

MEDICAL BIOCHEMISTRY AS SUBDISCIPLINE OF LABORATORY MEDICINE IN SERBIA

MEDICINSKA BIOHEMIJA KAO GRANA LABORATORIJSKE MEDICINE U SRBIJI

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Summary

Medical biochemistry is the usual name for clinical biochemistry or clinical chemistry in Serbia, and medical biochemist is the official name for the clinical chemist (or clinical biochemist). This is the largest sub-discipline of the laboratory medicine in Serbia. It includes all aspects of clinical chemistry, and also laboratory hematology with coagulation, immunology, etc. Medical biochemistry laboratories in Serbia and medical biochemists as a profession are part of Health Care System and their activities are regulated through: the Health Care Law and rules issued by the Chamber of Medical Biochemists of Serbia. The first continuous and organized education for Medical Biochemists (Clinical Chemists) in Serbia dates from 1945, when the Department of Medical Biochemistry was established at the Pharmaceutical Faculty in Belgrade. In 1987 at the same Faculty a five years undergraduate study program was established, educating Medical Biochemists under a special program. Since the academic year 2006/2007 the new five year undergraduate (according to Bologna Declaration) and four-year postgraduate program according to EC4 European Syllabus for Postgraduate Training in Clinical Chemistry and Laboratory Medicine has been established. The Ministry of Education and Ministry of Public Health accredited these programs. There are four requirements for practicing medical biochemistry in the Health Care System: University Diploma of the Faculty of Pharmacy (Study of Medical Biochemistry), successful completion of the professional exam at the Ministry of Health after completion of one additional year of obligatory practical training in the medical biochemistry laboratories, membership in the Serbian Chamber of Medical Biochemists and licence for skilled work issued by the Serbian Chamber of

Kratka sadržaj

Medicinska biohemije je uobičajeni naziv za kliničku biohemiju ili kliničku hemiju u Srbiji i medicinski biohemičar je uobičajeni naziv za kliničkog hemičara (ili kliničkog biohemičara). Ovo je najveća pod-disciplina laboratorijske medicine u Srbiji. Uključuje sve aspekte kliničke hemije, kao i laboratorijske hematologije sa koagulacijom, imunologijom itd. Medicinsko-biohemijske laboratorije u Srbiji i medicinski biohemičari kao profesija su deo zdravstvenog sistema u njihovoj aktivnosti je regulisana: Zakonom o zdravstvenoj zaštiti, i pravilima Komore biohemičara u Srbiji. Prva kontinuirana i organizovana edukacija medicinskih biohemičara (kliničkih hemičara) u Srbiji datira još iz 1945. godine, kada je otvoren Zavod za medicinsku biohemiju na Farmaceutskom fakultetu u Beogradu. Godine 1987. na istom Fakultetu uvedeno je petogodišnje obrazovanje medicinskih biohemičara po specijalnom programu studija. Počev od školske 2006/2007 uveden je novi petogodišnji program studija prema Bolonjskoj deklaraciji, kao i četvorogodišnje specijalističko obrazovanje prema EC-4 European Syllabus for Postgraduate Training in Clinical Chemistry and Laboratory Medicine. Ovi programi su akreditovani kod Ministarstva prosvete i zdravlja. Prema Zakonu o zdravstvenoj zaštiti postoje četiri zahteva za obavljanje medicinske biohemije: univerzitetska diploma Farmaceutskog fakulteta (studije medicinske biohemije), uspešno položen stručni ispit u Ministarstvu zdravlja nakon obavljanja prakse u laboratoriji prema utvrđenom programu, članstvo u Komori biohemičara Srbije, kako i licenca o obavljanju delatnosti Komore biohemičara Srbije. Kako bi se praksa laboratorijske medicine-medicinske biohemije prezentovala ovaj rad će se baviti sledećim: srpskom nacionalnom legislativom, organizacijom zdravstvene službe, pod-disciplinama laboratorijske medicine i medicinskom biohemijom kao najznačaj-

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Medical Biochemists. In order to present laboratory medical biochemistry practice in Serbia this paper will be focused on the following: Serbian national legislation, healthcare services organization, sub-disciplines of laboratory medicine and medical biochemistry as the most significant, education in medical biochemistry, conditions for professional practice in medical biochemistry, continuous quality improvement, and accreditation. Serbian healthcare is based on fundamental principles of universal health coverage and solidarity between all citizens.

