

*"Establishment of the Public Agency for Accreditation and Continuous Quality Improvement of Health Care in Serbia" is a joint project of the Ministry of Health of Republic of Serbia and the European Union for whose implementation the EU has secured EUR 1.5 million from the IPA financial instrument for Serbia. The Project has an 18 month duration - 15 June 2009 – 14 April 2011.*

*For more information about project please visit web-site [www.accreditationproject.rs](http://www.accreditationproject.rs)*

*Project team*

### **Foreword from State Secretary Ministry of Health Republic of Serbia**

Quality and safety assurance in health care is at the top of international and European health system agendas. It has been recognised for some time that, in the increasingly fast changing, complex and pressured health care environment, much can and needs to be done to ensure universally high standards of health service quality and safety, which all users of health care systems are entitled to expect. However, quality, safety and effectiveness are not the only issues. International industry and commerce has long recognised the connection between effectiveness and efficiency, the latter being an equally important issue in the difficult health system resource climate. The philosophy of 'getting it right first time' has long been the centrepiece of Total Quality Management, which has dominated industrial and commercial development since the middle of the last century and has more recently been embedded into the principles of evidence-based health care and evidence-based medicine.

The Public Agency for Accreditation of Health Care Institutions in Serbia was established in 2008 to lead the development of a number of related areas of health care con-



tinuous quality and safety improvement and is a 'youthful' addition to the long established health sector in Serbia. Its proposed role and functions lie at the heart of Serbia's own efforts and commitment to keep pace with best European practice in assuring quality and safety, in both the private and public health care sectors. Major performance management systems such as accreditation and certification, the core business areas of the Agency, are increasingly common features of European health systems, representing rigorous systemic

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Establishment of the Public Agency for Accreditation and Continuous Quality Improvement of Health Care in Serbia  
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and systematic efforts to ensure that all citizens, wherever they live in Europe in general or Serbia in particular can be confident that primary care centres, hospitals, pharmacies laboratories etc. and their staff are offering and providing evidence-based diagnosis and treatment in a way that conforms to what are considered best practice standards.

This project, “Establishment of the Public Agency for Accreditation and Continuous Quality Improvement of Health Care in Serbia” is an EU-funded (1.5 M EUR) was designed to assist and support the Agency in the early stages of its development. It formed part of the European Union’s assistance to healthcare in Serbia. Through project activities, which are described in detail in this booklet, the Agency and its staff have been well supported in the development of its role and functions by experienced experts from across Europe and North America, who have been able to bring experience and models of best practice from across the international health care arena, and have joined with the Agency and the Ministry of Health in evaluating international developments in the context of the particular needs of the Serbian health care system. The project has also provided recognised international and European expertise and practical experience, which has assisted and supported the Agency in designing key systems and processes for Serbia. This experience and insight has enabled the Agency to learn, not only from good practice, but also to try to avoid developmental and implementation mistakes made in other countries, which are further down the road in system development. Specific support has been provided by the Project in key areas of legislation and governance development, accreditation system development, standard setting, indicator development, quality strategy improvement, safety strategy development, Health technology Assessment capacity building, clinical practice development and many other aspects of activity. All support received from the Consortium, its team leader and the team of experts has been highly appreciated and highly valued and has contributed to significant progress being made over the past two years, towards Serbia’s wish and clear intention to incorporate systematic quality and safety performance monitoring and management into its health care system.

My own and the Agency’s deep thanks are expressed here for the support provided over the past two years which has proved invaluable in setting down strong foundations for a continuous quality and safety assurance and improvement system and process, to compare with the best in Europe. Much still needs to be done by the Agency, but the foundations laid with the Project’s support should serve the people of Serbia well in the difficult years ahead.

