

**Standard Summary Project Fiche – IPA centralised programmes**  
**Project fiche: 14**

**1. Basic information**

**Background:**

**1.1. CRIS Number:** 2010/022-154

**1.2. Title:** Implementation of the European Blood Transfusion System

**1.3. ELARG Statistical code:** 03.19 – Social Policy and Employment

**1.4. Location:** Montenegro

**Implementing arrangements**

**1.5. Contracting Authority**

Delegation of the European Union to Montenegro

**1.6. Implementing agency**

N.A.

**1.7. Beneficiary ( including details of project manager) :**

Ministry of Health

Rimski trg br. 46

20000 Podgorica

Montenegro

Tel: 020/ 242-276      Fax: 020/242-762

Project Manager: Sanja Marković

Email: sanja.markovic@gov.me

Contact person: Nataša Žugić

Email: natasa.zugic@gov.me

Contact person: Gordana Rašović

Email: r.branko@t-com.me

**Costs:**

**1.8. Overall costs:** EUR 3.000.000

**1.9. EU contribution:** EUR 1.800.000

**1.10. Final date for contracting**

Two years from the date of the signature of the Financial Agreement

**1.11. Final date for execution of contracts**

Two years from the final date for contracting

**1.12. Final date for disbursements**

One year from the final date for the execution of contracts

**2. Overall Objective and Project Purpose**

### **2.1. Overall Objective**

A modern system for blood transfusion harmonized with the EU standards in order to make safe blood available for all citizens of Montenegro is set up

### **2.2. Project purpose**

To secure sufficient quantities of safe blood and blood products to meet the needs of all patients, in regular and emergency situations, provided as part of a sustainable and modern blood transfusion programme within the existing health care system in accordance with the EU standards for blood transfusion.

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

This programme is a contribution towards the implementation of the Stabilization and Association Agreement, which obliges Montenegro to undertake necessary measures in order to provide for a gradual harmonization with Community Regulations and European Standards, certificates and procedures for assessing the level of harmonization in the area of, amongst others, transfusion medicine.

The Accession Partnership pays special attention to the process of implementing Directives of the European Parliament and the Council of Europe, including Directives 2002/98 EC, 2004/33, 2005/61, 2005/62, relating to the implementation of quality and safety standards with respect to collection, testing, processing, keeping and distributing human blood and blood components.

The National Plan for Adoption of the Acquis in its article 3.28.2.1 states that the aim of the Safe Blood Strategy is to secure sufficient quantities of safe blood for meeting the needs of its citizens, from its own resources, in line with Directive 32002L0098. Securing (safe) blood assumes a standardized product used in everyday treatment of patients, as well as sufficient quantities of blood reserves for emergencies. On institutional level, the transfusion service will be reorganized and relevant regulations will be passed.

### **2.4. Link with MIPD**

Component 1 of the Multi-annual Indicative Planning Document (MIPD) 2009-2011 relates to the support to transition and strengthening of institutions. Special attention has been paid to the health sector, with a special emphasis on EU standards, i.e. the necessity to implement Directives, accreditation and processes for the certification of relevant systems.

Partially, these Directives have been already introduced into Montenegrin legislation, but mainly as bylaws. Accreditation and certification procedures are at an incipient stage. This project, in accordance with the approach defined by the MIPD, aims at the harmonization of legislation relevant to blood transfusion and securing safe blood, setting up a system that will secure quality standards, setting up an up-to-date integrated information system, as well as the establishment of the National Service for Blood Transfusion (Uniform Service for Blood Transfusion for the entire territory of Montenegro).

### **2.5. Link with National Development Plan**

Montenegro has initiated activities in preparing the Development Strategy for the period 2010-2014, which will serve as a basis for NDP. In the area of blood transfusion relevant legislation will be harmonized with EU regulations and standards, in order to establish quality and safety standards of final products equal to quality and safety standards of products from EU member states, and in order to achieve self-sufficiency in securing safe blood and blood products. The purpose of this project is therefore fully compliant to the strategic development planning of the Government of Montenegro.

## **2.6. Link with national/ sector investments plan**

The project is directly connected with the following key documents and action plans:

- Safe Blood Strategy; adopted by the Government of Montenegro
- Programme of voluntary blood donations
- Technical assistance for supporting the Montenegro National Service for Blood Transfusion

## **3. Description of project**

### **3.1. Background and justification**

EU membership is recognized as the most significant aim leading to future safety and prosperity of Montenegro. One of the most important processes that must be completed by Montenegro during the pre-accession and accession period is meeting the EU recommendations for introducing EU standards and directives. This affects also the blood transfusion system in Montenegro.

Transfusion always had its special place within the healthcare system. Because of the nature of medicines produced from human blood, upon which the safety of transfusion treatment greatly depends, the EU has passed recommendations which are not only seen as the professional requirements, but also as a moral and ethical imperative. Therefore, because of its importance and recent developments in this area, the WHO and EU, through their relevant bodies, pay special attention to safety and quality of blood transfusion.