Keywords: Laboratory Medicine, Medical Biochemistry, education, professional qualifications, laboratory organization; Serbia

Introduction

Medical biochemistry is the usual name for clinical biochemistry or clinical chemistry in Serbia, and medical biochemist is the official name for the clinical chemist (or clinical biochemist). This is the largest sub-discipline of the laboratory medicine in Serbia. It includes all aspects of clinical chemistry, and also laboratory hematology with coagulation, immunology, etc. Medical biochemistry laboratories in Serbia and medical biochemists as a profession are part of Health Care System and their activities are regulated through: the Health Care Law and regulations issued by the Chamber of Medical Biochemists of Serbia.

The beginning of continuous and organized education for Medical Biochemists (Clinical Chemists) in Serbia dates from 1945, when the Department of Medical Biochemistry was established at the Faculty of Pharmacy University of Belgrade. In 1987, a separate, four year medical biochemistry study program was started, and in 1991 it evolved in a five years undergraduate study program in medical biochemistry. Since the academic year 2006/2007 the five year undergraduate study program has been adjusted to meet the principles of the Bologna Declaration and postgraduate program of four-year specialization according to EC4 European Syllabus for Post-Graduate Training in Clinical Chemistry and Laboratory Medicine has been established. The Ministry of Education and Ministry of Public Health accredited these programs.

Four requirements for practicing medical biochemistry have been defined in the Health Care System of the Republic of Serbia: University Diploma of the Faculty of Pharmacy (Studies of Medical Biochemistry), successful completion of the professional exam at the Ministry of Health after completion of one year of residency training in the medical biochemistry laboratories, membership in the Chamber of Medical Biochemists of Serbia and licence for skilled work issued by the Chamber (1–4).

In order to present laboratory medicine practice in Serbia this paper will be focused on the following: Serbian national legislation, healthcare services

nijom granom iste, edukacijom medicinskih biohemičara, uslovima obavljanja profesionalne prakse, stalnim poboljšanjem kvaliteta i akreditacijom laboratorija. Srpski zdravstveni sistem se zasniva na fundamentalnim principima univerzalnog pokrivanja zdravstvene zaštite na principima solidarnosti među građanima.

Ključne reči: laboratorijska medicina, medicinska biohemijska, edukacija, profesionalne kvalifikacije, laboratorijska organizacija, Srbija

organization, sub-disciplines of laboratory medicine and medical biochemistry as the most significant, education in medical biochemistry, conditions for professional practice in medical biochemistry, continuous quality improvement, and accreditation. Serbian healthcare is based on fundamental principles of universal health coverage and solidarity between all citizens (5–7).

Serbian National Legislation

Serbian National Legislation consists of the Healthcare Law of the Republic of Serbia, Guidelines on closer terms of providing healthcare in health centers and other healthcare institutions, Guidelines on internal organization of healthcare institutions, Guidelines on files and medical documentation, staff reports, equipment, rooms, and medicines in healthcare institutions, expert methodological instructions for the work and organization of medical biochemistry laboratory service, Law on standardization, Guidelines on healthcare quality indicators, Law on safety at work, etc. (5, 6).

Funding of Healthcare in the Republic of Serbia is designed basically on the Bismarck's model of the social insurance since more than 90% of resources for the realization of rights from the mandatory health insurance are provided from the contribution of citizens for mandatory health insurance. However, the Healthcare law also implies financing from the budget of the Republic for persons not included in mandatory health insurance (unemployed, refugees, persons on welfare, etc.) which is the feature of the Beveridge model. So, we may say that in Serbia we have the combined financing system from almost exclusively public sources – contributions and the state's budget. Serbia allocates >10% of GDP per capita for healthcare, which is above the EU average (according to the WHO), but these resources are small because of the relatively low level of GDP in Serbia. The latest statistics shows that the GDP in Serbia in 2016 was ~4500 € per capita, out of which to healthcare was allocated ~450 € (8, 9).