*Dr. Nevena Karanovic, PhD  
State Secretary  
Ministry of Health Republic of Serbia*

### Foreword from Director of the Agency for Accreditation of Healthcare Institutions

Agency for Accreditation of Health Care Institutions in Serbia was founded in October 2008 to perform professional, regulatory and development activities in the process of accreditation of health care institutions. It started its operations in July 2009, aiming to fulfill its designated duties that include establishment of health care accreditation standards, evaluation of quality of health care provided to general population, decision making in health care accreditation management issues, awarding accreditation status and issuing public accreditation certificates, and keeping records of accreditation certificates issued.



Funds for the establishment of the Agency for Accreditation were provided from the Budget of the Republic of Serbia. Project “Establishment of the Agency for Accreditation and Continuous Quality Improvement of Health Care in Serbia”, funded by the European Union, was launched in July 2009, and in two years of its duration it ensured capacity building of the Agency for Accreditation of Health Care Institution through technical assistance it provided. All throughout the Project duration, Agency staff and External Surveyors were in continuous training.

Establishment of the Accreditation Program is a long and difficult process that demands engagement of large material and human resources. Availability of worldwide renowned international consultants, who led and assisted us to create a credible national program according to international principles and standards, was of the utmost importance for the future of the accreditation of the health care institutions in Serbia and of the Agency itself.

Approach to our common working activities was based on extensive consultations with all project key stakeholders, applying strategic definition of health care quality and patient safety through proposals for revision of Strategy for Continuous Improvement of Health Care Quality and Patient Safety. Through these activities we tried to determine the right place



of the Agency for Accreditation in the overall map of health care institutions who deal with recording and improvement of health care quality.

One of the Project activities was to ensure the viability of the Agency through self-financing, but unfortunately with no results. Agency financing remains one of the most important issues for the Agency to deal with in future.

European integrations and relevance of the activities related to improvement of health care quality and patient safety on that road are integrated into accreditation process. National interest in patient safety area is recognized by the Agency and emphasized through its dedication to activities in this field.

Providing proposals for redefining the Strategy for Continuous Improvement of Health Care Quality and Patient Safety shows best our dedication to improvement of quality of health care services through promotion, development and implementation of Good Clinical Practice Guidelines.

Project activities are described in detail in this booklet. Results of the Project are great and significant for both Serbian Health Care System and Serbian Citizens that are using it. I would like to extend my gratitude to Ms. Annette Katrava and all members of the Project Team for their exquisite cooperation and dedication to their work. I would like to also thank the Ministry of Health, Institute of Public Health of Serbia "Dr Milan Jovanovic Batut", National Expert Committee for Continuous Quality Improvement and Patient Safety, Health Professionals Chambers, Chamber of Healthcare Institutions of Serbia, National Expert Committee for development and implementation of Good Clinical Practice Guidelines, Ministry of Health Projects funded by The World Bank loans, health care institutions that helped us test the accreditation program, namely: General Hospital Uzice, General Hospital Zrenjanin, BelMedic Hospital, Primary Health Care (PHC) Centre Kragujevac, PHC Centre Leskovac, PHC Centre Dr Ristic, Pharmacy Subotica, Pharmacy Farmanea, Laboratory Biomedica and all pilot institutions from other Projects that were engaged in testing of quality indicators that will be included in the accreditation process.

I certainly hope that the Project results will be used in the best possible way and be of use to all stakeholders of health care system in further development and reforming of health care system.

*Director*  
*Dr. Snezana Manic*

### Foreword from Team Leader of the Project

Access to high quality healthcare is a basic right which is increasingly recognized and valued by the European Union and its Institutions. Citizens expect that health systems make every effort to ensure the quality and safety of health care services provided.

In 2005, the Government of Serbia embarked on its own reform programme designed to improve efficiency and quality, contain escalating costs and strengthen the financial sustainability of its health care system. A key reform element was the establishment of a Public Agency for Accreditation of Health Care Institutions in Serbia (Article 214 of the Health Care Law) in October 2008 to support healthcare organizations in improving the quality of care "through the application of a variety of quality tools and approaches and through a range of activities." A key responsibility of the Agency being the design and implementation of a 'best practice' accreditation program to assure the safety and quality of health care services provided by Serbian health care institutions.