Apart from the necessity to reduce the risks of blood transfusion to a minimum, this area is permanently facing new challenges and risks. Therefore, it is necessary to introduce a quality control system which allows for an ongoing production in accordance with internationally adopted standards, reduces the risks from errors to a minimum and sets up modern technical, organizational and management standards. Furthermore, quality improvement, increased safety of patients, improved quality of services and cost reduction are obligations to be fulfilled in the process of EU integration. Setting up and implementing a quality control and management system in the Montenegro health system is one of the milestones of the entire healthcare system, with blood transfusion being a priority area.

The main beneficiary of the project is the Ministry of Health, while the second beneficiary is the Montenegro Institute for Blood Transfusion.

Collecting, testing, processing, keeping, issuing, controlling quality and usage of blood and blood components is carried out by the Montenegro Institute for Blood Transfusion, which is located in Podgorica. The Institute undertakes its activities through its organizational units in seven general hospitals and one special hospital throughout the country. Professional staff of the Institute, including staff in its organizational units, consists of 12 doctors – specialists in transfusion medicine and 3 doctors on specialization, 32 technicians - transfusologists and 16 general medical technicians and laboratory technicians. The Institute for Blood Transfusion is situated on the first floor, in a 350m<sup>2</sup> facility which was not constructed for that purpose and is not in accordance with international basic safety, security, hygiene and sterility standards. The facilities of the Institute used for accommodating blood donors are situated on the same floor. They are too small to meet up to date requirements, are inappropriately furnished, with old furniture that does not allow for adequate hygienic maintenance. There is no information and no adequate documentation system, no quality system and management. Documentation is kept manually in paper files. Operational procedures vary and do not comply with standards

in all transfusion units. Equipment is inadequate, mostly outdated, and a reliable control of temperatures in the refrigerators and freezers is impossible.

In addition, in 2008 the percentage of blood donors in Montenegro amounted to only 2.28% of the population.

### **3.2. Assessment of project impact, catalytic effect, sustainability and cross border impact**

Project realization will achieve several impacts, such as:

- Contribute to establishing a sustainable and responsive blood service, able to ensure sufficient coverage of needs and improved quality of care
- Increase responsibility of the health authorities with respect to blood transfusion with a special focus on integration of the blood service with the various levels of care (first, second and tertiary levels of care)
- Reduction of blood transfusion related risks, through various mechanisms including its rational use at clinical level, towards strengthened patient safety
- Standardized protection of donors and recipients' health with respect to blood transfusion.

All the abovementioned should have a catalyst effect to a more efficient and financially sustainable treatment of patients using blood components and medicines prepared from blood. Simultaneously, modern transfusion treatment requires the introduction of new therapeutic procedures.

In addition, legal harmonization and the implementation of a modern blood transfusion service in line with the acquis and up to date quality control will enable the Institute for Blood Transfusion to exchange blood products with blood transfusion services of EU member states. .

### **3.3.Results and measurable indicators**

#### Component 1: Legal and organizational framework

##### Result 1

Legal and regulatory framework harmonized with EU requirements and WHO recommendations

##### Measurable indicator for Result 1:

- All legislation relevant for the functioning of the blood services developed/revised, harmonized with the acquis and submitted for adoption to the Parliament

##### Result 2

System of voluntary non-remunerated blood donation extended

##### Measurable indicators for Result 2:

- 3% of the total population are blood donors by end of project
- at least 50% of the total blood supply provided by voluntary blood donors by end of project (against status of 2008: 30% voluntary unpaid + 70% replacement donations)

##### Result 3

Quality control system established and initiated

#### Measurable indicator for Result 3:

- 100% of the Standard Operational Procedures (SOP) developed and implemented in the daily routine of the transfusion service

#### Component 2: Capacity building

##### Result 4

Staff involved in the blood transfusion service adequately trained according to assessed needs

#### Measurable indicators for Result 4:

- 100% of all staff involved in the blood transfusion service successfully (as per certificate) trained
- all staff trained under this project signed a commitment to stay within the Montenegro National Service for Blood Transfusion for a minimum period

#### Component 3: Physical infrastructure

##### Result 5

Facilities of the Institute for Blood Transfusion constructed according to legal, work process and transfusion requirements

#### Measurable indicators for result 5:

- Permit for use of construction of Institute for Blood Transfusion issued
- Certification/accreditation agency gives a positive opinion on meeting requirements with respect to work process, allowing for certification procedure to begin

##### Result 6

Laboratory equipment for Institute for Blood Transfusion purchased and installed

#### Measurable indicator for result 6:

- All equipment purchased fully functional 9 months after project start.

##### Result 7

Equipment for national information system network for blood transfusion service procured, installed and IS established

#### Measurable indicator for result 7:

- National information system for blood transfusion service established and functional twelve months after project start.