Table I Health Care Organization in Serbia (9).

| Level of healthcare | Number of institutions |
|---|------------------------|
| Primary level | |
| Community Health Centres | 161 |
| Independent Institutions for particular population (students, workers, elderly...) and specialized care (dermatology, pulmonary disease etc.) | 21 |
| Secondary level | |
| General Hospitals | 41 |
| Specialized Hospitals | 35 |
| Tertiary level | |
| Specialized independent clinics | 6 |
| Institutes | 16 |
| Clinical Hospital Centres | 4 |
| Clinical Centres | 4 |

Table II Health care organization in Serbia – hospital beds (10).

| | Hospital beds | |
|---|---------------|----------------------|
| | Total | Per 1000 inhabitants |
| Short term hospitalization of acute conditions and injuries | | |
| a) Secondary level | 24 000 | up to 3.2 |
| b) Tertiary level | 6000 | up to 0.8 |
| Long term hospitalization | | |
| a) Psychiatric patients | 3500 | up to 0.47 |
| b) TB, unspecific pulmonary diseases, and other chronic illnesses | 1000 | up to 0.13 |
| Specialized rehabilitation | 3000 | up to 0.40 |
| Total | 37 500 | up to 5 |

Healthcare institutions are organized as ambulatory and hospital care in the public sector. Health insurance rights are ensured through National Health Insurance Fund. Healthcare law in its *Article 1* states that the law governs the healthcare system of the Republic of Serbia, the organization of the health service, social care for the health of the population, general interest in healthcare, supervision of its implementation, as well as other matters of significance for the organization and provision of healthcare. *Article 2* defines that the healthcare, in terms of this law, is an organized and comprehensive activity of the society, aimed at achieving the highest possible level of preserving the health of the citizens and family. Healthcare includes implementation of measures and activities for preserving and improving the health

of the citizens of Republic of Serbia, for the prevention, suppression, and early discovery of disease, injuries, and other health disturbances, and timely, efficient and effective treatment, care, and rehabilitation. The right to healthcare have every citizen of Republic of Serbia, and every foreign citizen or person without citizenship who is permanently or temporarily residing in the Republic of Serbia or is passing through the territory of the Republic of Serbia. They have the right to healthcare, according to law, and a duty to preserve and improve their health and the health of all other citizens, as well as the living and working environment conditions (*Article 3*) (5).

Healthcare implementation is enabled through three levels of professional organization: primary level is represented by health centers; facilities of the secondary level are general and specialized hospitals; tertiary level is provided at clinics, clinical hospital centers or clinical center. There are some healthcare services provided at several levels, like blood banking or forensic medicine (see *Table I* and *Table II*).

Laboratory Medicine – Medical Biochemistry

The term laboratory medicine covers medical biochemistry (clinical chemistry), laboratory hematology, microbiology, immunology, immunohematology analysis, toxicology analysis, cytogenetics and molecular genetics, tissue typing, and histopathology. **Medical biochemistry** is the synonym for clinical chemistry in Serbia, and it includes all aspects of clinical chemistry, laboratory hematology with coagulation, immunochemistry, and laboratory endocrinology.

Medical Biochemistry is a common term for clinical chemistry or clinical biochemistry since 1939, and professional name for the clinical biochemist or clinical chemist is medical biochemist. It is the the largest sub-discipline of laboratory medicine (1, 7, 11). More than 1500 laboratory parameters of the 3000 defined in the National Nomenclature for various sub-disciplines of laboratory medicine are processed in medical biochemistry laboratories. Medical biochemistry laboratory diagnostics is performed in an appropriate scope according to the level of healthcare (primary, secondary, tertiary) as regulated by the Nomenclature of Laboratory Services (12). Guidelines on the Nomenclature of laboratory healthcare services determine the Nomenclature of laboratory healthcare services at the primary, secondary and tertiary level of healthcare, and they have been applied since 1 July 2012. The extracts from the official **Nomenclature of healthcare services** with the level of healthcare where the particular service should be available are shown on *Tables III* and *IV*. Firstly the common general laboratory services, like blood sampling (micro sampling) and venipuncture, with the

Table III Nomenclature of Laboratory Medicine tests in Serbia (common laboratory services examples).

| A. COMMON GENERAL LABORATORY SERVICES | | | |
|---------------------------------------|---------------------------------|---|------------------------------|
| Nr. | Name of service | Description of service | Level of healthcare |
| 1. | Blood sampling (micro sampling) | Obtaining capillary blood samples (micro sampling) for determination of biochemical and hematological parameters using a closed blood sampling system | primary, secondary, tertiary |
| 2. | Blood sampling (venipuncture) | Obtaining full blood samples (venipuncture) for determination of laboratory parameters using a closed blood sampling system | primary, secondary, tertiary |