This project, "Establishment of the Public Agency for Accreditation and Continuous Quality Improvement of Health Care in Serbia" was an EU-funded (1.5 M EUR) from IPA (Instrument for Pre-Accession Assistance) 2007 program, formed part of the European Union's assistance to healthcare in Serbia. The project's main objective was to support the Agency during the early stages of its development and in the design and testing of an accreditation process, to ensure a safe, equitable, viable and high-performance oriented health care system, with health care providers stimulated to achieve continuously increasing standards of efficiency, effectiveness and quality. Project objectives, were closely linked to Serbian Health Policy, the European Partnership and the SAA requirements. It aimed to respond to the needs of key stakeholders, the Agency, Health Care Institutions (HCI) and Ministry of Health (MoH), and wider target groups, such as the Health Insurance Fund (HIF), Institutes of Public Health (PHI), professional associations, health care providers and, above all, patients.





The project was implemented by a consortium led by EPOS Health Management with NHS NICE, CHKS and HD-ECG as members of the consortium. It lasted for 22 months (June 2009 to April 2011). The team of consultants included 3 long term experts and over 30 short term experts representing Canada, France, Greece, Hungary, Ireland, Italy, New Zealand, Republika Srpska, Serbia, Slovenia, UK, and USA.

Accreditation (and similar systems of external assessment against standards) has been introduced in many countries world-wide, as part of an overall strategy for continuous improvement of healthcare institutions, systems and outcomes with benefits to consumers, regulators, financiers, managers, and other stakeholders. But, the effectiveness, sustainability and affordability of an accreditation programme, depends ultimately on the healthcare environment of the host country, the type of programme selected, and how it is implemented. The rationale for setting up a National agency for healthcare accreditation is to assist health care organizations to improve the quality of their health and health care services and outcomes. The Agency aims to accomplish this through setting standards, measuring performance, providing consultation and education where needed, and ultimately awarding accreditation to those organizations which meet the required standards.

The project has supported the Agency in identifying and introducing quality and patient safety standards in Serbia as part of an accreditation process designed as a blueprint for achieving excellence in everyday clinical and management practice. With the support of the project the Agency has begun to transform traditional approaches into a CQI effort that encourages health care institutions to use accreditation standards as operational tools for routinely assessing and documenting their strengths as well as identifying and correcting their weaknesses, making accreditation the by product of sound management performance and practice.

In reality, health system improvement will be limited, not by the capacity of the Agency to identify institutional compliance with standards, but by the capacity of institutions - and municipalities and the Ministry of Health - to absorb and develop more effective systems for planning, operational management and performance management, and delivering services, which should be visible in a National strategy for continuous quality and safety improvement.

The project team extends its profound thanks to the Director of the Accreditation Agency, Dr. Snezana Manic and her team with whom we have had a great pleasure and privilege to work collaboratively. Also to the Ministry of Health, former Minister Prof. dr. Milosajevic, and Dr. Nevena Karanovic, State Secretary and President the

Project Steering Committee, members of the Project Steering Committee: Dr Snezana Manic - Director of Agency for Accreditation of Health Care Institutions of Serbia; Dr Maja Vuckovic-Krcmar - Project Manager Health and Social Affairs, Delegation of the European Union to the Republic of Serbia; Prim. Dr Tatjana Radosavljevic - Director of Serbian Medical Chamber; Prim. Dr Ilija Tripkovic - President of the Governing Board of Chamber of Health Care Institutions; Prim. Dr Tanja Knezevic - Director of Institute of Public Health of Serbia "Dr Milan Jovanovic Batut"; Ms. Svetlana Vukajlovic former Director of Republic Institute for Health Insurance, and Prof. Snezana Simic and Dr. Vesna Korac, Ministry of Health Quality Commission, for their guidance and support. Thanks are also due to Mr. Sasa Rikanovic, Director Ministry of Health World Bank Project - DILS, SHP-AF and his team for his help in pursuing an integrated approach to overlapping project activities.

