

**Standard Summary Project Fiche – IPA centralised programmes**  
(Regional / Horizontal programmes ; centralised National programmes)

**1. Basic information**

**1.1 CRIS Number: 2007/19322**

**1.2 Title: Support to the Health Care Accreditation Agency**

**1.3 ELARG Statistical code: 02.28**

**1.4 Location: Serbia**

**Implementing arrangements:**

**1.5 Contracting Authority (EC) EC**

**1.6 Implementing Agency: N/A**

**1.7 Beneficiary (including details of project manager): Ministry of Health**

**Financing:**

**1.8 Overall cost: 1.5 million €**

**1.9 EU contribution: 1.5 million €**

**1.10 Final date for contracting: 3 years after the signature of the Financing Agreement**

**1.11 Final date for execution of contracts: 5 years after the signature of the Financing Agreement**

**1.12 Final date for disbursements: 6 years after the signature of the Financing Agreement**

**2. Overall Objective and Project Purpose**

**2.1 Overall Objective:**

Improve health care in Serbia by internalising continuous quality improvement and service delivery with in the overall system

**2.2 Project purpose:**

- Continuous improvement of the quality of health service delivery in the Serbian health sector
- Capacity building support to the Public Agency for Accreditation and promotion of balanced internal (professional/institutional) driven quality improvement processes through external assessment mechanisms

**2.3 Link with AP/NPAA/EP/SAA**

For the European Partnership, the reform of the health system is a key objective in terms of improved service provision and public administration reform (public finances).

Under the Thessaloniki Agenda reform of the health care system finances was highlighted as an important factor in addressing the sustainability of public finances and helping to reduce government debt ratios.

Access to high quality healthcare is a key human right recognized and valued by the European Union, its Institutions and the citizens of Europe. Accordingly, patients have a right to expect

that every effort is made to ensure their safety as users of all health services”<sup>1</sup>.

Under **Article 77 of the SAA** (Standardization, metrology, accreditation and conformity assessment) Serbia should take the necessary measures in order to gradually achieve conformity with Community technical regulations and European standardisation, metrology, accreditation and conformity assessment procedures.

## **2.4 Link with MIPD**

Administrative and operational capacities improved and improved quality and efficiency of services which are providing in health care system, especially in conditions of limited resources. Preventive health services improved. Curriculum of the Schools of Medicine to promote mutual recognition of health professional qualifications adopted. Existing legislation (i.e. laws on health protection, health insurance and various chambers) revised. (page 20).

## **2.5 Link with National Development Plan (where applicable)**

N/A

## **2.6 Link with national/ sectoral investment plans (where applicable)**

N/A

# **3. Description of project**

## **3.1 Background and justification:**

In April 2004, the Ministry of Health of the Republic of Serbia launched the process of establishing the mechanisms for Quality improvement, by producing the document “Explanatory Note on Monitoring the Quality of Performance in Health Institutions”.

In the first half of the 2005, the joint IPH, Ministry of Health, and Health Insurance Fund teams collected and analyzed quality indicators, waiting lists and patients’ satisfaction biannual data. Preliminary results of this research indicated the lack of adequate data and clear and defined methodology for quality indicators and waiting lists. This document launched the process of establishing and promoting the culture of quality improvement in the Serbian health care system

Safeguarding the quality of health care services delivery is an essential regulating element required for the efficient and effective functioning of the sector. During the last ten years there has been a rapid growth in accreditation programs. Accreditation has developed as an effective framework for continuous quality improvement in health institutions, with significant benefits to patients, regulators, insurers/payers and other stakeholders. The main benefits are identified by Rooney<sup>2</sup> including:

- Improved quality of care through the establishment of optimal achievement goals in meeting standards for health care organizations; Stimulate and improve the integration and management of health services;

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<sup>1</sup> On April 5, 2005, European Commission adopted the Luxemburg Declaration on Patient Safety – “Patient Safety – Making it Happen”

<sup>2</sup> Rooney AL, Van Ostenberg PR. Licensure, Accreditation and Certification: Approaches to Health. Bethesda: Quality Assurance Project 1999.