Table IV Nomenclature of Laboratory Medicine tests in Serbia (specific laboratory tests by separate branches examples).

| B. MEDICAL BIOCHEMISTRY LABORATORY TESTS | | | |
|--|---|---|------------------------------|
| Nr. | Name of service | Description of service | Level of healthcare |
| 1. | Acetoacetic acid in blood | Spectrophotometric determination of acetoacetic acid in blood by a UV-kinetic (3-HBDH) method | tertiary |
| 2. | Acid-base status (pH, pO ₂ , pCO ₂) of blood | Assessment of acid-base status (pH, pO ₂ , pCO ₂) of blood by ion-selective electrode (ISE) on an automated analyzer | secondary, tertiary |
| 3. | Adenosine diphosphate (ADP) in blood | Spectrophotometric determination of adenosine diphosphate (ADP) in blood by a UV-kinetic (pyruvate kinase) method | secondary, tertiary |
| 4. | Adenosine monophosphate (AMP) in blood | Spectrophotometric determination of adenosine monophosphate (AMP) in blood by a UV-kinetic (pyruvate kinase) method | tertiary |
| 5. | Alanine aminotransferase (ALT) in blood – POCT method | Spectrophotometric determination of alanine aminotransferase activity (ALT) in blood – »point of care« (POCT) IFCC method | primary, secondary, tertiary |

description of service are listed. The same is for all biochemical tests in blood, like presented in *Table IV*, serum, plasma, and all other types of samples, as well as for all other tests covered with the term laboratory medicine. The POCTs are also distinguished.

Education in Medical Biochemistry

Considering the education in medical biochemistry, in Serbia, organized university education in Medical Biochemistry dates from the year 1945 when the Institute of Medical Biochemistry was founded at the Faculty of Pharmacy, University of Belgrade. In the year 1955, additional three years healthcare specialization in Medical Biochemistry was introduced. Then, in 1987, a separate four-year Medical Biochemistry study program was introduced, and in 1991, it evolved

in a five-year study program in Medical Biochemistry. In 2006/2007, the five-year study program was adjusted to meet the principles of the Bologna Declaration (12–17).

Medical Biochemistry study program at the Faculty of Pharmacy is an integrated academic course lasting five academic years, i.e. 10 semesters. It brings 300 ECTS (European Credit Transfer System) credits and ends with writing a thesis and its oral defense. Upon graduation, the title Master of Pharmacy – Medical Biochemist is obtained. The program has been developed so as to train students to provide healthcare services in medical biochemistry laboratories, toxicology and sanitary laboratories. Creative work and research in medical biochemistry requires broad formal training in basic natural sciences and medicine and extensive laboratory experi-