This project could not have succeeded without the generous participation of countless professionals who shared their time, knowledge and expertise in project activities. A special thank you to the project team (listed below) which implemented the project with professionalism and dedication to improve the health care system in Serbia. To all of you, I extend my deep appreciation.

Equipped with the results of the project, and their undoubted energy and enthusiasm for progress, we wish the Accreditation Agency great success in supporting health care institutions, and ultimately patients, a safe environment for the delivery of high quality health care services.

*Annette Katrava  
Team Leader/ Health Accreditation Expert*

### Closing conference of the Accreditation project

The closing conference of the Ministry of Health of Republic of Serbia and European Union funded joint project "Establishment of the Public Agency for Accreditation and Continuous Quality Improvement of Healthcare in Serbia" was held on March 18th 2011 at Sava Center in Belgrade.



The conference **“Health care Quality and Accreditation in Southeast Europe”** was organized on the occasion of the presentation of results of the 22 month project, with special emphasis on evaluation of pilot testing of the proposed national accreditation programme and process.



The welcoming speech was given by Doc. Dr. Nevena Karanovic, State Secretary of Serbian Ministry of Health and Mrs. Yolanda San Jose, Head of Operations I, Delegation of the European Union to the Republic of Serbia.

Main speakers at the conference were Dr. Snezana Manic, Director of the Agency of Accreditation of Health care Institutions of Serbia and Mrs. Annette Katrava, Team Leader/Health Accreditation Expert who represented joint accomplishments of the Project and the Agency.



The project and international experts Mr. Brane Dobnikar, Health Legislation Expert and Mr. George Boulton, Health Systems and Policy Expert presented way to create an environment to ensure self-sustainable accreditation in Serbia. The evaluation of pilot sites results, which were included in the project, was given by Mr. Aleksandar Labus, senior professional associate for quality improvement of the Agency. Dr. Gordana Kozlovački, Director of General hospital “Đorđe Joanović” from Zrenjanin presented experiences of testing proposed national accreditation standards. This hospital was the pilot healthcare institution included in the project.

The conference was attended by representatives of Serbian dom zdravlja's, hospitals and other state and private health care institutions.

The international guests at the conference were accreditation experts from Slovenia (Ms. Biserka Simcic), Hungary (Dr. Akos Peter Mayer), Republika Srpska (Dr. Sinisa Stevic) and Italy (Dr. Andrea Gardini). They held presentations about accreditation process in their countries and presented perspective of the future of healthcare quality and accreditation in Southeast Europe.

The project's main purpose was to support the initial activities in development of the Agency for Accreditation of the Health Care Institutions of Serbia (AZUS) so that appropriate institutional, organizational and management arrangements as well as system capacities are in place in order to perform accreditation program in Serbia in a competent and self-sustainable manner. The objectives of Accreditation are improvement of health care quality and patient safety and establishment of trust of health care service users in health care system.



During 22 months total of 67 educational workshops, training sessions and conference events were organized with around 3500 participants. A modern and comprehensive set of regulations was developed / reviewed for the accreditation legal framework to ensure that Serbian accreditation legislation is consistent with the EU legislative framework. The Agency was supported to develop a strategic plan and 3-year business plan including proposed functional and structural developments.

With the support of the project, the proposed national accreditation programme for hospitals and primary health care centres was further enhanced to meet ISQua (International Society for Quality in Healthcare) principles by enhancing existing accreditation standards, and by developing new standards for clinical support services – laboratories, pharmacies and diagnostics imaging – through workgroups of key stakeholders.





9 pilot sites (5 public and 4 private health care institutions – General Hospital in Uzice, General Hospital in Zrenjanin, Dom zdravlja in Leskovac, Dom zdravlja in Kragujevac, Pharmacy in Subotica, General Hospital Bel Medic, Dom zdravlja Dr Ristic, Pharmacy Farmanea, Biochemical laboratory Biomedica) were included in the project and passed through process of assessment and self assessment.

