιοχημεία (Clinical Chemistry, Clinical Biochemistry)
Hungary	Orvosi Laboratoriumi Diagnosztika (Medical Laboratory Diagnostics)
Ireland	Clinical Biochemistry, Clinical Chemistry
Italy	Biochimica Clinica

Latvia	Laboratora Medicina
Lithuania	Laboratorine Medicine
Luxemburg	Biologie Clinique/Biochemie
Malta	Patologija Kimika
Netherlands	Klinische Chemie
Poland	Laboratoryjna Diagnostyka Medyczna
Portugal	Analises Clinicas (PharmD); Patologia Clinica (MD)
Romania	Medicina de Laborator
Slovak Republic	Laboratorna medicina/Klinickej biochemie
Slovenia	Medicinska Biokemija
Spain	Bioquimica Clinica (monovalent), Analisis clinicos (polyvalent)
Sweden	Klinisk Kemi
UK	Clinical Biochemistry/Chemical Pathology
Republic of Macedonia	Medicinska biohemija (Medical Biochemistry)

Adopted from Oosterhuis WP. (5)

Fields of interest and responsibilities in Clinical Chemistry/Laboratory Medicine

Laboratory medicine does include different fields in different countries, and sometimes is called "polyvalent" or general and "monovalent" if it includes only one field of interest (5). In our country, there are monovalent specializations: in Medical Biochemistry, Immunology, Microbiology, Transfusion Medicine, Medical Genetics, Pathology and Hematology (4). If the laboratory medicine includes at least biochemistry, hematology and microbiology, we can arbitrarily define as general one (5).

Table 2. Laboratory Medicine and fields of interest in EU member states and in the Republic of Macedonia.

		EU	Republic of Macedonia
Biochemistry	Yes	100%	100%
	Partly*	/	

	No	/	
Hematology	Yes	92%	
	Partly*		100%
	No	8%	
Microbiology (11% not applicable)	Yes	46%	
	Partly*	7%	Partly# (only specialized laboratories are performing routine tests for detection of virus infections).
	No	36%	
Transfusion (11% not applicable)	Yes	32 %	
	Partly*	18%	
	No	39%	100%
Immunology	Yes	72	
	Partly*	16	# Only routine tests
	No	12	
Endocrinology (11% not applicable)	Yes	86	
	Partly*	4	#100%
	No	/	

Addopted from Oosterhuis WP. (5)

*Partly in the EU countries: some laboratories perform these tests, or only in part (e.g., routine tests)

Partly in the Republic of Macedonia: all laboratories perform just the routine tests.

According to these data and to the arbitrary definition, we may say that 60% of the EU countries as well as, our country are having general fields of interst.

Postgraduate education

Each country inside and outside the EU does decide about the physician's specialized education and training implementing the recommended standards for training specialists in laboratory medicine. In general, decisions are based on historical, geographical and economical-political background. The

variation in specialty training for both monovalent and polyvalent specialization exists despite the efforts of EU of Medical Specialists (UEMS), Section of Laboratory Medicine, Medical Biopathology and EC4 European Register of Specialists in Laboratory Medicine. Furthermore, from one nation to another (inside EU) monovalent specialist education and practice are not absolutely equal, and some overlaps between them can be seen (7). There are some overlaps and differences in the vocational training in the monovalent specializations in medical biochemistry, hematology, transfusion medicine, microbiology and immunology exist in our country too.

Table 3. Duration (in months) of vocational training in monovalent specializations in the Republic of Macedonia.

Specialization in	Duration of the total period of training (months)	Vocational training in Biochemistry/Clinical Chemistry (months)	Vocational training in Hematology (months)	Vocational training in Transfusion (months)	Vocational training in Microbiology (months)	Vocational training in Immunology (months)
Medical Biochemistry	48	27,5	3	3	4	0.5
Hematology	72	1	24	1	1	1
Transfusion	60	0.5	3.5	38.2	0.5	2.5
Microbiology	48	1	0	0	42	0
Immunology	48	1	2	5	1.5	17

If we compare the vocational training and the main fields of interests among the countries that were historically connected as a part of former Yugoslavia we can see that the duration of specialization and the length of training in the main fields of interests differ in between the countries (8, 9, 19, 11, 12).

Table 4. Duration of the vocational training in some countries that were a part of former Yugoslavia.

