

## **FINAL VERSION**

### **1. Basic information**

- 1.1 CRIS Number:** 2009/021-665
- 1.2 Title:** Strengthening of the blood safety system
- 1.3 ELARG Statistical code:** 3. 28
- 1.4 Location:** Nation wide project activities

### **Implementing arrangements:**

#### **1.5 Implementing Agency**

The Central Finance and Contracting Department (CFCD) will be the contracting authority and will be responsible for all administrative and procedural aspects of the tendering process, contracting matters and financial management including payment of the project activities, upon conferral of management. The head of CFCD will act as the programme Authorizing Officer (PAO) of the project:

Mrs.Radica Koceva (PAO)  
Central Financing and Contracting department  
Ministry of finance  
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fax:+3892-3106612  
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#### **1.6 Beneficiary (including details of SPO):**

The leading beneficiary institution is the Ministry of Health. The co-beneficiary is National Institute for Transfusion Medicine, Skopje, and the former Yugoslav Republic of Macedonia.

Contact points for this project are: the SPO from the Ministry of Health - Mrs. Snezana Cicevalieva, Head of the Sector for European integration (075/254-932, e-mail: [scicevalieva@gmail.com](mailto:scicevalieva@gmail.com), [snezana.cicevalieva@zdravstvo.gov.mk](mailto:snezana.cicevalieva@zdravstvo.gov.mk)), and

Prim Dr. Risto Dukovski, from the National Institute for Transfuzion Medicine, (071/ 383-191, [dukovski50@gmail.com](mailto:dukovski50@gmail.com))

## **Financing:**

**1.7 Overall costs (VAT excluded)<sup>1</sup>:** EUR 1 099 800

**1.8 EU contribution:** EUR 897 150

**1.9 Final date for contracting:**

Two years from the date of the conclusion of the Financing Agreement.

**1.10 Final date for execution of contracts:**

Two years from the final date of contracting.

**1.11 Final date for disbursements:**

One year after the final date for execution of contracts.

## **2. Overall Objective and Project Purpose**

### **2.1 Overall Objective**

To provide quality, efficient and continuous health care to the population of the former Yugoslav Republic of Macedonia through providing safety of blood and blood components, as well as through protecting the population from communicable diseases.

### **2.2 Project purpose:**

The purpose of the project is strengthening of the blood safety system, through appropriate implementation of the national legislation in the area of blood safety, aligned with the EU Acquis, as well as through providing safe, optimal and self-sustainable supply with blood and blood components to all health institutions in the country.

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

#### **2.3.1 Link with National Plan for Adoption of Acquis**

National Plan for Adoption of Acquis includes several short term and medium term priorities in the field of blood safety, as follows: to further legal development and harmonisation of legislation with the Acquis, to strengthen administrative and technical capacity in order to implement the legislation and EU standards, especially the following ones: 32002L0098, 32004L0033, 32005L0061, 32005L0065 and Council Recommendation 98/463.

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<sup>1</sup> The total costs of the project should be net of VAT and/or other taxes. Should this not be the case, the amount of VAT and the reasons why it should be considered eligible should be clearly indicated.

### **2.3.2 Link with Progress Report (2008)**

Reference to the **Progress Report (2008)**: The latest progress report makes the following evaluation: “Progress was made in the field of public health. Implementing of the blood safety and quality strategy was postponed owing to insufficient financial resources. Preparations in this field have started.”

### **2.4 Link with MIPD**

Ability to assume the obligations of membership and approximation to European standards /harmonise quality infrastructure standards with EU standards:

- This Project is responding to priorities 28. Consumer and Health Protection, Public Health.
- Improved risk assessment will provide for improved safety of blood and blood components and will provide for improved application of international (EU) and harmonized national standards for blood safety.

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

The National Development Plan stipulates strengthening and improvement of health, prevention of diseases and insurance of quality of the health services, as well as reducing of at least 1/3 of the existing differences in the health status of the population of the Former Yugoslav Republic of Macedonia and population from the EU member states.

### **2.6 Link with national /sectorial investment plans**

Links with national plans refer especially to:

- National Health Strategy;
- National Strategy on Prevention and Control of HIV/AIDS; and
- Law for Safety of Blood and Blood Components (Official Gazette No. 110/2007).

## **3. Description of project**

### **3.1 Background and justification:**

Blood and blood products in the former Yugoslav Republic of Macedonia are accepted as an integral part of health care delivery. Their life-sustaining role goes beyond medical emergencies to routine surgical procedures and prolonged quality-of-life therapies. The degree to which these products are used, demands that their quality, safety, and efficacy be ensured in order to prevent the transmission of diseases. This is the basic fact that underlies the efforts of the health authorities to ensure that requirements are in place to protect donors and the recipients of blood and blood products.

Currently the Blood Transfusion Service (BTS) is fragmented, and not coordinated on the national level. Many of the vital components are missing: adequate infrastructure (facility and equipment), significant variation in working conditions between the units of the BTS, unstable financial support, and inadequate distribution of human resources, in the absence of continuous medical training.

There are 22 units of BTS in the country, but only one is a blood establishment (National Institute of Transfusion Medicine). The remaining units are hospital based transfusion units

managed by hospital managers, who generally lack knowledge about blood safety, quality and the requirements of modern transfusion medicine. The number of specialists in transfusion medicine is sufficient.

Blood donation in general is organised around the principles of voluntary, anonymous and non remunerated blood donors. Blood testing is mandatory, but the equipment, the tests reagents and staff training are not unique and equal, so that the quality of the final result varies. Clinical use of blood is not standardised within the health system, because of the inadequate education of the clinical staff. The documentation in BTS is not standardised, as a result of the lack of a nationally coordinated quality system in BTS and Haemovigilance system.

Within the framework of bilateral cooperation with the Government of Republic of France, the Agreement for financing the project “Support of the sector for transfusion medicine in Macedonia” was signed. This project was successfully completed. Main achievements of the project were endorsement of the new Law on Blood and blood products safety (Official Gazette No 110/07) completely aligned with EU Blood Directives, training of the personnel for preparing working protocols and supply of the equipment for cryopreservation

There are ongoing activities for preparing the ground for the merging of all existing 22 centres in one Blood Transfusion System covering the whole country. It will consist of a National Institute for Transfusion Medicine, 3 regional centres and 18 hospital units. It will be independent from and organizational and financial point of view, but fully integrated in the health system of the country.

A major challenge will be implementation of common policies for collection, processing and testing, which now largely depends on the financial situation of the institution/hospital where the service is situated, as well on local conditions (building, equipment and staff).

The reorganisation of the blood transfusion system will lead to a nationally coordinated system and will enable implementation of the EU standards and norms of quality and safety during the process of collection, testing, processing, storage, and distribution. into daily practice.