Over 90 external surveyors were trained for standards interpretation, survey process, documentation review, specific or specialized areas (safety, infection control, etc) and report-writing skills. The training programme for external surveyors was jointly developed by the Agency, the Belgrade School of Medicine/School of Public Health and the project. Accreditation, as defined in the Serbian 2005 Healthcare Law, is voluntary and is paid for by a fee payable by the institution. As project result, a decision has been taken in principle to introduce mandatory 'certification' of health care institutions, to operate alongside accreditation, but focused on a more limited range of patient safety indicators.

The Agency, with the support of the project, has designed a Patient Safety Strategy incorporating action in five specific patient safety areas: hand hygiene, safe surgical practices,

safe medication practice, patient identification and minimizing adverse events. Safety of the patients is one of the basic objectives of the National Strategy for continuous quality improvement and patients' safety, adopted in 2009.



At the end of the conference, Dr. Snezana Manic and Ms. Annette Katrava delivered certificates of participation to representatives of the pilot sites for national accreditation standards developed during project activities.



### Healthcare Quality and Accreditation in South East Europe Workshop

The workshop “Healthcare quality and accreditation in South East Europe” was organized by the EU funded Project „Establishment of the Public Agency for Accreditation and Continuous Quality Improvement of Health Care in Serbia“ and Ministry of Health World Bank project “Delivery of Improved Local Services” – DILS, held in Belgrade on March 16th, 2011.

The workshop was organized with the main objective to analyze current situation in Serbia in quality improvement and accreditation, to provide feedback regarding evaluation of pilot sites and to provide regional know-how on lessons learnt and future directions for Serbia’s national accreditation programme and process.



Welcoming speech was held by Doc. Dr. Nevena Karanovic, State Secretary Ministry of Health. Ms. Annette Katrava, Team Leader of the Project and Health Accreditation Expert and Mr. Sasa Rikanovic, Director MoH WB Projects DILS/SHPAF who in introduction speech stressed importance of the accreditation process in Serbia and welcomed regional experts to share their experience in the accreditation process. Dr. Snezana Manic, Director of AZUS presented current situation of healthcare quality and accreditation in Serbia stressing the role of the Agency in future. Dr. Dragana Atanasijevic, Coordinator for Quality Component, MoH DILS/SHPAF Projects presented activities in healthcare quality and accreditation in Serbia implemented by the WB Project.

Evaluation of pilot sites results which were included in the project “Establishment of the Public Agency for Accreditation and Continuous Quality Improvement of Health Care in Serbia“ was given by Mr. Aleksandar Labus, Senior professional associate for quality improvement AZUS. 9 pilot sites (5 public and 4 private

health care institutions – General Hospital in Uzice, General Hospital in Zrenjanin, Dom zdravlja in Leskovac, Dom zdravlja in Kragujevac, Pharmacy in Subotica, General Hospital Bel Medic, Dom zdravlja Dr Ristic, Pharmacy Farmanea, Biochemical laboratory Biomedica) were included in the project and passed through process of external survey and self assessment.



Regional experts in quality and accreditation from neighboring countries (Ms. Biserka Simcic, Accreditation Programme Evaluator EPOS, Head of Quality and Safety in Health Care Division, Ministry of Health Republic of Slovenia, Dr. Akos Peter Mayer, Accreditation Programme Evaluator EPOS, Project Director Institute of Healthcare Quality Improvement and Hospital Engineering, Hungary, Dr. Sinisa Stevic, Accreditation Programme Evaluator EPOS, Director of Agency for Accreditation and Healthcare Quality Improvement in Republika Srpska, BiH, Dr. Andrea Gardini, Accreditation Programme Evaluator EPOS, Medical Director, Ferrara City and University Hospital, Founding member ISQua, Chairman, Italian Society for Quality in Health Care, Italy, Dr. Renato Mittermayer, Director of the Agency for Quality and Accreditation in Health Care, Croatia and Prof. Dr Isuf Kalo, Director of the Agency for Quality and Accreditation in Health Care, Albania) presented their experiences in accreditation process in their countries.