- Establishment of comparative databases of health care organizations to meet selected structure, process and outcome standards/criteria;
- Reduction of health care costs by focusing on increased efficiency and effectiveness of services
- Education and consultation to health care organizations, managers and health professionals on quality improvement strategies and 'best practices' in health care;
- Strengthen the publics' confidence in the quality of health care;
- Reduce risks associated with injury and infections for patients and staff.

The Health Policy of Serbia adopted in February 2002 aims at safeguarding and improving the health status of the population and ensuring equal accessibility to health care for all citizens while improving health care for the most vulnerable populations. The vision statement agreed in August 2002, sets out nine guiding principles and strategic directions, A key guiding principle is that "...Quality of services and facilities will be promoted, strengthened, monitored and continuously improved based on a quality assurance and licensing system..."

The Republic of Serbia is developing ambitious plans for improving the quality of health care for the population. The national quality improvement strategy aims to set out a framework for the ways in which the quality of health care services delivered to the population will be improved. It describes the aspirations of the government and sets an international context for these.

In line with the Serbia EU integration Strategy and according to the current EU regulations, health protection and health protection systems are the responsibilities of EU Member States. The member states decide how they will manage their health systems, the amount of funds they will spend on health and health protection of their citizens, which medication they will make available to patients, as well as which health (medical) technologies they will use in the diagnostics and medical treatment.

The accreditation approach is beneficial in achieving change and quality improvements 'on the ground' in healthcare organisations. This has been seen at both a micro level in individual services and departments, such as the development of staff induction programmes, and even affecting the practice of individual clinicians, (e.g. the application of standards for hand-washing in relation to infection control), and organisation-wide, where it has been instrumental in ensuring that programmes of risk management are fully implemented.

In November 2005, the Government of Serbia adopted the new set of health related laws (Health Care Law, Health Professionals Chambers Law, and Health Insurance Law<sup>3</sup>), which underlines the principle of continuous quality improvement as one of the core principles. Also in 2005, the Government embarked on a health sector restructuring plan with the aim of increasing the sector's efficiency (service/cost) and quality.

The legal framework for Government health policy in Serbia is derived from the Constitution and the Health Care and Health Insurance Laws. A revision of these two laws is under preparation. Serbia has recently signed the European Social Chart which includes articles on the right to health protection and prohibitions on any form of discrimination. Furthermore, the

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<sup>3</sup> Official Gazette of the Republic of Serbia, Vol. 107/05, December 2005

adoption of Health Care Law and Health Professionals' Chambers Law in November 2005, laid down the foundation for continuous quality improvement.

After the initiatives launched by the Ministry of Health and according to the new Health Care Law, the department for quality improvement in health care was established in order to implement the activities prescribed by the Ministry of Health.

The Chambers of Health Professionals are expected to be operational by the end of 2007 via the Health Professionals' Chambers Law, adopted in November 2005. Five different chambers are envisaged (physicians, nurses, dentists, pharmacists and biochemists).

The Agency is to be an organization which discharges professional, regulatory, and developmental affairs based on Article 214 of the Health Care Law. It is also to comply with the law regulating public agencies. The *Agency* is to administer a voluntary accreditation program which assesses the quality of health care of Serbian health care institutions.

This project is designed to support the *Public Agency for Accreditation and Continuous Quality Improvement of Health Care in Serbia* to manage the accreditation program, develop the health system performance indicators and funding options for continuous quality improvement in Serbian health sector.

Institutionally the distinction between inspection services and quality accreditation agencies will be clarified. Criteria for measurement of quality standards in health care institutions and of staff performance will be further developed.

Institutions that are involved and have a stake in the field of quality improvement in health sector are: Ministry of Health, Health Insurance Fund (since the financing system is based on inputs in the system, close collaboration is required in order to build consensus of including the quality criteria in contracting with health care institutions in Serbia), Chambers of Health Professionals, Serbian Medical Association (SLD), a voluntary, independent, membership organization which currently has 11,000 subscribers among the 25,000 doctors and dentists in Serbia. Medical faculties - four university faculties manage undergraduate and specialty training, and have begun to develop CME programmes.