### **3.4 Activities**

#### Component 1: Legal and organizational framework

##### Activities related to Result 1

- 1.1 Assessing the existing situation with respect to legislation related to blood transfusion and its approximation to EU regulations
- 1.2 Harmonization of Montenegrin legislation and bylaws with EU legislation
- 1.3 Preparation of four bye-laws related to blood transfusion and required by law

#### Activities related to Result 2

- 2.1 Setting up a network of organizations of professionals and volunteers for the promotion of voluntary blood donations
- 2.2 Establish a registration system for voluntary blood donors and family donors
- 2.3 Raising public awareness on significance of voluntary blood donations by flyers, and in radio, TV, newspapers
- 2.4 Raising awareness and providing information through a liaison person to the public
- 2.5 Develop/update existing curricula, manuals and documents for the education of elementary students on blood transfusion
- 2.6 Educating elementary and secondary school students on blood transfusion (elementary school student within the curriculum for "Healthy Living")
- 2.7 Information, recruitment and retaining of blood donors by providing adequate, exhaustive information and assistance

#### Activities related to Result 3

- 3.1 Setting up and initiating quality management in the entire chain of blood transfusion, in accordance to EU standards
- 3.2 Develop and introduce a questionnaire for blood donors
- 3.3 Develop criteria and the system for the selection of blood donors
- 3.4 Setting up a quality management for the processing of blood and blood components
- 3.5 Develop and implement Standard Operational Procedures (SOP)
- 3.6 Initiate the accreditation of the Institute and the certification of procedures

#### Component 2: Capacity building

##### Activities related to Result 4

- 4.1 Training needs assessment for all staff
- 4.2 Development of individual training plans
- 4.3 Training of medical staff of all levels, specialists in blood transfusion, medical and laboratory technicians, technicians involved in blood transfusion services
- 4.4 Management training (administration, finance, personnel, quality management and control, etc.) for staff involved in administration, finance, personnel, quality management and control, and for management
- 4.5 Training of staff responsible for the maintenance of equipment
- 4.6 Training of PR liaison person

#### Component 3: Physical infrastructure

##### Activities related to Result 5

- 5.1 Preparation of building plans and legal approval for the construction of the facilities for the Institute for Blood Transfusion according to legal and transfusion requirements
- 5.2 Construction of facilities for the Institute for Blood Transfusion

##### Activities related to Result 6

- 6.1. Needs assessment of furniture and technical equipment
- 6.2 Development of technical specifications for tender
- 6.3 Procurement of equipment required
- 6.4 Installation of equipment
- 6.5 Training of staff in using the equipment

### Activities related to Result 7

- 7.1 Needs assessment (hard- and software)
- 7.2 Development of technical specification for tendering (software and hardware)
- 7.3 Procurement of IT equipment (hard- and software) required
- 7.4 Installation of hard- and software
- 7.5 Setting up a national information system on blood donors and medical/technical issues related to blood transfusion
- 7.6 Training of staff in use, management and maintenance of national information system, including data protection, and allowing continuous internal and external monitoring
- 7.7 Piloting national information system

### **3.5. Conditionality and sequencing**

The Project encompasses the following conditions:

- the beneficiary appoints personnel and provides work space and equipment before the beginning of the process of announcing the tender
- consent of key persons who will be engaged on the basis of individual agreements upon the vacancy competition
- in accordance with the project work plan appropriately qualified staff is appointed, which will be engaged as members of working groups in relevant activities and in the work of the Committee for management and coordination
- the Beneficiary will appoint qualified staff which will assist in education activities in line with the project work plan.

### **3.6. Linked activities**

The Ministry of Health has recognized the essence and importance of this branch of medicine, and made the decision to consider blood as a drug for treatment of its population, as an issue of national interest.

Therefore, the Commission for blood transfusion has been established in the year 2003, as an expert and advisory body within the MoH (article 15 of the law of state management – Official Gazette Republic MN no. 38/2003). This Committee represents a multidisciplinary body compounded by all responsible persons involved in this process, with the main task to systematically approach the creation and implementation of this programme. The Committee consists of representatives of the Ministry of Health, the Health Insurance Fund, the Montenegro Red Cross, the Ministry of Education and Science, medical doctors specialized in transfusion, clinical doctors who are using blood and a representative from voluntary blood donors.

In parallel, a working group has been established with the task to draft the new law for the supply of blood for the needs of the inhabitants of Montenegro, in accordance with the EU Directives (article 15 of the Law of state management – Official Gazette Republic MN no. 38/2003 in accordance with the EU Directives).

Alongside with these activities, actions related to the project of “The Safe Blood” are being carried out, according to the schedule defined in 2004. As a part of component I of this project, the “National report on the policy of providing blood, organization of the service and availability” and the “Report on the quality control in the transfusion service” have been prepared and delivered.

Two regional meetings have been organized, which included the presentation of the current situation in legislation, ways of providing blood donations, and the organization of the transfusion service, financial matters and clinical cooperation.

Within the Strategy “Fight against HIV/AIDS, tuberculosis and malaria in Montenegro” one of the priorities has been given to the activities of the project “The Safe Blood”, aiming at the provision of sufficient quantities of safe blood for the treatment of the inhabitants of Montenegro. This Strategy, adopted by the Government of Montenegro and the Global Fund, provided new resources for important activities in this area.

In 2005 an analysis of the current situation in the transfusion service in Montenegro has been carried out and presented to the Health Authority.

In 2006 the “Strategy of Safe Blood” was adopted by the Government. By this act, the Government of Montenegro acknowledged the provision of safe blood for the needs of its population to be in the national interest and its obligation, and gave priority to this branch of medicine as the base of the health care system. The main aim of the Strategy is to provide sufficient blood supply from safe donors to the needs of the inhabitants of Montenegro by establishing the Service for Blood Transfusion as an independent system within the health care system at the national level with a national institute as referential institution and nine local units in Government hospitals.