In parallel, according to the Law on Healthcare Protection, a National Blood Donation Programme has been implemented. This programme is financed from the State Budget and provides support for organizing blood donation campaigns, issuing pedagogical material, educative sessions, the aim is to motivate people to donate but also to avoid frequent donors (more than 10 times/year) as this might be not good for their health. This Programme has to be strengthened with respect to better motivation, recruitment and retaining voluntary, anonymous and unpaid blood donors who will donate blood regularly.

In the framework of the SEE Health Network (SEE Regional Cooperation Council) the project “Increasing regional self-sufficiency in relation to safer blood and blood components” has been developed.” Component Two of this project aims to strengthen the capacity of the national stakeholders and professionals in the blood services to achieve good practices and implement quality management systems across the whole blood chain, from donor to recipient, including national programmes for education, promotion and retention of voluntary non-remunerated blood donors.

Starting from 2008 there are ongoing activities (trainings) related to increasing availability of blood through sustainable promotion of voluntary non-remunerated blood donation, and to capacity building in quality management to support implementation of EU requirements.

In parallel, to ensure better haemovigilance throughout the whole system for blood safety in the country, the computerisation of the blood system in the entire country has to be introduced. The IT system of the National Institute for Transfusion Medicine in Skopje is currently being upgraded.

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

The project will contribute to strengthen the capacity in terms of staff training, so as to be able to perform the required duties and activities in the most efficient way in the new organizational scheme, thus providing a significant improvement of quality and safety of blood products in the country and effective functioning of the blood transfusion system. It will have catalytic effect on the fundamental ongoing reforms of the system based on the national legislation for blood safety, fully harmonized with the EU Acquis.

Providing unified equipment for the BTS in the whole country and equal conditions throughout the country in the whole blood supply will be some of the initial steps in the ongoing efforts for improving the system,. This will allow further upgrading of the equipment, relevant procedures and standards. EU funding will not replace other funding from the government or Blood institutions.

Health professionals trained in EU countries on the basis of their good practices show already visible effects on the whole blood system.

Transformation from the fragmented, mainly hospital based blood services under the legal and financial responsibilities of various entities into a nationally coordinated service, will ensure an adequate supply of blood and blood components of comparable quality and safety on national and regional level. Development and implementation of harmonised, recognized and accepted quality and safety standards for the blood supply will support and enhance the trans-national availability of safe blood and blood components for emergencies of any kind (natural disasters, global health threats).

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

The main result of the Project is to establish an integrated and well coordinated and sustainable blood safety system that provides for accessible blood and blood products with high quality and safety that will prevent communicable disease, serves the main functions of the national healthcare system and provides for efficient and effective health care in emergencies (both nationally and regionally).

#### Results:

- Book of Regulations on blood safety is developed and adopted;
- Guidelines on Blood Safety are developed, published and distributed;
- Practitioners' Guide on Blood Safety are developed, published and distributed;
- Training Programs for health professionals are developed and implemented in the following areas:
  - Good clinical practice for use of blood and blood components;

- Information for blood donors related to the donation of blood and blood component (both legal and ethical issues to be addressed);
  - Testing the blood and blood components;
  - Labelling of blood and blood components;
  - Keeping records of blood donors;
  - System for identification of each blood donation;
  - Haemovigilance: Reporting for adverse reaction/events related to use of blood and blood components;
  - Traceability systems;
- Training provided, according to the requirements for continuous medical education for implementation of quality assessment standards, of standard operational procedures, of good laboratory practice, of separation processes, as well as components processing, for the health professionals, 30 in total, as follows:
- medical doctors/transfusion medicine specialists - 10;
  - medical laboratory technicians - 15;
  - biologists/biochemists - 5.
- On-site training provided, in blood transfusion institution in EU country for the period of 3 months, for 12 health professionals in total, as follows:
- National Institute - 3 health professionals;
  - 3 regional centres - 3 persons per each institution, 9 in total.
- Supply of the following equipment: (see ANNEX 6)

<b>Equipment</b>	<b>Quantity</b>
Blood bags cold centrifuges	5
Refrigerators on - 40° C	5
Refrigerators on - 80° C	3
Refrigerators on + 4° C	20
Platelet incubators	5
IT Server	1
Personal Computer	33
Lap top	9

Measurable indicators:

- Book of Regulations on blood safety adopted, printed in 50 copies and distributed to BTS and MoH;
- Guidelines on Blood Safety developed, , published in 100 copies and distributed to all BTS;
- Practitioners’ Guide on Blood Safety developed, published in 200 copies and distributed to all BTS;
- 9 Training Programs for health professionals developed and 150 staff trained in special focus area;
- 30 staff trained in implementation of quality assessment standards;
- 12 health professionals trained on site;
- Type and quantities of the necessary equipment indicated in this project, provided.

### **3.4 Activities:**

#### **1. Development and adoption of the Book of Regulations on blood safety (as a Compendium of the Legislation and all other legal and policy documents in the field of blood safety):**

- Establishment of Working Group for drafting the Book of Regulations, that scopes:
  - 4 experts from National Institute for Transfusion Medicine
  - 4 experts from Ministry of Health
- Preparation of draft Book of regulations
- Evaluation of the Draft version of the Book of regulations
- Adoption of Book of regulations
- Printing and publishing the Book of Regulations
- Distribution of the Book to the main institutions (to all institutes for transfusion medicine)

#### **2. Development of Guidelines on Blood Safety**

- Establishment of Working group for drafting the Guidelines on blood safety including:
  - 4 experts from Republic Institute for transfusion medicine;
  - 3 experts from Ministry of Health.
- Preparation of draft Guidelines on blood safety;
- Evaluation of the Draft version of the Guidelines on blood safety;
- Adoption of Guidelines on blood safety;
- Printing the Guidelines on blood safety;
- Distribution of the Guidelines on blood safety.

#### **3. Development of Practitioners' Guide on Blood Safety**

- Establishment of working group for drafting the Practitioners' Guide on blood safety, that scopes:
  - 4 legal experts;
  - 3 technical experts.
- Preparation of Draft Practitioners' Guide on Blood Safety;
- Evaluation of the Draft version of the Practitioners' Guide on Blood Safety;
- Adoption of Practitioners' Guide on Blood Safety;
- Printing and publishing the Practitioners' Guide on Blood Safety;
- Distribution of the Practitioners' Guide on Blood Safety.

#### **4. Development of General Training Programs for health professionals and training of all the health professionals working in the newly integrated BTS (Blood Transfusion System) on the following issues:**

- Good clinical practice for use of blood and blood components;
- Information for blood donors related to the donation of blood and blood component (both legal and ethical issues to be addressed);
- Testing the blood and blood components;
- Labelling of blood and blood components;

- Keeping records of blood donors;
- System for identification of each blood donation;
- Reporting for adverse reaction related to use of blood and blood components;
- Keeping records blood and blood component;
- Haemovigilance.