Participants at the workshop concluded that establishment of the **Regional Network for Quality and Accreditation in SEE** will be good way to exchange experiences and results in the region. Also, this will improve cooperation between them and could improve accreditation in the countries where accreditation is still in the process taking into account the fact that a lot of issues regarding accreditation process in the region are common for all the countries.





## Evaluation of Pilot Sites Accreditation Survey Results Workshops

The Evaluation of Pilot Sites Accreditation Survey Results Workshops were organized by the project and held in Project premises in Belgrade on February 17th and 25th, 2011. Purpose of the workshops was to revised, analyzed and evaluated the results of pilot testing.



The introductory speech was given by Annette Katrava, Team Leader of the Project and Health Accreditation Expert. She greeted representatives of 9 pilot sites from public and private sector who participated in the pilot testing of accreditation standards and thanked them for their effort on behalf of Project. She reminded everyone that the results of “accreditation award” are part of the testing of the accreditation standards and process. The pilot sites, as well as other health care institutions will need to apply to the Agency and go through “real” accreditation once the standards have been approved by the Serbian government.

Miroslav Obrovacki, Training Programme Coordinator, EPOS presented the statistical analyses of results of pilot testing and explained the concept of assessing and surveying and their linkage in view of their variation and similarities between different health care institutions. He also emphasised that the data base increases throughout the process, eventually resulting in a compiled final report and will be used as a basis for a continuous quality improvement plan of the institution.

Aleksandar Labus, Senior professional associate for quality improvement, AZUS presented the analyses of compiled evaluation forms filled by participants in ac-

creditation process i.e. self-assessment teams and external survey teams. The evaluation forms comprised of teams assessing each other and themselves.

Dr. Snezana Manic, Director of AZUS informed participants that for the first time private health institutions have been a part of pilot testing with respect to existing differences between these two sectors and their specificities. In addition, she encouraged participating institutions to provide all comments and remarks in written form in order for the Agency to be able to analyse the executed proceeding and improve further process.

Mr. George Boulton, health system and policy expert, stressed that this was just the beginning of accreditation process in Serbia and that the Agency and overall knowledge will grow together with the data base increasing hence developing the implementation mechanisms. He emphasized that accreditation a part of bigger process of changing health culture. He further stressed that accreditation should be turned into a learning process as an integral part of continuous quality improvement.



Representatives of participating institutions agreed that the accreditation has enabled them to focus on what is good, what is not good and what requires improvement in their institutions and are very thankful for all the support and advice provided by the Agency and external surveyors.

Participants have stressed that they had an excellent cooperation within their teams as well as with representatives of health care institutions and expressed great pleasure for being given such an opportunity. In addition, they exchanged their experience and stressed that it will be of great importance and very useful for their future even more successful work.





Dr. Snezana Manic stressed in final conclusion that the trend in Europe is that all countries will in future be obliged to have some form of mandatory accreditation or basic certification and that our legislation will be altered and amended accordingly. She thanked the external surveyors for their efforts and achieved success, noting that their work was actually the most successful part of the pilot testing. Dr. Manic reviewed the specificities of

private sector and how the differences between this and public sector were taken into account. She stressed that it is necessary to reach agreement and to adopt common attitude on how the surveyors will behave in certain situations.

A result of these evaluations will be an updated/revised Self-Assessment Guidebook for Surveyors.



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**EPOS**  
Health Management

**ASST**  
Assessment of Health and Clinical Standards

**CHKS**

**CHKS**



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Agency for Accreditation of Health  
Care Institutions of Serbia

  
Republic of Serbia  
MINISTRY OF HEALTH