In 2007 the Law “ Supply of Blood” was prepared in agreement with Directive 2002/98 EC and adopted by the Assembly of Montenegro. It is aimed at the establishment of conditions and standards of quality, safety and overseeing the process of collection, testing, preparation, stocking, distribution, issuing and use of human blood and blood components, and the organization of a transfusion service on national level ensuring self-sufficiency in safe blood..

During 2008 three premises for regional transfusion units were rehabilitated respectively constructed.

### **3.7. Lessons learned**

It is obvious that inadequate investment and general neglect in the blood transfusion service in Montenegro during the past years has caused numerous problems, which are an obstacle for the possibility of exchanging blood products with blood transfusion services of EU member states. Therefore the Government has recognized the importance of setting up a modern system of safe blood in Montenegro, and has passed the »Safe Blood Strategy«. For its implementation, apart from improving the technical equipment of the Institute for Blood Transfusion, it is necessary to set up an entire quality infrastructure and to complete the process of harmonization of legal instruments. However, because of the lack of resources, these processes are going with a slow pace. A lesson learned from previous experience is that Montenegro can not by itself and in a proper time period complete this process and that it needs support, which is to be provided by this Project.



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

				SOURCES OF FUNDING								
			TOTAL EXP.RE	IPA COMMUNITY CONTRIBUTION		NATIONAL CONTRIBUTION					PRIVATE CONTRIBUTION	
ACTIVITIES	IB	INV	EUR (a)=(b)+(c)+(d)	EUR (b)	%	Total EUR (c)=(x)+(y)+(z)	%	Central EUR (x)	Regional/ Local EUR (y)	IFIs EUR (z)	EUR (d)	%
contract 1		X	1.200.000			1.200.000	100 %					—
contract 2	X		700.000	700.000	100 %							—
contract 3		X	1.100.000	1.100.000	100 %							—
.....												
TOTAL IB			700.000	700.000	100 %							
TOTAL INV			2.300.000	1.100.000	48%	1.200.000	52%					
<b>TOTAL PROJECT</b>			<b>3.000.000</b>	<b>1.800.000</b>	<b>60%</b>	<b>1.200.000</b>	<b>40%</b>					

Amounts net of VAT

Contract 1 will be a works contract financed by national contribution, Contract 2 under IPA will be a direct grant contract with WHO, Contract 3 financed by IPA will be a supply contract (supply contract for all necessary technical equipment and supply contract for establishing an up to date integrated information system). Please see annex 5 below for more details

## **5. Indicative Implementation Schedule (periods broken down per quarter )**

Contracts	Start of Tendering	Signature of contract	Project Completion
Contract 1 NC works	Q3 2010	Q3 2010	Q2 2011
Contract 2 IPA direct grant	not applicable	Q4 2010	Q4 2012
Contract 3 IPA Supply	Q1 2011	Q3 2011	Q3 2012

All contracts will be ready for tendering in the first quarter upon signing the FA (Financial Agreement).

## **6. Cross cutting issues**

### **6.1. Equal Opportunity**

Montenegro has created legal preconditions providing respect for dignity and physical and psychological integrity to **all** patients using the healthcare system. These legal preconditions include patients' basic rights, methods of their protection, as well as their obligations when enjoying the benefits of the healthcare system.. Establishing the European system of safe blood in Montenegro will strengthen the rights of all patients and increase their protection.

The envisaged plan for human resources development in the healthcare system addresses personnel management including the development of specialization plans, managing personnel and employment policies, and defining staffing requirements, including staff for the Institute for Blood Transfusion, where women tend to take more significant positions than in other sectors of the health sector.

### **6.2. Environment**

Blood transfusion by its nature produces waste, including hazardous waste requiring special treatment, which is the subject of a currently ongoing project of the Ministry for Spatial Planning and Environmental Protection.

### **6.3. Minorities**

Montenegro has legislation that protects the rights of minorities. Through this project minorities will be addressed as potential donors and thus also benefit from the application of the Strategy for fighting against HIV/AIDS and other blood transmitted diseases.

## **ANNEXES**

- 1 - Logical framework matrix in standard format
- 2 - Amounts contracted and disbursed per quarter over the full duration of the programme
- 3 - Description of Institutional Framework
- 4 - Reference to laws, regulations and strategic documents
- 5 - Details per EU funded contract