### **3.2 Assessment of project impact, catalytic effect, sustainability and cross border impact (where applicable)**

The quality of Serbia's healthcare system has major socio-economic benefits. Health care reform is positioned within the wider Public administration reform framework and the second has been pioneering new developments in terms of service quality/value for money that serve as an example to other branches of the public sector. This project will further develop the culture of health care quality and the role of patients and medical associations in quality assurance will be properly defined. The project will provide a legal framework and education/training packages appropriate for continuous quality improvement of health care. The accreditation process will provide the health sector to better utilise funds from the Health Insurance funds and the Ministry of Finance.

### **3.3 Results and measurable indicators:**

Results and measurable indicators in relation with activity 1

1. The *Public Agency for Accreditation and Continuous Quality Improvement of Health Care in Serbia* is capable of ensuring high quality health care services by efficiently and effectively performing their accreditation activities and moves towards self-sustainability
2. The *Agency* has achieved the full membership in ISQua
3. The necessary legal framework is prepared giving advantage for contracting to the health institutions with accreditations

### **3.4 Activities:**

- Organisational Review with Policy/legislative gap analysis identifying obstacles to the introduction of accreditation standards in the Health System. Recommendations made must be consistent and in accordance with international accreditation standards.
- Capacity building for the *Agency* including HR training, organisation management, communication, health promotion campaigns via the implementation of a marketing plan to reach out to all health care facilities in Serbia; Assessment of ICT support that would support the accreditation and quality improvement processes.
- Instruction and training of surveyors and clinical staff in health care institutions, as well as major stakeholders in the MOH, HIF, IPH etc;
- Introduction of improved legal framework; common standards and clinical guidelines/protocols for accreditation and quality assurance at all levels (primary, secondary and tertiary health care) available to the public; preparation of targets/benchmarking for health care institution accreditation

This project will be implemented through one service contract.
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### **3.5 Conditionality and sequencing:**

- All legislation necessary to create the Public Agency for Accreditation and Continuous Quality Improvement of Health Care in Serbia must be in place
- The Agency has personnel, offices and budget in place
- Full commitment by all stakeholders for training and instruction
- Revision of health laws should be duly taken into account
- Minorities will have full access to all health services

### 3.6 Linked activities

The EU, via the European Agency for Reconstruction (EAR) has been a major driver for quality change in the health care system. EAR projects have supported quality management and the strengthening of public health services in Serbia (through Projects “Strengthening the Public Health in Serbia” and “Support to Preventative Health Services”) as well as supporting the “Development of Health Information Systems for Basic Health and Pharmaceutical Sector in Serbia”.

The process of continuous quality improvement and culture promotion is substantively supported from the proceeds of the **World Bank** (WB) IDA credit that supported the implementation of the *Serbia Health Project* (SHP). Through one of SHP subcomponent, the following activities were supported: (i) the definition of a national strategy on quality improvement as a guiding document for future activities for quality improvement and for future investments in the health sector (during and after the project), (ii) the establishment of a licensing and re-licensing system for health professionals to guarantee basic professional competence and protect the patients from incompetent health professionals, in combination with (iii) a mandatory system for continuous professional development, (iv) activities towards the establishment of an accreditation system for health care institutions, (v) activities to support health care providers (including the pilot hospitals) in developing quality improvement programs to comply with MOH quality benchmarks, including the capacity to formulate indicators and benchmarks for quality of services delivery at the level of the health care providers as well as at the level of departments of hospitals (vi) the development of a basic capacity for health technology assessment (HTA).

Starting September 2006, the **Canadian International Development Agency** (CIDA) will support the implementation of the “PHC Policy Project in Balkans”, where one of the component will be the quality improvement of PHC services in the health care system in Serbia. Project will be implemented by the Canadian Society for International Health and the Queens University from Canada

### 3.7 Lessons learned

Key lessons for this project as identified in the World Bank ‘Toolkit for Accreditation Programmes’<sup>4</sup> which are integrated into the design of this fiche include the following:-

- Failure to get the balance right between focusing on internal development (improvement) and external control (regulation);
- Lack of clarity about the difference between accreditation, licensing and regulation;
- Lack of ownership and involvement of stakeholders; Inappropriate culture, due to a reliance on directives and sanctions, rather than encouraging self improvement;
- Independence of programme from government, lack of clarity about objectives and unrealistic expectations; lack of appropriate relationships between insurers, professional organizations, chambers, medical schools and patient representatives;
- Failure to establish transparent procedures for conducting assessments, failure to recognize the need for sustainable funding; failure to take into account experiences from accreditation programmes in other countries.