Trainings will be provided by 3 international (EU) experts, as it follows:

- training sessions - 3 x 2 days
- trained health professionals - 150

**5. Specific (update) Training provided** - for the specialists in transfusion medicine (continuous medical education) for the following issues: implementation of quality assessment standards, standard operational procedures, good laboratory practice, separation processes, as well as components processing,:

- medical doctors/transfusion medicine specialists - 10;
- medical laboratory technicians - 15;
- biologists/biochemists - 5;
- training sessions - 3x 2 day.

**6. On-site training provided,** in blood transfusion institution in EU country (preferably France) for the period of 3 months, for 12 health professionals in total, as it follows:

- National Institute - 3 health professionals;
- 3 regional centres - 3 persons per each institution, 9 in total.

## **7. Providing of equipment:**

Equipment will be provided through international tender procedure. Budget breakdown is provided at the end, attached to this document.

## **Project Management and Administration**

A project Steering Committee will be established to oversee the implementation process of the project activities. Advisory services will be provided to Ministry of Health and to the National Institute for Transfusion Medicine. The national health authorities will appoint a national contact person to support the project. He/she will be responsible for the overall activity implementation, additional expertise to implement the training activities, infrastructure project development and implementation, as well as to address the cross-cutting issues.

A team leader will be responsible for the overall management, representation (co-ordination with the EU and other international bodies) as well as reporting. The team leader is responsible for an appropriate management of resources. During the inception phase of the project, a detailed deployment plan will be developed under the coordination of a Steering Committee in which each stakeholder will be represented to ensure appropriate inclusion.



### **The contracting arrangements are expected to be as it follows:**

- 1 service contract will be concluded following an international restricted tender process. The contract has an expected duration of 12 months, and is expected to be signed in the 1st quarter 2011 and have a budget of EUR 482 000 (IPA funds of EUR 433 800 and national co-financing of EUR 48 200)
- 1 supply contract will be concluded following an open international tender process. The contract has an expected total duration of 24 months (duration of a supply contract consist of implementation period 12 months, plus 12 months warranty period), and is expected to be signed in the 1st quarter 2011 and have budget of EUR 617 800 (IPA funds of EUR 463 350 and national co-financing of EUR 154 450)

### **3.5 Conditionality and sequencing**

The project includes the following conditions:

1. Endorsement by all key stakeholders of Terms of References, specifications for the individual contracts to be engaged;
2. Appointment of counterpart personnel by the beneficiary before the launch of tender process;
3. Allocation of the working space and facilities by the beneficiary for technical assistance before the launch of the tender process;
4. Participation by beneficiary in tender process as per EU regulations;
5. Organisation, selection and appointment of members of working groups, steering committee, training programmes;
6. Appointing the relevant staff by the beneficiaries to participate in training activities as per work plan.

In the event that conditions are not met, suspension or cancellation of project will be considered.

### **3.6 Linked activities**

This project is a continuation of the project “Support of the sector for transfusion medicine in Macedonia” within the bilateral cooperation with the Government of Republic of France. That project was successfully finished and under that project, a Law for Safe Blood and Blood Components was endorsed. the implementation of the Law for Blood and Blood Products Safety is fundamental step for transition from the currently fragmented blood transfusion system to a nationally coordinated one aligned with the EU blood directives on standards on quality and safety for the blood and blood components,. The envisaged project complements the activities made by the mentioned project as it will be a crucial step for reforming the transfusion sector implementing the new law on blood safety.

### **3.7 Lessons learned**

This is the first IPA Project in the area of health, thus lessons learned in the other areas (sectors) that have already implemented IPA Projects will be used.

In previous years, a large focus has been made on establishing the legal frameworks in the country. The capacity to enforce the law, however, has received insufficient attention, leading to a situation where the legal reform is rather well advanced, but the practice – law

enforcement and implementation - has not followed. The present project, therefore, focuses on increasing these capacities.

Within the framework of bilateral cooperation with the Government of Republic of France, the Agreement for financing the project “Support of the sector for transfusion medicine in Macedonia” was signed. This project was successfully finished. Main achievements of the project were endorsement of the new Law on Blood and blood products safety (Official Gazette No 110/07) completely aligned with EU Blood Directives, training of the personnel for preparing working protocols and supply of the equipment for cryopreservation.) The main lessons learned from the project are:

- The importance of good coordination and good establishing of the rights and responsibilities of the persons engaged in the project;
- The significance of establishing of good management structure;
- The importance of establishing of good structure for monitoring and evaluation of the activities in all phases of the project;
- The importance of the preparation and realisation of financial framework and procurement plan;
- The effectiveness of learning by doing” approaches.

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

			SOURCES OF FUNDING									
			TOTAL EXP.RE	TOTAL PUBLIC EXP.RE	IPA COMMUNITY CONTRIBUTION		NATIONAL PUBLIC CONTRIBUTION					PRIVATE CONTRIBUTION
ACTIVITIES	IB (1)	INV (1)	EUR (a)=(b)+(e)	EUR (b)=(c)+(d)	EUR (c)	% (2)	Total EUR (d)=(x)+(y)+(z)	% (2)	Central EUR (x)	Regional/Local EUR (y)	IFIs EUR (z)	EUR (e)
Service Contract Covering activities 1,2,3,4,5,6,	X		482 000	482 000	433 800	90	48 200	10	48 200	-	-	-
Supply Contract Activity 7		X	617 800	617 800	463 350	75	154 450	25	154 450	-	-	-
TOTAL IB			482 000	482 000	433 800	-	48 200	-	48 200	-	-	-
TOTAL INV			617 800	617 800	463 350	-	154 450	-	154 450	-	-	-
<b>TOTAL PROJECT</b>			<b>1 099 800</b>	<b>1 099 800</b>	<b>897 150</b>	<b>-</b>	<b>202 650</b>	<b>-</b>	<b>202 650</b>	<b>-</b>	<b>-</b>	<b>-</b>

NOTE: DO NOT MIX IB AND INV IN THE SAME ACTIVITY ROW. USE SEPARATE ROW

Amounts net of VAT

(1) In the Activity row use "X" to identify whether IB or INV

(2) Expressed in % of the **Public** Expenditure (column (b))

(3) Expressed in % of the **Total** Expenditure (column (a))

In case of local or foreign training the project will fund from incidentals – whenever necessary - the renting of training rooms and equipment, the printing of training material and accessories as well as per diems/allowances for participants in the way and to the level normally financed by the government, but never higher than the per diem rates published by the EU.