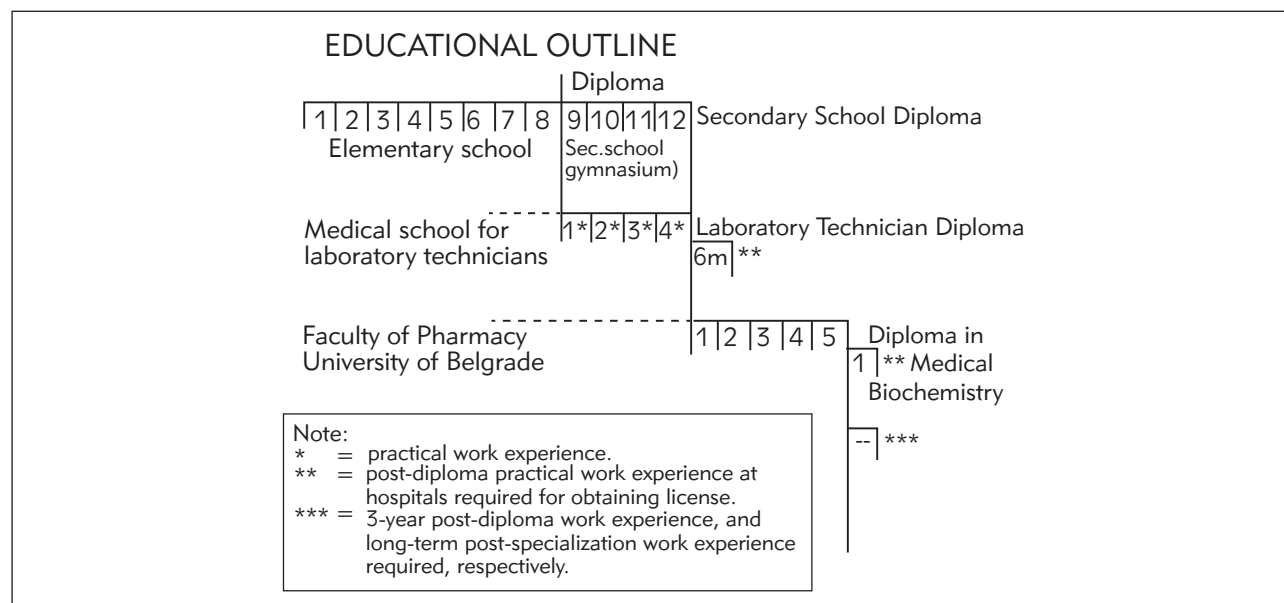


Figure 1 Education outline in Medical Biochemistry.

Table VI Medical biochemists in Serbia in comparison to EC4 Register Standard.

| Equivalence of standards – Serbia | |
|---|---|
| EC4 Register Standard | Equivalent National Standard SERBIA |
| University degree | University degree: <ul style="list-style-type: none"> • Pharmacy-Medical Biochemistry: 5 years • Medicine: 6 years |
| Minimum of 9 years undergraduate and postgraduate study | Minimum of 10 years undergraduate and postgraduate study |
| Minimum of 4 years specialist training in an approved laboratory including Training: multidisciplinary or in a single discipline | <ul style="list-style-type: none"> • 1 year common training in clinical chemistry and haematology laboratory with state examination • 4 years specialist training in an approved clinical chemistry, haematology and microbiology laboratories according to the European Syllabus. After the training students have to pass an state examination. |

ence. During the course of these 10 semesters studies Pharmacy-Medical Biochemistry, medical biochemist develop skills for laboratory work in three branches: medical biochemistry, toxicology, sanitary chemistry, use of laboratory methods and equipment, quality control of all working processes, patients and laboratory staff safety, etc. (15).

In the course of education, a student is expected to acquire **knowledge** on: human organism, disease, role of biochemical laboratory in diagnostics and health care system. In the course of the study, a student is expected to acquire abilities and **skills** for: laboratory work, quality control that assures continuous process of checking and assessment measuring values to obtain reliable result and medicinally relevant information, handling with instruments and

equipments, protection of laboratory staff and safe handling with chemicals and biological materials as well as pharmaceutical/medicinal waste.

Postgraduate education in Medical Biochemistry can be achieved through specialist program and doctoral academic studies. A 3-year specialist program in medical biochemistry existed from 1953 until 2006. After coordination with the European legislation and EC4 European Syllabus for Postgraduate Training in Clinical Chemistry and Laboratory Medicine, a four-year Medical Biochemistry Specialist program was prepared. The Faculty of Pharmacy in Belgrade organizes the specialization studies in the health care area in accordance with the Health Protection Act of the Republic of Serbia. However, in order to enroll in this course one should get the approval of Serbian

Ministry of Health, on the basis of the request from the director of the organization in which applicant medical biochemists works, and according the *Rules and regulations: on the health care specialization studies* (www.pharmacy.bg.ac.rs).

Additionally, for Medical Biochemistry Specialists, three one year sub-specializations programs are available in Clinical Enzymology, Laboratory Endocrinology, and Clinical Immunochemistry. They all end with writing a thesis and its oral defense. Besides the education at the Faculty of Pharmacy, in medical biochemistry laboratories work medical doctors with the specialization in Clinical Biochemistry. These specialization studies at the Faculty of Medicine last for three years, after which the professional title of Specialist in Clinical Biochemistry is obtained. Although the syllabuses of specializations in medical biochemistry at the Faculty of Pharmacy and in clinical biochemistry at the Faculty of Medicine are not equivalent, these two specialists are equal according to the Healthcare Law. Either education of medical biochemists/clinical biochemists of Serbia is equivalent with EC4 Register Standard (18).