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<sup>4</sup> ISQua.Toolkit for Accreditation Programmes. Washington: World Bank, 2003 in press

#### 4. Indicative Budget (amounts in million €)

Activities	TOTAL COST	SOURCES OF FUNDING										
		EU CONTRIBUTION				NATIONAL PUBLIC CONTRIBUTION					PRIVATE	
		Total	% *	IB	INV	Total	% *	Central	Regional	IFIs	Total	% *
Activity 1	1.5	100		1.5								
contract 1.1	1.5	100		1.5								
contract 1.2												
Activity 2												
contract 2.1												
contract 2.2												
.....												
<b>TOTAL</b>	<b>1.5</b>											

\* expressed in % of the Total Cost

#### 5. Indicative Implementation Schedule (periods broken down per quarter)<sup>5</sup>

Contracts	Start of Tendering	Signature of contract	Project Completion
Contract 1.1	T+1Q	T+2Q	T+8Q

All projects should in principle be ready for tendering in the 1<sup>ST</sup> Quarter following the signature of the FA

#### 6. Cross cutting issues (where applicable)

Development Policy Joint Statement by the Council and the European Commission of 10 November 2000 establishes that a number of Cross-cutting Issues shall be mainstreamed into EC development co-operation and assistance.

Cross-cutting issues will be addressed in the project so as to comply with the best EU standards and practice in that area and in a way which demonstrates how they will be dealt with within the project's framework, its activities and outputs.

Cross-cutting issues will be addressed in a proactive manner, and will present a specific component of projects (at all levels of projects' development, starting from the project identification stage). Synergies between the projects and the objectives of will be identified and developed. Also, the projects' objectives and activities need to be screened in order to ensure they won't impact negatively on gender equality, minorities' inclusion and environment.

Finally, the beneficiary will make sure its objectives, policies and interventions have a positive impact on and are in line with the main principles of gender equality, minorities' inclusion and environment.

<sup>5</sup> T equals date of signature of the FA and xQ equals the number (x) of quarters (Q) following T

## **6.1 Equal Opportunity**

During the implementation of the project there will be no discrimination on the grounds of race, sex, sexual orientation, mother tongue, religion, political or other opinion, national or social origin, birth or other status. Equal opportunities for women, men and minorities will be ensured during the implementation of the project. The Serbian laws and regulations concerning the equal opportunities for women, men and minorities will strictly be followed.

The issue of gender equity in the Serbian Health Sector should be located into the broader context of equality policies in the public sector. There is evidence that the debate is generally fragmented and uncoordinated, with progress being dependent mostly on individual enthusiasm rather than organisational commitment.

There are major differences in the patterns of health needs experienced by men and women. The most obvious reflect biological or sex differences. Diseases such as cancer of the cervix or prostate are sex specific but research indicates that there are broader genetic hormonal and metabolic differences between the sexes that have to be taken into consideration in benchmarking quality health care services.

## **6.2 Environment**

Training, as a component of this programme, should take into account the need to raise awareness of importance of healthy environment and environmental hazards.

## **6.3 Minorities**

Minority groups in Serbia (e.g. Roma) have differing health care requirements than mainstream groups in society. The Accreditation Agency has to be sensitive to these issues and determine the quality of health care provision by institutions in also how they reach out to the specific needs of minority communities.