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

	Start of Tendering	Signature of contract	Project Completion
Service Contract 1	Q2 2010	Q1 2011	Q2 2012
Supply Contract 1	Q2 2010	Q1 2011	Q1 2013

## 6. Cross cutting issues

Transformation from the fragmented, mainly hospital based blood services under the legal and financial responsibilities of various entities into a nationally coordinated service, will ensure an adequate supply of blood and blood components of comparable quality and safety on national and regional level. Development and implementation of harmonised, recognized and accepted quality and safety standards for the blood supply will support and enhance the trans-national availability of safe blood and blood components for emergencies of any kind (natural disasters, global health threats).

### 6.1 Civil Society development and dialogue

n/a

### 6.2 Environmental consideration

n/a

### 6.3 Equal opportunities and non-discrimination

Regarding the Law of health protection, all people of the Former Yugoslav Republic of Macedonia have equal opportunities and non-discriminated access to the health services, regardless of gender or ethnic background.

### 6.4 Minority and vulnerable groups

n/a

### 6.5 Good governance, with particular attention to fight against corruption

n/a

## ANNEXES

- 1- Log frame in Standard Format
- 2- Amounts contracted and Disbursed per Quarter over the full duration of Programme
- 3- Description of Institutional Framework
- 4 - Reference to laws, regulations and strategic documents:
  - Reference list of relevant laws and regulations
  - Reference to AP /NPAA / EP / SAA
  - Reference to MIPD
  - Reference to National Development Plan
  - Reference to national / sector investment plans
- 5- Details per EU funded contract (\*) where applicable:
  - For *TA contracts*: account of tasks expected from the contractor
  - For *twinning covenants*: account of tasks expected from the team leader, resident twinning advisor and short term experts
  - For *grants schemes*: account of components of the schemes
    - For *investment contracts*: reference list of feasibility study as well as technical specifications and cost price schedule + section to be filled in on investment criteria (\*\*)
    - For *works contracts*: reference list of feasibility study for the *constructing works* part of the contract as well as a section on investment criteria (\*\*); account of services to be carried out for the *service part* of the contract

(\*) non standard aspects (in case of derogation to PRAG) also to be specified

(\*\*) section on investment criteria (applicable to all infrastructure contracts and constructing works):

- Rate of return
- Co financing
- compliance with state aids provisions
- Ownership of assets (current and after project completion)

## ANNEX 1: Logical framework matrix in standard format

LOGFRAME PLANNING MATRIX FOR THE PROJECT FICHE: Strengthening of the Blood Safety System	Programme name and number: National Programme for the former Yugoslav Republic of Macedonia under the IPA Transition Assistance and Institution Building Component for 2009		
	CRIS number: 2009/021-665		
	Contracting period expires two years from the date of the conclusion of the Financing Agreement	Execution period expires two years from the final date for contracting	Disbursement period expires one year from the final date for execution of contracts.
		<b>Total budget:</b> EUR 1 099 800	<b>IPA budget:</b> EUR 897 150

Overall objective	Objectively verifiable indicators	Sources of Verification
To provide quality, efficient and continuous health care to the population of the Former Yugoslav Republic of Macedonia through providing safety of blood and blood components, as well as through protecting the population from communicable diseases		

Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions
The purpose of the project is strengthening of the blood safety system, through appropriate implementation of the national legislation in the area of blood safety, aligned with the EU Aquis, as well as through providing safe, optimal and self-sustainable supply with blood and blood components to all health institutions in the country.	<ul style="list-style-type: none"> <li>- Appropriate and timely implementation of the project;</li> <li>- Timely contracting of the project;</li> <li>- Timely implementation of the project tender processes;</li> <li>- Availability of beneficiary and staff.</li> </ul>	<ul style="list-style-type: none"> <li>- Published Books of Regulations, Guidelines and Practitioners' Guide;</li> <li>- Contract records;</li> <li>- Audit reports.</li> </ul>	<ul style="list-style-type: none"> <li>- Government remains committed to EU accession and implementation of the Aquis, following up on comments provided in the regular progress reports;</li> <li>- Support of the country's authorities, support from the management team of the Institute for transfusion medicine, availability of the needed equipment and staff.</li> </ul>

Results	Objectively verifiable indicators	Sources of Verification	Assumptions
The main result of the Project is to establish integrated and well coordinated and sustainable blood safety system that provides for accessible blood and blood products with high quality and safety that will prevent communicable disease, serve the main functions of the national healthcare system and provide for efficient and effective health care in emergencies (both nationally and	<b>Measurable indicators:</b> <ul style="list-style-type: none"> <li>- Book of Regulations on blood safety adopted, printed in 50 copies and distributed to BTS and MoH;</li> <li>- Guidelines on Blood Safety developed, published in 100 copies and distributed to all BTS;</li> </ul>	<ul style="list-style-type: none"> <li>- project reports;</li> <li>- monthly reports from PIU;</li> <li>- published Book of Regulations, Guidelines and Practitioners' Guide;</li> <li>- reports from the trainings;</li> <li>- report for preformed operational</li> </ul>	<ul style="list-style-type: none"> <li>- Cooperation among the stakeholders;</li> <li>- Commitment from national authorities in the process.</li> </ul>

<p>regionally). The expected results are:</p> <ul style="list-style-type: none"> <li>- Book of Regulations on blood safety is developed and adopted;</li> <li>- Guidelines on Blood Safety are developed, published and distributed;</li> <li>- Practitioners' Guide on Blood Safety are developed, published and distributed;</li> <li>- Training Programs for health professionals are developed and implemented;</li> <li>- Training provided, according to the requirements for continuous medical education for implementation of quality assessment standards, of standard operational procedures, of good laboratory practice, of separation processes, as well as components processing, for the health professionals, 30 in total;</li> <li>- On-site training provided, in blood transfusion institution in EU country for the period of 3 months, for 12 health professionals;</li> <li>- Provided the equipment.</li> </ul>	<ul style="list-style-type: none"> <li>- Practitioners' Guide on Blood Safety developed, published in 200 copies and distributed to all BTS;</li> <li>- 9 Training Programs for health professionals developed and 150 staff trained in special focus area;</li> <li>- 30 staff trained in implementation of quality assessment standards;</li> <li>- 12 health professionals trained on site;</li> <li>- Type and quantities of the necessary equipment indicated in this project, provided.</li> </ul>	<p>qualification of the equipment.</p>	
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<b>Activities</b>	<b>Means</b>	<b>Costs</b>	<b>Assumptions</b>
<p><b>1. Development and adoption of the Book of Regulations on blood safety (as a Compendium of the Legislation and all other legal and policy documents in the field of blood safety)</b></p> <ul style="list-style-type: none"> <li>• Establishment of Working Group for drafting the Book of Regulations, that scopes: <ul style="list-style-type: none"> <li>▪ 4 experts from National Institute for transfusion Medicine;</li> <li>▪ 4 experts from Ministry of Health.</li> </ul> </li> <li>• Preparation of draft Book of regulations;</li> <li>• Evaluation of the Draft version of the Book of regulations;</li> <li>• Adoption of Book of regulations;</li> <li>• Printing and publishing the Book of Regulations;</li> <li>• Distribution of the Book to the main institutions</li> </ul>	<p>Service Contract and Supply Contract</p>	<p>Service contract: Total: EUR 482 000 IPA: EUR 433 800 Nat. co-fin. EUR 48 200</p> <p>Supply contract: Total: EUR 617 800 IPA: EUR 463 350 Nat. co-fin EUR 154 450</p>	<ul style="list-style-type: none"> <li>- Appropriate expertise is available;</li> <li>- Beneficiary institution can make (qualified) staff available.</li> </ul>

(to all institutes for transfusion medicine).