Country	Duration of training (years)	Vocational training in Biochemistry/ Clinical Chemistry (months)	Vocational training in Hematology (months)	Vocational training in Transfusion (months)	Vocational training in Microbiology (months)	Vocational training in Immunology (months)	Eligible to enroll the specialization training	Title received
Macedonia	1+4*	26.5	3	3	4	0.5	MDs, Pharmacists	Specialist in Medical Biochemistry
Slovenia	1+4*	20	4	1	2	2	MDs, Sc, Pharmacists	Specialist in Medical Biochemistry
Croatia	4	15	11		2	5	Pharmacists	Specialist in Medical Biochemistry
Croatia	5	14	11		1	3	MDs	Specialist in Laboratory Medicine
Serbia	4	20	6	NA	4	NA	Pharmacists	Specialist in Medical Biochemistry
Serbia	4	12	3			3		Specialist in Clinical Chemistry
Serbia	4	19	1	NA	NA	6	MDs	Specialists in Laboratory Medicine

*1+4 (four years specialization after 1 year practice with state examination).

Duration of the training differs between the EU member states and between MDs, pharmacists and scientists and is presented in Figure 1. In most of the EU countries duration of the training is 5 years for MDs, pharmacists and scientists (41%, 30 and 34 respectively) (5). In 48% of the EU countries there is no formal specialist training for pharmacists (for ex. In Croatia where 50% of the academics with background in pharmacy/medical biochemistry chooses not to do the specialization and work in clinical laboratories with limited responsibilities) (8).

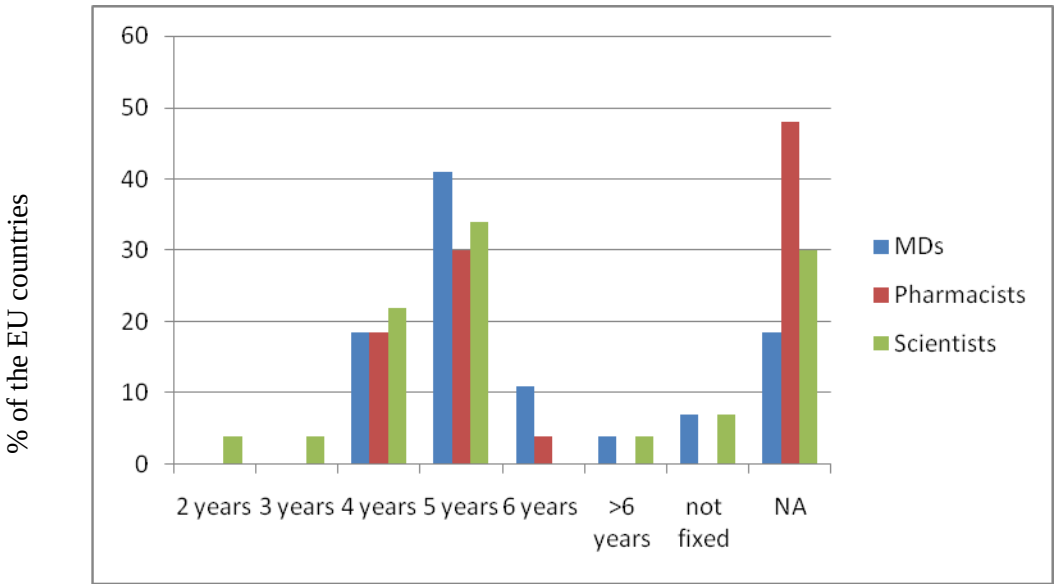

Figure 1. Duration of the specialization training in the EU member states.

In the Republic of Macedonia there is no specialization training in Medical Biochemistry for scientists, although they have almost the same responsibilities as MDs and pharmacists specialists in Medical Biochemistry, according to the Law and Bylaw, that is to say they validate the results and are appointed for a head positions (3, 4).

Responsibilities of the specialists

The responsibilities of scientists and pharmacists among the EU member states differ too. Medical doctors have no limited responsibilities in all the EU member states and in the Republic of Macedonia. In most of the EU countries the responsibilities of Pharmacists and Scientists specialists in Laboratory Medicine are not limited 44% and 52% respectively (5). More of the EU countries have limited responsibilities for specialist scientists than for pharmacists (40% and 16% respectively) (5) (Figure 2).