## ANNEX 1: Logical framework matrix in standard format

LOGICAL FRAMEWORK PLANNING MATRIX FOR Project			
<b>Implementation of the European Blood Transfusion System</b>		Contracting period expires 2 years after the signature of the Financing Agreement	Disbursement period expires one year after the final date for execution of the contract
		Total budget: <b>3.000.000 €</b>	IPA budget : <b>1.800.000 €</b>
<b>Overall aim</b>	<b>Objectively verifiable indicators</b>	<b>Sources of Verification</b>	
A modern system for blood transfusion harmonized with the EU standards in order to make safe blood available for all citizens of Montenegro is set up	<ul style="list-style-type: none"> <li>- 4 % of the total population are blood donors</li> <li>- 100 % of the blood donated is based on voluntary donation</li> <li>- International accreditation of Montenegrin blood services</li> </ul>	<ul style="list-style-type: none"> <li>- Reports from Institute for Blood Transfusion</li> <li>- Ministry of Health Reports</li> <li>- EC progress report</li> </ul>	
<b><u>Project purpose</u></b>	<b>Objectively verifiable indicators</b>	<b>Sources of Verification</b>	<b>Assumptions</b>
To secure sufficient quantities of safe blood and blood products to meet the needs of all patients, in regular and emergency situations, provided as part of a sustainable and modern blood transfusion programme within the existing health care system in accordance with the EU standards for blood transfusion.	<ul style="list-style-type: none"> <li>- 40% of the blood donated is based on voluntary donations</li> <li>- 100% of all blood units are subject to quality control</li> <li>- 50% of all EU and WHO directives, standards and recommendations for the system of blood transfusion have been implemented</li> <li>- Accreditation of the Institute for</li> </ul>	<ul style="list-style-type: none"> <li>- Official Gazette of Montenegro</li> <li>- Programme of blood donation in Montenegro and periodical reports</li> <li>- Final report of Institute for Blood Transfusion</li> <li>- Reports and analyses on the enforcement of quality control which reports</li> </ul>	<ul style="list-style-type: none"> <li>- Continued period of suitable political ambience and striving to reach the EU standards</li> <li>- Determination on behalf of the Government to undertake reforms with respect to blood</li> </ul>

	Blood Transfusion and certification of its procedures initiated	<ul style="list-style-type: none"> <li>- Internal Reports of the Ministry of Health</li> <li>- Annual Report on transfusion services provided</li> </ul>	<ul style="list-style-type: none"> <li>- transfusion Institute for Blood Transfusion provides accurate information on current situation</li> </ul>
<b>RESULTS</b>	<b>Objectively verifiable indicators</b>	<b>Sources of Verification</b>	<b>Assumptions</b>
<u><b>Component 1</b></u> <b>Legal and organizational framework</b> <ol style="list-style-type: none"> <li>1. Legal and regulatory framework harmonized with EU requirements and WHO recommendations</li> <li>2. System of voluntary non-remunerated blood donation extended</li> <li>3. Quality control system established and initiated</li> </ol>	<ul style="list-style-type: none"> <li>- All legislation relevant for the functioning of the blood services developed/revised, harmonised with the acquis and submitted for adoption to the Parliament</li> <li>- 3% of the total population are blood donors</li> <li>- At least 50% of the total blood supply provided by voluntary blood donors by end of project</li> <li>- 100% of the Standard Operational Procedures (SOP) developed and implemented in the daily routine of the transfusion service</li> </ul>		<ul style="list-style-type: none"> <li>- Proper financial support from external sources</li> <li>- Continuation and improvement of cooperation initiated with similar institutions in the region and EU countries.</li> <li>- Well designed courses or programs (seminars, workshops, trainings, ...)</li> <li>- Successful information</li> </ul>

<p><b><u>Component 2</u></b> <b>Capacity building</b></p> <p>4. Staff involved in the blood transfusion service adequately trained according to assessed needs</p>	<ul style="list-style-type: none"> <li>- 100% of all staff involved in the blood transfusion service successfully (as per certificate) trained</li> <li>- All staff trained under this project signed a commitment to stay within the Montenegro National Service for Blood Transfusion for a minimum period.</li> </ul>		<p>campaign on voluntary blood donation</p> <ul style="list-style-type: none"> <li>- Efficient cooperation with the Institute, Ministry of Health and other institutions</li> <li>- Readiness of institutions and Institute's personnel to implement changes</li> </ul>
<p><b><u>Component 3</u></b> <b>Physical Infrastructure</b></p> <p>5 Facilities of the Institute for Blood Transfusion constructed according to legal, work process and transfusion requirements</p> <p>6 Laboratory equipment for Institute of Blood Transfusion purchased and installed</p> <p>7. Equipment for national information system network for blood transfusion service procured, installed and IS established</p>	<ul style="list-style-type: none"> <li>- Permit for use of construction for Institute of Blood Transfusion issued</li> <li>- Certification/accreditation agency gives a positive opinion on meeting requirements with respect to work process, allowing for certification procedure to begin</li> <li>- All equipment purchased fully functional 9 months after project start</li> <li>- National information system for blood transfusion service established and functional 12 months after project start</li> </ul>		
<p><b><u>ACTIVITIES</u></b></p>	<p><b><u>Means</u></b></p>	<p><b><u>Costs (in €)</u></b></p>	<p><b><u>Assumptions</u></b></p>