**2. Development of Guidelines on Blood Safety**

- Establishment of Working group for drafting the Guidelines on blood safety including:
  - 4 experts from Republic Institute for transfusion medicine;
  - 3 experts from Ministry of Health.
- Preparation of draft Guidelines on blood safety;
- Evaluation of the Draft version of the Guidelines on blood safety;
- Adoption of Guidelines on blood safety;
- Printing the Guidelines on blood safety;
- Distribution of the Guidelines on blood safety.

**3. Development of Practitioners' Guide on Blood Safety**

- Establishment of working group for drafting the Practitioners' Guide on blood safety, that scopes:
  - 4 legal experts;
  - 3 technical experts.
- Preparation of Draft Practitioners' Guide on Blood Safety;
- Evaluation of the Draft version of the Practitioners' Guide on Blood Safety;
- Adoption of Practitioners' Guide on Blood Safety;
- Printing and publishing the Practitioners' Guide on Blood Safety;
- Distribution of the Practitioners' Guide on Blood Safety.

**4. Development of General Training Programs for health professionals and training of all the health professionals working in the newly integrated BTS (Blood Transfusion System) on the following issues:**

- Good clinical practice for use of blood and blood components;
- Information for blood donors related to the donation of blood and blood component (both legal and ethical issues to be addressed);
- Testing the blood and blood components;
- Labelling of blood and blood components;



<ul style="list-style-type: none"> <li>• Keeping records of blood donors;</li> <li>• System for identification of each blood donation;</li> <li>• Reporting for adverse reaction related to use of blood and blood components;</li> <li>• Keeping records blood and blood; component</li> <li>• Haemovigilance.</li> </ul> <p>Trainings will be provided by 3 international (EU) experts, as it follows:</p> <ul style="list-style-type: none"> <li>– training sessions - 3 x 2 days</li> <li>– trained health professionals -150</li> </ul> <p><b>5. Specific (update) Training provided</b> - for the specialists in transfusion medicine (continuous medical education) for the following issues: implementation of quality assessment standards, standard operational procedures, good laboratory practice, separation processes, as well as components processing :</p> <ul style="list-style-type: none"> <li>• medical doctors/transfusion medicine specialists – 10;</li> <li>• medical laboratory technicians – 15;</li> <li>• biologists/biochemists - 5;</li> <li>• training sessions - 3x 2 day.</li> </ul> <p><b>6. On-site training provided</b>, in blood transfusion institution in EU country (preferably France) for the period of 3 months, for 12 health professionals in total, as it follows:</p> <ul style="list-style-type: none"> <li>• -National Institute - 3 health professionals;</li> <li>• -3 regional centres - 3 persons per each institution, 9 in total.</li> </ul> <p><b>7. Providing of equipment:</b> Equipment will be provided through international tender procedure</p>			
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**Pre conditions:**

The project includes the following conditionalities:

- Endorsement by all key stakeholders of the Terms of Reference, specifications for the individual contracts to be engaged;
- Appointment of counterpart personnel by the beneficiaries before the launch of the tender process;
- Allocation of working space and facilities by the beneficiaries for technical assistance before the launch of the tender process (if required);
- Participation by the beneficiaries in the tender process as per EU regulations;
- Organisation, selection and appointment of members of working groups, steering and coordination committees, seminars by the beneficiaries as per work plan of the project;
- Appointing the relevant staff by the beneficiaries to participate in training activities as per work plan;
- Provision of the necessary authorisations for co-operating and sharing of information with the deployed advisory resources
- EU procedures to be followed for the procurement of supplies, contracting of technical assistance & training financed from pre-accession funds.

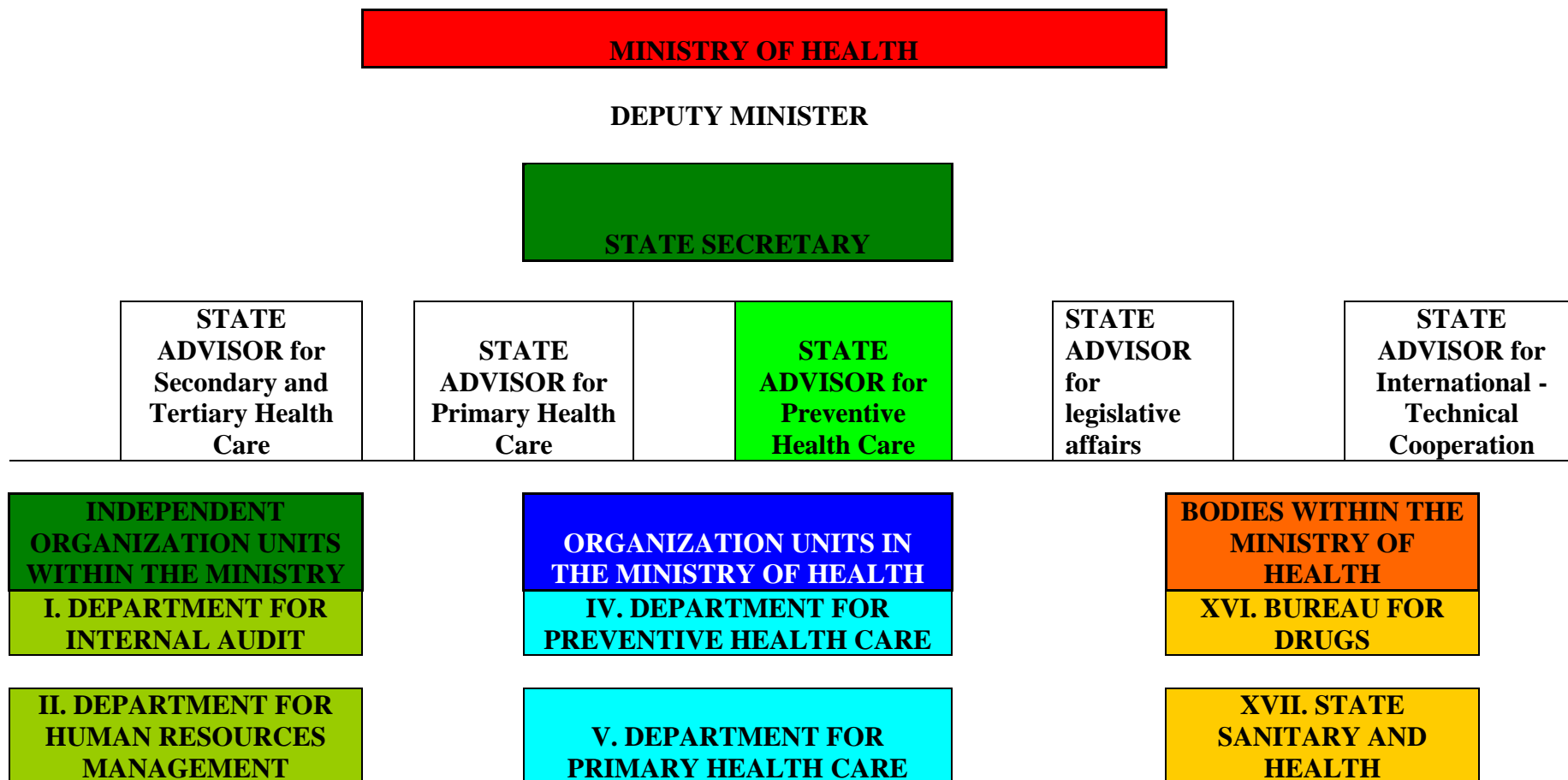
In the event that conditionalities are not met, suspension or cancellation of projects will be considered.