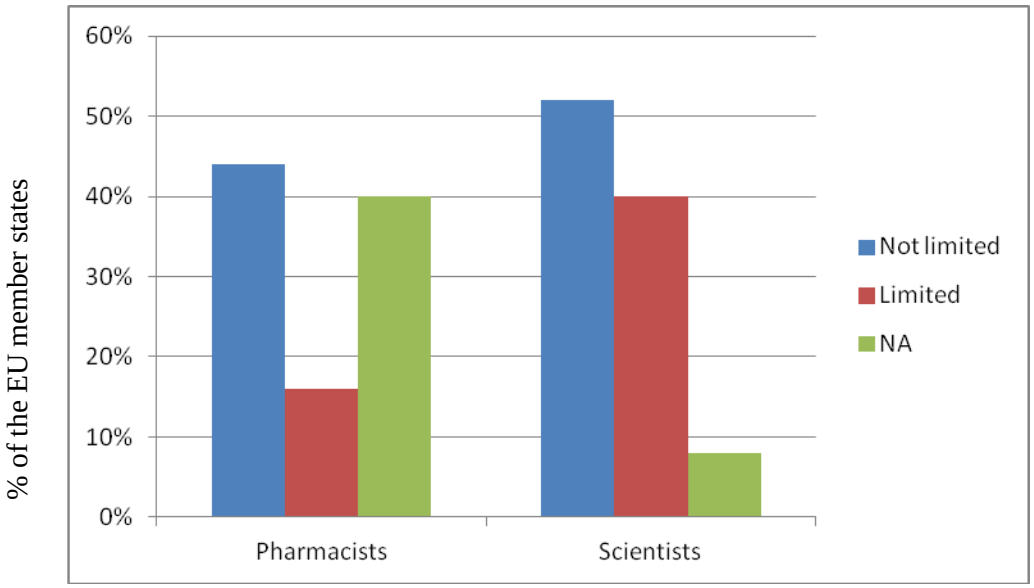

Figure 2. Responsibilities of the pharmacists and scientists in the EU member states.

Examination registration and re-registration

The evaluation of the competency in the Republic of Macedonia is defined by the Law and Bylaw and includes a few internal and one external examination which leads to the title specialist in Medical Biochemistry (3, 4). Most of the EU countries have final examination of the competences for MDs and scientists (63% and 52 % respectively) (Figure 3) (5). In most of the EU countries examination of pharmacists is not applicable due to the fact that there are no specialists or there is not available training.

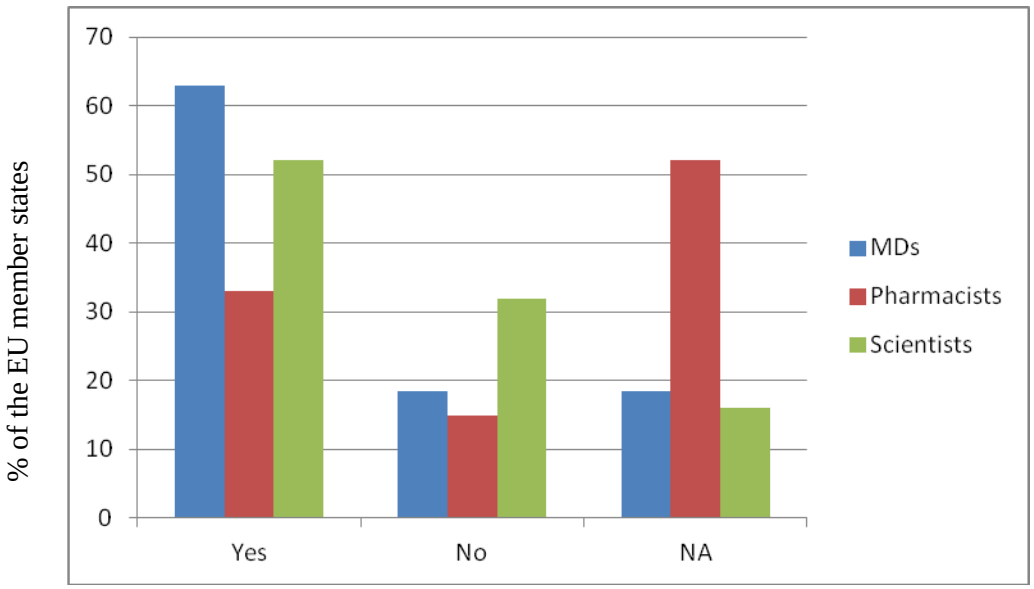

Figure 3. Examination of the competences in the EU member states.

Registration

Registration of the specialists of Medical Biochemistry in our country is the Register of specialists in Doctor's Chamber or Chamber of Pharmacists of the Republic of Macedonia for pharmacists respectively (3,4).

MDs are registered in all EU countries followed by scientists (63%) (Figure 4) (13). Not applicable registration for pharmacists is present in 44% of the EU countries due to the fact that there are no specialists in those countries (5, 8) .