<b><u>Component 1</u></b> <b>Legal and Organizational Framework</b>	1. works » turn key »	Co-financing: 1. national contribution: 1.200.000€	- no delays with respect to tender procedure
1.1. Assessing the existing situation with respect to legislation related to blood transfusion and its approximation to EU regulations	grant to WHO: 2. for achieving the self-sufficiency,	IPA budget: grant to WHO: 700.000€ for Activities 2 - 5	- Agreement on legal amendments; promptly undertaken legal procedure
1.2 Harmonization of Montenegrin legislation and bylaws with EU legislation	3. for harmonization of quality of the products,	supply contracts 1.100.000€ for Activities 6 & 7	- Ministry of Health officially accepts documents for initiating the certification procedure
1.3 Preparation of 4 bye-laws related to blood transfusion and required by law	4. for harmonization of Montenegrin legislation with EU recommendations and directives		- Ministry of Health officially accepts documents for initiating the certification procedure
2.1 Setting up a network of organizations of professionals and volunteers for the promotion of voluntary blood donations	5. for certification – accreditation of laboratories and establishment of the management system		- Readiness of the Ministry of Health to approve the increased number of necessary staff
2.2 Establish a registration system for voluntary blood donors and family donors	supply contract 6. supply contract for all necessary technical equipment and furniture		- Readiness of the Institute to implement changes and optimization of management
2.3 Raising public awareness on significance of voluntary blood donations by flyers, and in radio, TV, newspapers	7. supply contract for establishing an up to date integrated information system		- Secured training infrastructure
2.4 Raising awareness and providing information through a liaison person to the public			- Regular convening of coordination meetings of all stakeholders
2.5 Develop/update existing curricula, manuals and documents for the education of elementary students on blood transfusion			- Personnel of Montenegrin Institute for Blood Transfusion are interested in participating in the project, in implementing measures and in
2.6 Educating elementary and secondary school students on blood transfusion (elementary school students within the curriculum for "Healthy Living")			
2.7 Information, recruitment and retaining of blood donors by providing adequate,			

<p><b><u>Component 2</u></b> <b>Capacity building</b></p> <p>4.1 Training needs assessment for all staff  4.2 Development of individual training plans  4.3 Training of medical staff of all levels, specialists in blood transfusion, medical and laboratory technicians, technicians involved in blood transfusion services  4.4 Management training (administration, finance, personnel, quality management and control, etc.) for staff involved in administration, finance, personnel, quality management and control, and for management  4.5 Training of staff responsible for the maintenance of equipment  4.6 Training of PR liaison person</p>		-	
<p><b><u>Component 3</u></b> <b>Physical Infrastructure</b></p> <p>5.1 Preparation of building plans and legal approval for the construction of the facilities for the Institute for Blood Transfusion according to legal and transfusion requirements  5.2 Construction of facilities for the Institute for Blood Transfusion  .6.1 Needs assessment of furniture and technical equipment</p>		-	-



6.2 Development of technical specifications for tender 6.3. Procurement of equipment required 6.4 Installation of equipment 6.5 Training of staff in using the equipment  7.1 Needs assessment (hard- and software) 7.2 Development of technical specification for tendering (software and hardware) 7.3 Procurement of IT equipment (hard- and software) required 7.4 Installation of hard- and software 7.5 Setting up a national information system on blood donors and medical/technical issues related to blood transfusion 7.6 Training of staff in use, management and maintenance of national information system, including data protection, and allowing continuous internal and external monitoring 7.7 Piloting national information system			
			<b>Preconditions</b> - Sufficient number of employed - Secured co-financing resources Existence of documentation (technical documentation, construction permit...)

ANNEX 2: Amounts (in €) contracted and disbursed by quarter over the full duration of the project

<b>Contracted</b>	<b>Q3/2010</b>	<b>Q4/2010</b>	<b>Q1/2011</b>	<b>Q2/2011</b>	<b>Q3/2011</b>	<b>Q4/2011</b>	<b>Q1/2012</b>	<b>Q2/2012</b>	<b>Q3/2012</b>
Contract 2 (IPA)		700.000							
Contract 3 (IPA)					1.100.000				
<b>Cumulated</b>		<b>700.000</b>			<b>1.800.000</b>				
<b>Disbursed</b>	<b>Q3/2010</b>	<b>Q4/2010</b>	<b>Q1/2011</b>	<b>Q2/2011</b>	<b>Q3/2011</b>	<b>Q4/2011</b>	<b>Q1/2012</b>	<b>Q2/2012</b>	<b>Q3/2012</b>
Contract 2 (IPA)		300.000			170.000		160.000		70.000
Contract 3 (IPA)					660.000				440.000
<b>Cumulated</b>		<b>300.000</b>			<b>1.130.000</b>		<b>1.290.000</b>		<b>1.800.000</b>

### **Annex 3 - Description of the institutional framework**

For reviewing the present situation in the blood transfusion system in Montenegro, a SWOT analyses has been done. In this area a SWOT analyses demonstrates major

#### Advantages:

- Human resources which, with international technical assistance, are capable of realizing modern system of safe blood in Montenegro.
- Determination to associate with the EU in this subject area, as well as determination to associate on the regional level.

#### Disadvantages:

- Incomplete legislation
- Scarce number of blood donors and improper structure of blood donors
- Improper facilities used for transfusion
- Outdated and improper equipment
- Inexistence of standards in clinical application of blood and blood components
- Inadequate manner of keeping the records
- Inexistent informational system

#### Opportunities:

- Existing international cooperation of the Montenegro Institute for Blood Transfusion
- Action Plan and National Program of Montenegrin Government
- EU passed a decision on financing project on strengthening institutions in countries which are in the pre-accession or accession phase

#### Dangers:

- Financing mechanism of the Montenegro Institute for Blood Transfusion
- Inability of adequate transfusion treatment – application of directed chemotherapy in the most of the hospitals
- Inadequate manner of disposing infectious material.