The Faculty of Pharmacy in Belgrade organizes the doctoral academic studies (PhD). Medical Biochemistry is one of the doctoral studies moduls. These studies last for three years, i.e. six semesters with total of 180 ECTS credits. A student who completes the PhD academic studies acquires the scientific title Doctor of Medical Science – Pharmacy (Doctor of Pharmaceutical Science). The purpose of this study programme is to allow the students who have met the necessary requirements and who show affinities both toward scientific reasearch and systematic understanding of particular areas of medical biochemistry to master skills and methods of reasearch in given areas in order to be competent for future individual reasearch work. The purpose of this programme is to create new scientific-research oriented young generations of reasearchers who would reach new boundaries within their specific areas of interest during their professional careere, improve reasearch and teaching methods and become competent mentors to students of undergraduate, graduate and PhD studies (11, 16, 17).

Conditions for professional practice in Medical Biochemistry

On seven million residents of Serbia, we have 261 state laboratories, and 193 private laboratories registered at the Chamber of Biochemists of Serbia. In these laboratories work 295 Masters of Pharmacy-Medical Biochemists, 227 Medical Biochemistry Specialists (graduated at the Faculty of Pharmacy), and 276 Clinical Biochemistry Specialists, which are Doctors of Medicine. In total, there are 798 biochemists of either specialization. Also, there are around 150 Scientists (chemists, biologists, etc.) who

are unlicensed, 37 Masters of Science, 47 PhDs, and 48 Primaries.

Medical Biochemists and Medical Biochemistry as a profession in Serbia are part of the healthcare system whose position is regulated by Healthcare Law of the Republic of Serbia, Law on Chambers of health workers, and Guidelines of the Ministry of Health and the Chamber of Biochemists of Serbia. Medical biochemistry laboratories are an integral part of healthcare facilities of appropriate level organized depending on the level of healthcare (primary, secondary, tertiary) and according to the Guidelines for Providing Healthcare and Guidelines on Conditions for Providing Healthcare. According to the number and complexity of the tests performed as well as to the qualifications of the laboratory personnel in the medical biochemistry laboratories may be: General (in a primary healthcare setting), Specialized (in a general hospital), Subspecial (in a specialized hospital or clinical hospital center), and Clinical (in an University clinical center). Clinical medical biochemistry laboratories as parts of the University hospitals are a teaching units for undergraduate and postgraduate education of medical biochemists. Private laboratories are either general or special laboratories. All medical biochemistry laboratories and the list of tests performed are licenced through the Ministry of Health. Nomenclature of services defines the level of performance in the field of Medical Biochemistry (5, 12).

According to the Guidelines for Providing Healthcare and Guidelines on Conditions for Providing Healthcare in medical biochemistry laboratory must work at least one medical biochemists on 120.000 analysis performed, and one technician on 20.000 analysis performed per year (5, 6).

There are four requirements for practicing medical biochemistry in the Serbian Healthcare System:

1. University Diploma of the Faculty of Pharmacy (Studies of Medical Biochemistry),
2. Successful completion of the professional exam at the Ministry of Health after completion of one year of residency training (interim) in the medical biochemistry laboratories,
3. Membership in the Chamber of Medical Biochemists of Serbia,
4. Professional Licence for skilled work in healthcare practice issued by the Chamber of Medical Biochemists of Serbia

Chamber of Biochemists of Serbia was founded in 2006 according to the Healthcare Law. The law states that licenses should be renewed every 7 years, based on successful completion of Continuous Medical Education (CME) (*The Rules of Continuing Education of Medical Biochemists issued by the Chamber of Medical Biochemists* (www.komorabiohemsrbije.org.rs)). These programs may be offered by



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JOURNAL OF MEDICAL BIOCHEMISTRY

Published by The Society of Medical Biochemists of Serbia Belgrade

J Med Biochem Vol. 36 - No 1 - 2017

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Figure 2 Cover page of the Society Medical Biochemits website (www.dmbj.org.rs)

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Figure 3 Cover page of the Society Medical Biochemists website (www.dmbj.org.rs)

University Faculties (Pharmacy, Medicine), professional associations (Societies), individuals, etc. (19).

Very important role in Continuous Medical Education has the Society of Medical Biochemists of Serbia that offers different programs of CME. The Society of Medical Biochemists of Serbia (www.dmbj.org.rs) was established in 1955, and since its institution until these days, the Society has accomplished significant activities in the field of education of medical biochemists through the organization of congresses (biannually), Days of Biochemistry (annual), Innovations in laboratory medicine (annual), Congresses of Balkan Clinical Laboratory Federation, Scientific Conference »Professor Ivan Berkes« (annual), EFCC Symposium for Balkan Region, Educational seminars, etc. The Society has significant publishing activity through Journal of Medical Biochemistry (www.dmbj.org.rs) and professional-methodological guidebooks for the field of medical biochemistry.