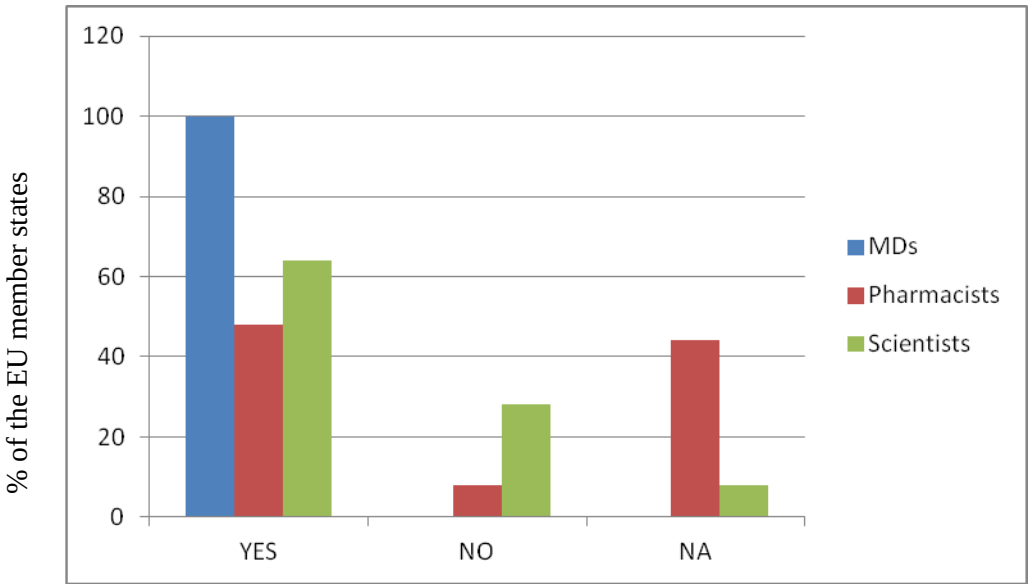

Figure 4. Registration of the specialists in EU member states.

Re-registration

Re-registration for MDs is not obligatory in most EU countries (Figure 5). It is linked to financial stimulus (health insurance, reimbursement), but is obligatory in 36% and in some of them like Belgium is not connected to the loosing of registration (5).

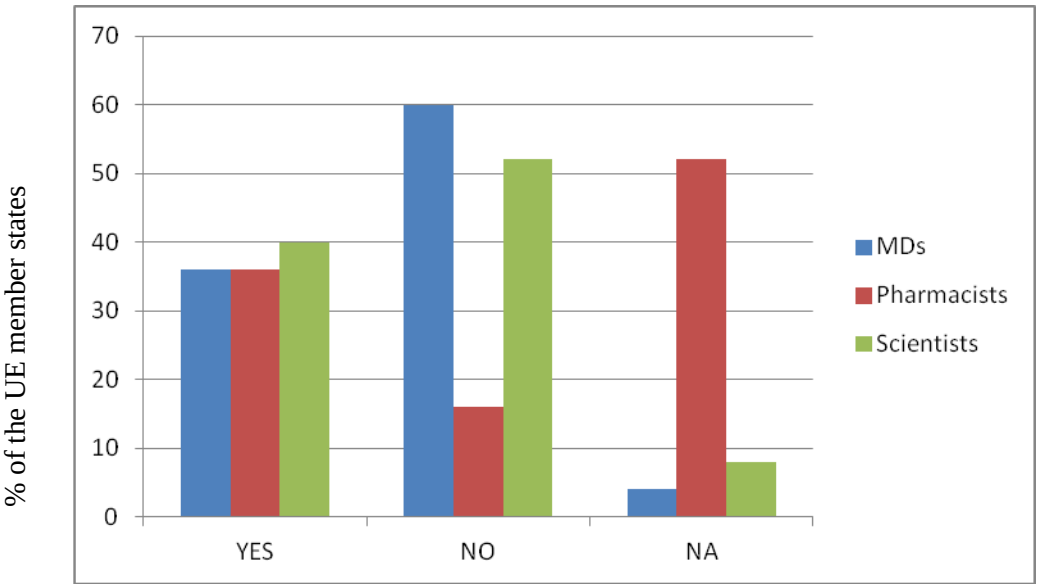

Figure 5. Re-registration within the EU member states.

Re-registration is obligatory in the Republic of Macedonia. The precondition for re-registration is continuous medical education and is regulated by the Law (3). Continuous medical education (CME) in the Republic of Macedonia is organized by the Macedonian Society of Medical Biochemistry and Laboratory Medicine trough the Doctors 'Chamber, Chamber of Pharmacists and Macedonian Medical Association.

The continuous medical education exists in 80% of the EU countries, but it differs in between the member states. For example in Austria and Germany it is only for physicians and in Spain it is used for professional and economical recognition within an institution; Sweden, Denmark and Bulgaria do not have CME system and in Finland it is connected to accreditation according to ISO 15189 Standard (5).