<b>ANNEX I LOGFRAME PLANNING MATRIX FOR Project Fiche</b>		Programme name and number <b>Establishment of the Public Agency for Accreditation and Continuous Quality Improvement of Health Care in Serbia</b>	
		Contracting period expires 5 years after the signature of the Financing Agreement	Disbursement period: expires 6 years after the signature of the Financing Agreement
		Total budget : <b>€1.5M</b>	IPA budget: <b>€1.5M</b>
<b>Overall objective</b>	<b>Objectively verifiable indicators</b>	<b>Sources of Verification</b>	
To improve the health care system in the Republic of Serbia in order to be an equitable, viable and performance oriented system that will enable environment for social, economic and political development	Reduced number of adverse events and accidents reported through the routine reporting system in health institution network (e.g. IPH); improved coverage with health services of vulnerable population groups; Legislation in place that will promote responsible and accountable	Routine data collected through the IPH network, the HIF network and Republican statistical Office of Serbia; Project documents and Reports; Current legislation in Serbia	
<b>Project purpose</b>	<b>Objectively verifiable indicators</b>	<b>Sources of Verification</b>	<b>Assumptions</b>
To have fully operational national accreditation programme for healthcare institutions in Serbia contributing to consumers' safety and satisfaction	Consumer satisfaction with health care services; Quality Indicators as defined by the Ministry of Health;	Consumers' satisfaction surveys routinely done in the health system; IPH network in Serbia; HIF network in Serbia; Republican Statistical Office of Serbia;	Continuing Government commitment and support for cooperation between all stakeholders; Health Insurance Fund of Serbia incorporates accreditation system as one of the contracting criteria
<b>Results</b>	<b>Objectively verifiable indicators</b>	<b>Sources of Verification</b>	<b>Assumptions</b>
1. Establishment of the Public Agency for Accreditation and establishment of balancing internal (professional/ institutionally driven) quality improvement process with external assessment mechanisms 2. Necessary legal framework prepared, supporting general endorsement of accreditation certificates (e.g. contracting advantages) 3. The Agency has achieved the full membership in ISQua	1. Accreditation reports; Developed internal regulation of the Agency; 2. Accreditation certificates are taken into account by the HIF when contracting with healthcare institution; 3. Agency has obtained accreditation certificate from ISQua	Project documents; Legal documents (Official Gazette of the Republic of Serbia); Accreditation Agency documents (Standards, Accreditation Surveys Reports); Health Insurance Fund of Serbia; Analyses and reports on the sustainability of healthcare institution accreditation system (i.e. international consultants); Printed materials and other media products and publications; Published standards	Professional skills and experience of stakeholders at different levels; The legislation necessary to create the Public Agency for Accreditation and Continuous Quality Improvement of Health Care in Serbia is adopted on time; The Agency is organized in a way that meets international (i.e. ISQua criteria).

Activities	Means	Costs (M)	Assumptions
<p>1.1 Further development and testing of the accreditation standards</p> <p>1.2 Inclusion of selected key quality indicators in the accreditation standards</p> <p>1.3 Development and testing of the accreditation survey process (including self-assessment, on-site visit by external evaluators - surveyors, accreditation reports, and awarding of accreditation status)</p> <p>1.4 Training of surveyors and clinical staff in health care institutions</p> <p>1.5 Development of the ICT support that would support the accreditation and quality improvement processes</p> <p>1.6 Provision of international TA to staff of the <i>Agency</i>, surveyors etc.</p> <p>2.1 Support to MoH for creating regulatory framework (development of by-laws)</p> <p>2.2 Capacity building and training for Government staff (MoH, HIF, IPH etc.)</p> <p>2.3 Development of the market for the <i>Agency</i> and communication to the public</p> <p>3.1 Set of accreditation standards for healthcare institutions is developed, accepted and communicated</p> <p>3.2 Continuous accreditation standards' reviews in order to ensure consistency with international accreditation standards</p> <p>3.3 Capacity building that would enable the membership of the <i>Agency</i> in the International Society for Quality in Health Care (ISQua)</p>	<p>One Service Contract of 1.5 MEURO</p>	<p>€1.5M</p>	<p>Voluntary accreditation (Considerable efforts must be expended to market the accreditation program);</p> <p>The <i>Agency</i> is appropriately staffed and staff is trained;</p> <p>Regulatory framework is consistently developed and ensures the sustainability of the <i>Agency</i>.</p>