**ANNEX 2 - Amounts (in €) contracted and disbursed by quarter over the full duration of the project (IPA funds only)**

<b>Contracted</b>	<b>2010</b>	<b>2011</b>				<b>2012</b>				<b>2013</b>			
	<b>Q4</b>	<b>Q1</b>	<b>Q2</b>	<b>Q3</b>	<b>Q4</b>	<b>Q1</b>	<b>Q2</b>	<b>Q3</b>	<b>Q4</b>	<b>Q1</b>	<b>Q2</b>	<b>Q3</b>	<b>Q4</b>
TA Service		433 800											
Supply		463 350											
<b>Cumulated</b>		<b>897 150</b>											
<b>Disbursed</b>													
TA Service		173 520		173 520			86 760						
Supply		278 010			185 340								
<b>Cumulated</b>		<b>451 530</b>		<b>625 050</b>	<b>810 390</b>		<b>897 150</b>						

**ANNEX 3 - Description of Institutional Framework**

**- ORGANIGRAM  
The Ministry of Health**





**III. CDEPARTMENT FOR STRATEGIC PLANNING, POLICY MAKING AND MONITORING**



**HEALTH SECTOR MANAGEMENT PIU**



**PIU for the Projects for reconstruction and building of the HEALTH CARE INSTITUTUINS**



**VI. DEPARTMENT FOR SECONDARY AND TERTIARY HEALTH CARE**

**VII. DEPARTMENT FOR HEALTH INSURANCE, MONITORING AND CONTROL OF THE HIF**

**VIII. DEPARTMENT FOR HEALTH MANAGEMENT AND INFORMATIC TECHNOLOGY**

**IX. DEPARTMENT FOR EU INTEGRATION**

**X. DEPARTMENT FOR LEGISLATIVE AFFAIRS**

**XI. DEPARTMENT FOR INTERNATIONAL COOPERATION AND TECHNICAL ASSISTANCE TO THE CABINET**

**INSPECTORAT**

**XVIII. FOOD DIRECTORAT**

**XII. DEPARTMENT FOR  
HEALTH SECTOR FOR  
CRISES MANAGEMENT IN  
HEALTH SECTOR AND  
DONATIONS**

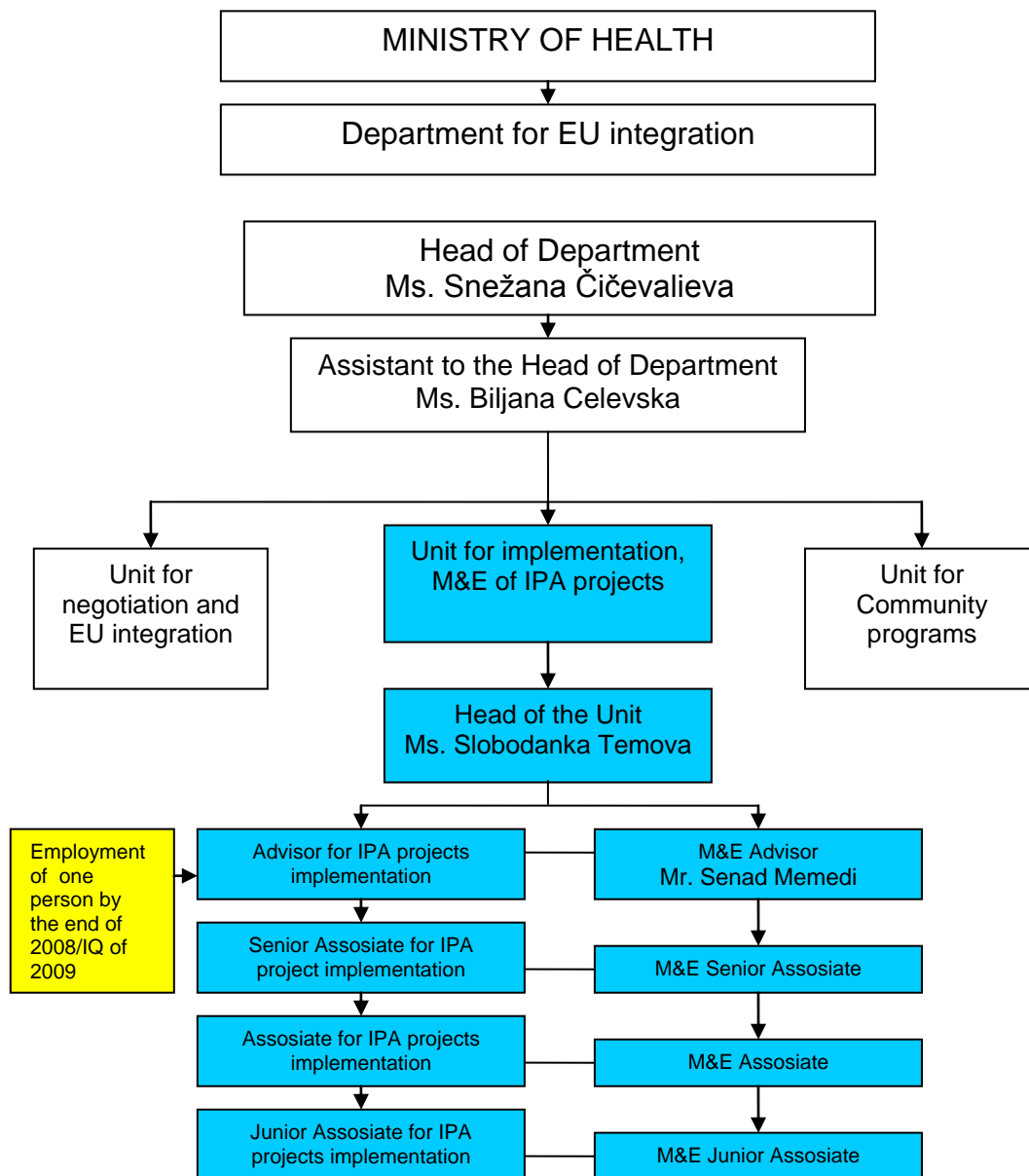
**XIII. DEPARTMENT FOR  
DENTAL HEALTH CARE**

**XIV. DEPARTMENT FOR  
BUDGET PLANNING, PUBLIC  
PROCUREMENT AND  
HEALTH CARE  
INVESTEMENT**

**XV. DEPARTMENT FOR  
COMMON ISSUES**

- Introduction of the **Ministry of Health** is the competent authority responsible for:
  - health protection and health insurance of the population in the former Yugoslav Republic of Macedonia ;
  - pollution of air, water, ground and food pollution;
  - organization and development of the health;
  - monitoring of the health status of the population;
  - health protection of the population from communicable diseases, gas, ionization radiation, noise, air pollution, water and ground;
  - food safety and product for general use;
  - sanitation - epidemiology condition;
  - medicinal product and medical devices;
  - poisons and narcotic drugs;
  - control in the field of health;
  - other matters determent by the laws (Law for safety of blood and blood components, (Official Gazette of No. 110/2007).

**- ORGANIGRAM**  
**(Department for EU Integration in the Ministry of Health)**



NOTE: Only positions in the Unit for IPA projects implementation are shown



## **- Introduction of the Department for EU Integration, positions, working tasks and duties**

### **• Head of Department for European Integration**

Goals: Management, monitoring and coordination of the policies and activities related to the process of EU accession, take care for complete implementation of the obligations established in the Operational Agreement concluded with CFCD, deliver information on the budget needed for national co-financing and programmed IPA budgets; continuously monitor information from the community programme for public health and deliver information to the relevant sectors

#### Working tasks and duties:

- manage the department, organize, coordinate the work of the Department and give instructions, guidance and expert assistance, take care on professional improvement and discipline of the personnel;
- monitor, analyze, coordinate, revise, approve and prepare documents needed for providing timely response to the obligation derived by process of EU accession in the field of health, continuously cooperate with the secretariat for European affairs, and with the other departments in the Ministry of Health and other relevant departments;
- provide opinion on harmonization of national legislation with international norms and standards, with EU legislation and implement activities for support and realisation of the association negotiation, NPAA planning and programming, SAA implementation, support activities of the relevant SAA bodies;
- prepare reports on NPAA and SAA implementation;
- manage the IPA programming process, encourage development of projects in the health area and provide technical and expert support to their implementation, take care about implementation of the obligations established in the Operational agreement concluded with CFCD, provide information on the budget needed for national co-financing and programmed IPA budgets, prepare criteria for selection of the specific bodies;
- control the process of project fiche preparing, preparing of the annual and multi-annual programs, ToRs, technical specifications and other documents needed for tender dossier preparation and continuously monitor projects implementation and communicate with the contractors;