Reviewing the situation clearly demonstrates the necessity of continuing strengthening of the safe blood system, including its functionality, through the establishment of priority aims, achievement of which will create conditions for continuous improvement of safety in transfusion treatment. It is not realistic to expect that Montenegro can implement reform project without donors' assistance, first of all from European Commission, and therefore it shows the necessity to secure finances for strengthening of a safe blood system through financing of this Project, the focus of which will be at:

- Securing adequate quantities of blood and blood products, as medicine, for meeting citizens', tourists' and foreign businessman needs, as well as safety of such medicine
- Preventing transfusion transmitted diseases

Introducing all WHO and EU principles and regulations.

### **The Organization of Transfusion Blood Service**

Transfusion Service in Montenegro is not organized at the national level. The transfusion activity is done through the work of nine autonomous units for blood transfusion within the General and Specialized Hospitals. The biggest one is Center for Blood Transfusion within Clinical Center of Montenegro in Podgorica, as the main referent institution, then 7 transfusion blood units within General Hospitals and 1 laboratory for transfusion blood within Special Medical Institution in Risan.

The total number of employed staff in the Transfusion Unit of Montenegro is the following: 12 doctors, then 3 doctors on medical specialization, 32 technicians - transfusologists and 16 general medical and laboratory technicians.

Based on the Law on Blood Supply reorganization of the Service for Blood Transfusion is planned which will include the Institute for Transfusion in Podgorica and 8 regional Units.

### **Financing of Transfusion Unit**

Transfusion Blood Units in Montenegro are financed from the hospital budgets, and there is no specially allocated budget for the Transfusion Service. Staff, equipment, reagents and medical consumables are financed by the Fund for Health Insurance.

The percentage of blood donation in Montenegro was 2,1% in 2004 and 2,7% in 2008. That is approximately 14.000–16.000 units of blood annually. The main problem is the structure of blood donors, because 80% blood units are collected by replacement donors from family members and only 20% blood units are collected from voluntary, non-remunerated blood donors.

#### **Annex 4 - Reference to laws, regulations and strategic documents:**

- The Law on Health Protection (Official Gazette of the Republic of Montenegro no. 39/04),
- The Law on Providing Blood (Official Gazette of Montenegro no. 11/07) (Directive 2002/98EC)
- Safe Blood Strategy (Directive 32002L0098) 01 June 2006
- HIV/AIDS Strategy, adopted in 2004
- Program of voluntary blood donations, adopted in July 2009

## Annex 5 – Details per EU funded contract

### Management and contracting arrangements

Surveillance over the process of implementation of project activities will be undertaken by a steering committee.

Consultant services will be provided to the beneficiary through the grant contract. The contract will contain and determine a position for a team leader, who will be engaged in key tasks with respect to management of quality infrastructure development, education, harmonization, IT development and other tasks.

The project team will consist of the team leader and other experts, who will be located in the Institute for Blood Transfusion.

The team leader will be responsible for the overall management of the project, coordination with the EU and other international bodies, as well as for reporting. At the beginning of the project a detailed Work Plan will be developed, in coordination with the Steering Committee and the participation of the Ministry of Health of Montenegro and the approval of the EC Delegation.

The expected contracting arrangements are:

Financed from IPA:

#### A. A grant contract with WHO.

The duration of the contract will be for a period of 24 months. Implementation is expected to begin in the third quarter of 2010, one month upon the contract is signed.

The value of the contract is EUR 700.000

### Estimation of Expenditures

Project component	Estimated costs
Component 1:	330,000
Legal and organizational framework	
Legal and normative framework set up	
▪ 2 external consultants	▪ 70,000
▪ 1 local consultant	
▪ working group meetings	
▪ translation	
	▪ 130,000
National donor programme reinforced	
▪ promotion campaigns (design + implementation)	
▪ information leaflet development	
▪ network development +webpage	
▪ adapt training curricula	
▪ 1 external consultants	
▪ 1 local consultant	
▪ translation	▪ 130,000
Quality management system established	
▪ 2 external consultants	
▪ 1 local consultant	
▪ translation	

Component 2	171,000
Capacity building <ul style="list-style-type: none"> <li>▪ 8 external consultants</li> <li>▪ 3 local consultants</li> <li>▪ translation</li> <li>▪ training</li> <li>▪ logistics</li> </ul>	
Component 3	150,000
Programme management <ul style="list-style-type: none"> <li>▪ local project coordinator</li> <li>▪ local project assistant</li> </ul>	
Programme support costs	49,000
Total	700,000

Justification for a direct grant to WHO:

Blood safety is at the heart of WHO's mandate.

WHO reaffirmed the right to access to safe blood and blood products in its respective recommendations, guidelines and other relevant materials and has a long experience in assisting countries to improve blood safety as a means to improve public health.

WHO has been supporting capacity development in transition countries to

- strengthen institutions,
- develop and implement national policies and regulations to ensure appropriate use of blood and to reduce unnecessary transfusions,
- establish sustainable national blood program that can ensure the provision of safe, high quality blood and blood products that are accessible to all patients requiring transfusion and their safe and appropriate use.

This capacity building activities includes also provision of training to technical and managerial staff in blood safety.

Having regard to the fact that

- WHO is implementing similar activities with the same beneficiary under, not only the strategic cooperation framework, but also under the auspices of the South East European Health Network,
- WHO holds vast expertise in this field

WHO represents the sole competent competitor for the implementation of the blood transfusion project in Montenegro.