Accreditation according to ISO 15189

Accreditation according to ISO 15189 Standard is obligatory by the Law in our country (3). Even so, only a few public and private laboratories have been accredited so far. If we compare our situation with the situation in EU member states we may see that in 40% of the EU member states, less than 5% of the laboratories are accredited according to ISO 15189, most of those are accredited by ISO 9000/9001 Standard (5, 14)(Figure 6). In 24% of the member states the number of accredited laboratories varies between 10 and 40%. In Ireland and Belgium 75% of the laboratories are accredited. In Slovenia accreditation is not obligatory by Law and in Sweden all laboratories are accredited according to ISO 15189.

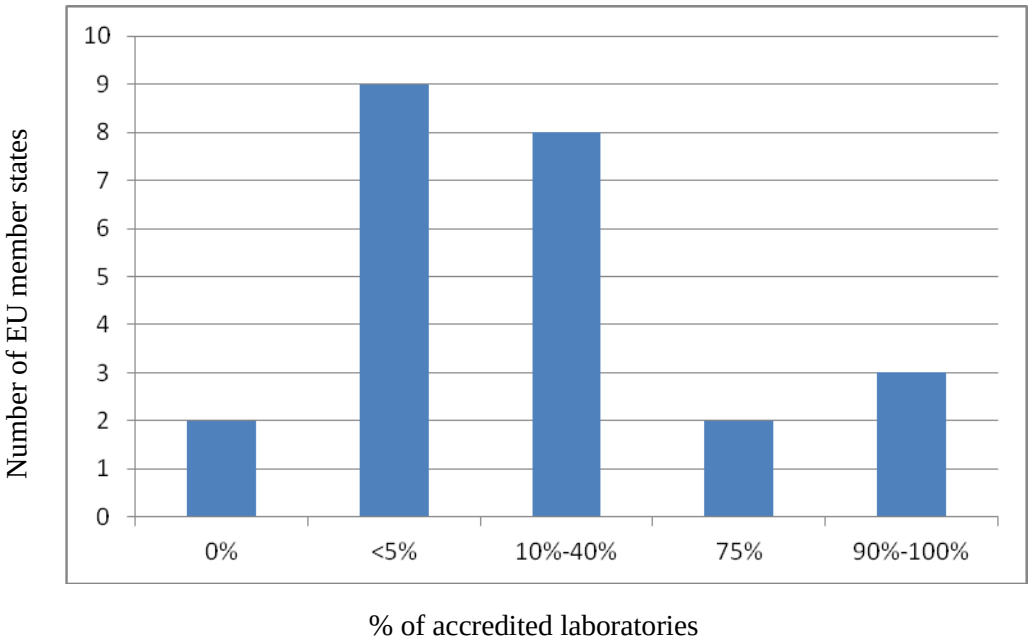

Figure 6. ISO 15189 Accreditation among EU member states.

Conclusions

In the dawn of accession of Macedonia in EU family, it is very important to harmonize Macedonian legislation in regard to the clinical chemistry/medical biochemistry profession, although the harmonization has been a goal for many years within EU member states (15).

Despite some differences from the EU member states, the profession in Republic of Macedonia has a similar interdisciplinary character. The total education for MDs and Pharmacists lasts for 10 years (6 and 5 years respectively undergraduate study plus 1 year of obligatory training plus 4 years of vocational training) (3, 4).

The vocational training is based on EC4 curriculum which is still in power. Recent suggestions to the Ministry of Health were according to the Recommendations of regulation and curricula for training of specialists in the different disciplines of Laboratory Medicine in EU in regard to time spent in vocational training in general chemistry plus hematology of at least 65% and flexibility as to the remaining 35% including general chemistry, hematology, microbiology and genetics in proportion consistent with the requirements of our country (7, 15, 16).

Recent developments with respect to the EU directive on Recognition of Professional Qualifications call for new initiatives to harmonize laboratory medicine both across national borders and across the borders of scientific and medical professions will allow free movement within EU. The goal for the former Association of Doctors of Medicine Specialists in Medical Biochemistry or for the new Macedonian Society of Medical Biochemistry and Laboratory Medicine (which has become a member of EFLM family) should be submission of an application for recognition of the Equivalence of Standards with Specialists in Laboratory Medicine across Europe as well as more active role in the healthcare strategies.

It will be of a great importance that the Ministry of health develops the strategies for the needs of our country for the near future in regard to monovalent specialization or to the polyvalent specialization in Laboratory Medicine. The strategies will improve the vocational training and healthcare system and fulfill the minimum standards for recognition of the profession within the EU.

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