- monitor the level of project implementation, prepare and deliver yearly and final reports;
- monitor the activities of different working groups for harmonization of national legislation with international norms and standards, as well as for the implementation of the SAA;
- Continuously monitor information from the Community health programmes and deliver information to the relevant departments and institutions, provide regular and continuous communication and coordination with the relevant institution, technical experts and NGOs involved in the projects implementation, monitor project implementation, provide project financial and program evaluation, perform assessment of the project results;
- provide data, quarterly and annual reports for the implemented and planned activities on regular basis to the Department for strategic planning, policy making and monitoring;

- in the framework of its authorization perform other duties and tasks given by the State Secretary.

- **Assistant to the Head of Department**

Goals: Provide assistance to the Head of department in the processes of Management, monitoring and coordination of the policies and activities related to the process of EU accession, suggest measures for directly involvement in their implementation, encourage development of the projects for technical assistance in the field of health

Working tasks and duties:

- provide expert assistance and advices to the Heads of Units;
- monitor, coordinate, analyze, revise, prepare and write materials and documents related to the process of EU accession in the field of health in order to provide on time response to all obligation deriving from the process;
- participate in the work of different inter-ministerial working groups and bodies, organise and provide support and participate in the process of negotiation for EU accession;
- provide materials and prepare opinions with regards to the harmonization of national legislation with international norms and standards;
- monitor, coordinate, analyze, revise, prepare and write materials and documents related to the response deriving from the WTO membership;
- continuously monitor information from the community programme for public health and deliver information to the relevant sectors, provide regular and continuous communication and coordination with the relevant institution, technical experts and NGOs involved in the projects implementation, monitor project implementation, provide project financial and program evaluation, perform assessment of the project results;
- control the process of IPA programming, encourage development of projects in the health area and provide technical and expert support to their implementation, take care about implementation of the obligations established in the Operational agreement concluded with CFCD;
- control the process of project fiche preparing, preparing of the annual and multi-annual programs, ToRs, technical specifications and other documents needed for tender dossier preparation and continuously monitor projects implementation and communicate with the contractors;
- monitor the level of project implementation, prepare and deliver yearly and final reports;
- provide data, quarterly and annual reports for the implemented and planned activities on regular basis to the Department for strategic planning, policy making and monitoring;
- substitute Head of Department with all his authorizations and responsibilities in case of his absence; prepare reports on the department activities.

## **- UNIT FOR IPA PROJECTS IMPLEMENTATION**

- **Head of Unit for implementation, monitoring and evaluation of IPA projects**

Goals: Programming of IPA, priority planning, preparing, assisting and monitoring of the project implementation

Working tasks and duties:

- Performing tasks in accordance to the instructions of the head of Department, monitor the work of the Unit, provide instructions for implementation of the working tasks and monitor and evaluates their performance, take care for complete implementation of the working tasks established in the Operational agreement concluded with CFCD;
- Participate in preparing project fishes, annual and multiannual programs, preparing ToR, technical specification and other document needed for tenders;
- prepare and deliver to CFCD: procurement plans, documents for concluding contracts, provide data for planning budget needed for national co-financing and programmed IPA budget;
- prepare draft list of the members of the Commission for evaluation (for CFCD) and take care for their presence on the meeting in CFCD;
- Organise on- site visits before concluding contracts/if necessary/ and provide for technical assistance to CFCD while concluding contacts;
- monitor the level of project implementation, prepare and deliver annual and final reports.