## B. Supply contracts

International tenders for

- equipment and furniture

- establishing a modern integrated information system

The budget for the supply tenders is EUR 1.100.000 (Results 6 and 7).

The preliminary list of equipment for the Institute for Blood Transfusion in Podgorica:

1. Centrifuge for separation of blood component with refrigeration and temperature control - Cryofuge (rotor 6 places) .....	2
2. Laboratory centrifuge for samples / 4000rpm.....	3
3. Laboratory centrifuge for samples / 4000rpm sa podešavanjem temperature.....	1
4. Laboratory centrifuge for immunohaemathology with automatic wash/4000 rpm.....	2
5. Microhaematocrit centrifuge.....	2
6. Storage cabinet for whole blood and erythrocytes concentrate with temperature control and visual and acoustic signal/ capacity	
- 300 L .....	1
- 400 L .....	4
- 700 L .....	4
- 1200 L .....	1
7. Refrigerator for reagents with temperature control and visual and acoustic signal/ capacity	
a. 300 L .....	2
b. 600 L .....	1
8. Refrigerator for samples of blood with temperature control and visual and acoustic signal/ capacity	
a. 300 L .....	3
9. Plasma storage cabinet (T-30 <sup>0</sup> C) with temperature control and visual and acoustic signal capacity	
a. 700 L .....	4
b. 379 L .....	2
10. Blast shock freezer .....	1
11. Deep freezer (-80 <sup>0</sup> C) with temperature control and visual and acoustic signal capacity .....	2
12. Automatic apparatus for testing samples on transmissible diseases NAT – ID (with necessary adding equipment) .....	1
13. Automatic immunanalysator for testing samples on transmissible diseases haemiluminiscences method .....	1
14. Mixer for platelets with cabinet storage ( capacity 96 bags) .....	2
15. Water bath .....	2
16. Blood heater .....	5
17. Laboratory thermostat .....	4
18. Dry sterility cabinet .....	2
19. Apparatus for distillation .....	1
20. Apparatus for automatic work for blood group in microtitar plates .....	1
21. Apparatus for automatic work for blood group in gel-technical ....	1
22. Laminar cabinet .....	1
23. Apparatus for inactivation pathogens in blood component .....	2
24. Apparatus for detection of bacterial contamination in blood component ..	1
25. Apparatus for irradiation of blood component .....	1
26. Apparatus for sterile connection .....	2



27. Apparatus for automatic separation of blood components .....	3
28. Apparatus for collection of blood and blood components by aphaeresis procedures .....	1
29. Apparatus for donors' plasmapheresis .....	1
30. Apparatus for therapeutic aphaeresis procedures ( plasma exchange )....	1
31. Apparatus for separation platelets from BC .....	1
32. Automatic cells counter .....	2
33. Bleeding Management System (Trombelastograph) .....	1
34. Haemoglobinometre .....	5
35. Bed/Chair for blood donors .....	5
36. Chair for blood donors for aphaeresis procedures .....	2
37. Hospital beds for ambulance transfusion .....	3
38. Bed/Chair for blood donors – mobile .....	10
39. Scales with mixer for blood donation .....	15
40. Transport refrigerators with battery (different capacity) .....	5
41. Scales for blood unit .....	4
42. Apparatus for destroying potential infectious material .....	1
43. Microscopes .....	2
44. Immunoflorescent Microscopes .....	1
45. Apparatus for towing plasma .....	2
46. PC support for IS with Bar-Code	

#### Information system for Department for Blood Transfusion

Montenegro does not have an information system in the Department for Blood Transfusion. The project will support its purchase with the aim to provide a data base on all blood donors, their epidemiologic data (TTI results), data on blood products (Er, SSP,Tr, Kp) and their clinical use (identification of recipients). Support will encompass software and hardware (computers, printers and servers, as well as setting up a network between the Center for Blood Transfusion and the transfusion units). This will allow for tracing the blood from the donor to the recipient. Confidentiality must be guaranteed in order to provide for privacy protection of blood donors.

A combined donor–recipient register will provide for the surveillance of all available epidemiologic data in TTI testing in order to secure donors from risk groups.

C. (A.+ B.) Total: EUR 1.800.000

#### D. National contribution

Construction of a new building specially designed for the National Institute for Blood Transfusion in Podgorica

EUR 1.200.000 for a works contract for Result 5

The new building, specially constructed for the Institute for Blood Transfusion in Podgorica, has to be with adequate, well air-conditioned space, of a total size 1500-1800m<sup>2</sup>, with five premises, with separate elevators for people and for blood units.

Movements of staff, donors, patients, unprocessed and processed blood, non-sterile and contaminated, clean and sterilized material must be in the focus of the design of the

premises. All hygiene requirements set by international professional bodies, including the EC recommendations, require exclusive internal communication of the staff from Institute.

Walls and floors in the premises have to be built in accordance with EU and WHO standards.

The external carpentry, windows and doorways should be made of a high-quality material, according to the schemes in the design.

- I Q 2010 completing of documentation needed for building construction
- II Q 2010 tendering for construction works
- III Q 2010 starting of works
- II Q 2011 ending of works