On Figures 2 and 3 the web page of the Society of Medical Biochemists of Serbia with the cover page of its official journal – Journal of Medical Biochemistry, the member of COPE, EASE, and WAME are presented.

The Society of Medical Biochemists of Serbia gathers medical biochemists in promoting and developing the profession in the provision of healthcare. The tasks of the Society include achieving uniform work standards in medical biochemistry laboratories, providing continuous education for medical biochemists at all academic levels, instigating scientific/research activities, establishing work norms and emphasizing the code of ethics of healthcare workers. The members of the Society have participated in the preparation of series of expert guidelines in the field of Medical Biochemistry that may be delivered to Serbian Ministry of Health in respect of laboratory organization, and all other laboratory standards. Also, the Society is engaged in important publishing activities.

Continues Quality Improvement of Laboratory Service in Serbia

At the national level, all stages of laboratory work will be subjected to standardization by the implementation of a Total Quality Management System (TQM), external and internal control of the quality of work, and good medical laboratory practice which ensures that laboratories will issue accurate and valid results (20). This calls for conducting continuous quality improvement. There are some specific segments important for control of the work of medical biochemistry laboratories related to analytical procedures used.

The activities of the laboratory/laboratory service are clearly defined, from qualified staff, laboratory procedures through appropriate space and equipment, to

LIS, quality and safety. Patient is provided a service by the laboratory/laboratory service provided by adequately qualified staff. There are procedures and guidelines for providing services within the laboratory/laboratory service. Laboratory/laboratory service is organized in an appropriate space. The equipment meets all the requirements for providing services in a laboratory/laboratory service. Information system is in the function of efficient delivery of laboratory services. Laboratory/laboratory service monitors the quality of work and the safety of patients, etc. (21–23).

SNEQAS-Serbian National External Quality Assessment Scheme is the member of the European Organization for External Quality Assurance Programs in Laboratory Medicine (EQALM). It is conducted by the Society of Medical Biochemists of Serbia – Commission for Quality Control and Accreditation via Center for Medical Biochemistry of the Clinical Center of Serbia. It is conducted twice a year, and it is aimed to control biochemical parameters. Around 300 medical biochemistry laboratories are included from the territory of the Republic of Serbia.

The medical laboratories in Serbia are subject of accreditation since 1999. The **Accreditation Body of Serbia** (ATS) as the national accreditation body was founded by the Republic of Serbia and is located in Belgrade. Pursuant to the Law on Accreditation, ATS has a task to assess the competence of conformity assessment bodies (CABs) to perform testing, calibration, inspection, and certification of products, management systems and persons. In the process of accreditation of healthcare institutions that will be conducted by the **Agency for Accreditation of Healthcare Institutions of Serbia**, one of the requirements for accreditation is the assessment of the work of laboratory service, which will be made on the basis of standards and criteria that have been specifically developed to meet the needs of all types of laboratories. In preparation of standards for accreditation of laboratory service in healthcare institutions that will be conducted by the Agency for Accreditation of Healthcare Institutions of Serbia, the members of the Society of Medical Biochemists of Serbia and Chamber of Biochemists of Serbia took very important role. So far, in Serbia, ATS has accredited 25 medical biochemistry laboratories, 12 as competent according to SRPS ISO 15189 and 13 according to SRPS ISO 17025. Agency for Accreditation of Healthcare Institutions accredited 190 medical laboratories as integral parts of their corresponding healthcare institutions.

We may conclude that in Serbia, the term laboratory medicine is practically equal with the medical biochemistry (as the synonym of clinical chemistry/clinical biochemistry). Medical biochemistry laboratories are integral part of healthcare institutions to which they provide laboratory services, and the scope of their performance depends on the level of the

belonging institution. Education of laboratory medicine professionals is equivalent with the EC4 register standards and every aspect of medical biochemistry laboratories performance is regulated by law and accompanying guidelines. In professional development, leading role belongs to the Society of Medical Biochemists of Serbia and Chamber of Biochemists of

Serbia, and continuous quality improvement is ensured through the process of accreditation.

Conflict of interest statement

The authors stated that they have no conflicts of interest regarding the publication of this article.

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Received: January 21, 2016

Accepted: February 23, 2016