**ANNEX II: amounts (in M €) Contracted and disbursed by quarter for the project**

<b>Contracted</b>	<b>Q1</b>	<b>Q2</b>	<b>Q3</b>	<b>Q4</b>	<b>Q5</b>	<b>Q6</b>	<b>Q7</b>	<b>Q8</b>	<b>Q9</b>	<b>Q10</b>	<b>Q11</b>
Contract 1.1		1.5									
Contract 1.2											
Contract 1.3											
Contract 1.4											
.....											
<b>Cumulated</b>		<b>1.5</b>									
<b>Disbursed</b>											
Contract 1.1		900,000	100,000	100,000	100,000	100,000	100,000	100,000			
Contract 1.2											
Contract 1.3											
Contract 1.4											
.....											
<b>Cumulated</b>		<b>900,000</b>	<b>1,000,000</b>	<b>1,100,000</b>	<b>1,200,000</b>	<b>1,300,000</b>	<b>1,400,000</b>	<b>1,500,000</b>			

## **ANNEX III**

### **Description of Institutional Framework**

The Ministry of Health is in charge of implementation and monitoring of this project. The work, mandate and authorisations of the Ministry are regulated by the Law on Ministries (adopted on May 15, 2007 (Official Gazette of Republic of Serbia no. 48/07) – i.e. Article 21.

The Ministry consists of the following sectors:

- Sector for organisation of health service
- Sector for health insurance
- Sector for international relations
- Sector for health policy
- Sector for public health

## **ANNEX IV**

### **Reference to laws, regulations and strategic documents:**

#### **Reference list of relevant laws and regulations in the health sector**

##### *General:*

- Constitution of the Republic of Serbia
- Law for the Implementation of the Constitution of the Republic of Serbia
- National Strategy for Serbia and Montenegro's Accession to the European Union
- Action Plan for the Implementation of the European Partnership
- Poverty Reduction Strategy Paper

##### **Laws**

- Law on drugs
- Law on health care
- Law on health insurance
- Law on population protection from infective diseases that have influence on whole country
- Law on food
- Law on water
- Law on health inspection of food
- Law on sanitary inspection

##### **Regulations**

- Regulations on sanitary-hygienic conditions for food production and trade objects
- Regulations on conditions and ways of exceeding rights
- Regulations which enclose with the claim for sanitary agreement
- Regulations on warning signs on forbidding tobacco sale to underage
- Regulations on warning signs for tobacco transport

##### **Decisions**

- Decision on content and scope of health care

## **Reference to AP /NPAA / EP / SAA**

For the European Partnership, the reform of the health system is a key objective in terms of improved service provision and public administration reform (public finances).

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Access to high quality healthcare is a key human right recognized and valued by the European Union, its Institutions and the citizens of Europe. Accordingly, patients have a right to expect that every effort is made to ensure their safety as users of all health services”<sup>6</sup>.

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## **Reference to MIPD**

Administrative and operational capacities improved and improved quality and efficiency of services which are providing in health care system, especially in conditions of limited resources. Preventive health services improved. Curriculum of the Schools of Medicine to promote mutual recognition of health professional qualifications adopted. Existing legislation (i.e. laws on health protection, health insurance and various chambers) revised. (page 20).

## **Reference to National Development Plan**

N/A

## **Reference to national / sectoral investment plans**

N/A

## **ANNEX V**

### **Details per EU funded contract (\*) where applicable:**

- Organisational Review with Policy/legislative gap analysis identifying obstacles to the introduction of accreditation standards in the Health System. Recommendations made must be consistent and in accordance with international accreditation standards.
- Capacity building for the *Agency* including HR training, organisation management, communication, health promotion campaigns via the implementation of a marketing plan to reach out to all health care facilities in Serbia; Assessment of ICT support that would support the accreditation and quality improvement processes.

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<sup>6</sup> On April 5, 2005, European Commission adopted the Luxemburg Declaration on Patient Safety – “Patient Safety – Making it Happen”

- Instruction and training of surveyors and clinical staff in health care institutions, as well as major stakeholders in the MOH, HIF, IPH etc;
- Introduction of improved legal framework; common standards and clinical guidelines/protocols for accreditation and quality assurance at all levels (primary, secondary and tertiary health care) available to the public; preparation of targets/benchmarking for health care institution accreditation