- **Advisor for IPA projects implementation**

Goals: participation in programming of IPA, priority planning, preparing, assisting and monitoring of the project implementation

Working tasks and duties:

- Performing tasks in accordance to the instructions of the head of Unit analyze NPAA and participate in planning of the needs according to NPAA, participate in coordination and preparing the project fishes and annual and multi-annual programs;
- Participate in preparing ToR, technical specification and other documents needed for preparing tender dossier;
- participate in preparing and delivering the procurement plan to the CFCD and documents needed for concluding contracts;
- prepare and deliver to CFCD documents related to the tender procedure;
- participate in preparing draft list of the members of the Commission for evaluation (for CFCD) and take care for their presence on the meeting in CFCD;
- Organize on- site visits before concluding contracts/if necessary/ and provide for technical assistance to CFCD while concluding contacts;
- Continuously monitor level of implementation of the projects and communicative with the contractor;
- prepare technical meetings and other events, perform other duties in accordance with the given instructions, monitor implementation of other projects and analyze project complementarity and their programme and financial management, participate in

coordination of the work of the beneficiary of technical assistance and propose harmonized administrative procedures for financial management of the assistance;

- monitor the level of project implementation, prepare analytical reports;
- cooperate on regular base with the Secretariat for European affairs and Ministry of Finance on issues related to technical assistance and programs developed in the framework of IPA;
- continuously monitor calls for financing of the projects from EU, other EU organizations and association, perform assessment of the possibilities for application in accordance to the needs presented in NPAA and adopted public health strategies;

- **Advisor for Monitoring and evaluation**

Goals: monitoring and evaluation of the implementation of the Operational programme and IPA projects

Working tasks and duties:

- Performing tasks in accordance to the instructions of the head of Unit, participate in programming and coordination of the activities of different departments related to EU accession and realisation of the activities of Ministry of Health and other relevant departments as established in NPAA and other strategic documents;
- monitor the level of projects implementation and prepare reports, sectorial yearly reports and propose reports changes;
- participate in the meetings of Sectorial M&E Committee and prepare documentation necessary for the annual meetings of the Committee;
- prepare annual and final reports for operative programs; prepare reports during the implementation of the projects (read/approved);
- follows the achievement of the tasks and results from the activities taken in the framework of operational programme and delivering of the related information to CFCD, follows irregularities and inform CFCD of the determined irregularities;
- organize technical meeting and meetings related to field of work, prepare documents needed for the work of inter-ministerial working groups;
- monitor the implementation of the EU rules for logo and format;
- prepare projects tasks for performing evaluation by external persons;
- continuously cooperate with Secretariat for European affairs, Ministry of Finance, as well as with other departments in the Ministry of Health;

- **Senior Associate for IPA projects implementation**

Goals: participation in programming of IPA, assistance in preparing and monitoring of the projects implementation

Working tasks and duties:

- Performing tasks in accordance to the instructions of the head of Unit, analyze NPAA and participate in planning of the needs according to NPAA, provide assistance in preparation of the project fiche and provide documentation needed for preparing annual and multi-annual plans;
- provide assistance in preparation of the technical specification and other documents needed for preparing tender dossier;
- assist in preparing and delivering the procurement plan to the CFCD;
- assist in preparing documents related to the tender procedure;

- prepare technical meetings and other events related to the work of the Commission for evaluation and prepare minutes from the meetings;
- assist in organization of the on-site visits before concluding contracts/if necessary/ and provide for technical assistance to CFCD while concluding contacts;
- Continuously participate in the process of monitoring the level of implementation of the projects and communication with the contractor;
- assist in the monitoring of implementation of other projects and analyze project complementarity and their programme and financial management, participate in coordination of the work of the beneficiary of technical assistance and propose harmonised administrative procedures for financial management of the assistance;
- cooperate on regular base with the Secretariat for European affairs and Ministry of Finance on issues related to technical assistance and programmes developed in the framework of IPA;
- continuously monitor calls for financing of the projects from EU, other EU organizations and association, perform assessment of the possibilities for application in accordance to the needs presented in NPAA and adopted public health strategies.

- **Senior Associate for Monitoring and evaluation**

Goals: monitoring and evaluation of the implementation of the Operational programme and IPA projects

Working tasks and duties:

- Performing tasks in accordance to the instructions of the head of Unit assist in programming and coordination of the activities of different departments related to EU accession and realisation of the activities of Ministry of Health and other relevant departments as established in NPAA and other strategic documents;
- Assist in monitoring the level of projects implementation and prepare reports, - prepare sectorial yearly and final reports, prepare analyze and participate in proposal for reports changes;
- assist in preparation of the annual and final reports for operative programmes; prepare reports during the implementation of the projects (read/approved);
- follows the achievement of the tasks and results form the activities taken in the framework of operational programme and delivering of the related information to CFCD;
- participate in preparation of analytical documents and distribution of information and reports for the status of project realisation;
- prepare technical meeting and meetings related to field of work, prepare documents needed for the work of inter-ministerial working groups, propose written procedures(protocols) and indicators for coordination, M&E in agreement with Secretariat for European Affairs and other relevant sectors;
- -continuously cooperate with Secretariat for European Affairs, Ministry of Finance, as well as with other departments in the Ministry of Health.

- **Associate for IPA projects implementation**

Goals: participation in programming of IPA, priority planning, assistance in preparing and monitoring of the projects implementation

Working tasks and duties:

- Performing tasks in accordance to the instructions of the head of Unit provide technical and expert support and participate in the work of the working group;
  - provide information and data needed for implementation of the projects, collect and deliver data needed for analyze and development of the projects, provide data needed for preparing technical specifications and other documents for the tender dossier;
  - provide information to the Public Relation Unit on the status of the projects;
  - create and maintain data base for the projects;
  - monitor implementation of other projects and prepare information on their financial and administrative management;
  - participate in preparation of the technical meetings and other events, prepare minutes and perform other tasks in accordance with the instructions given by the Head of the Unit.
- **Associate for Monitoring and evaluation**

Goals: monitoring and evaluation of the implementation of the Operational programme and IPA projects

Working tasks and duties:

- in accordance to the instructions of the head of Unit, participate in preparation of the plans for Operational programme and IPA projects;
  - provide documents needed for monitoring of the level of project implementation and for preparation of reports;
  - assist in preparation of the annual and final reports for operative programmes, as well as in preparation of the reports during the implementation of the projects;
  - provide documentation and information needed for programming, monitor the realisation of the training programme for human capacity building in the fields of M&E, and realisation of the training programmes related to EU;
  - participate in the preparation of the analytical documents and distribute information and reports on the status of implementation of the IPA projects and other strategic documents, programmes and projects;
  - deliver reports to the Public Relations Unit and to the Department for Strategic planning;
  - continuously cooperate with Secretariat for European Affairs, Ministry of Finance, as well as with other departments in the Ministry of Health.
- **Junior Associate for IPA projects implementation**

Goals: participation in preparing and implementation of IPA projects

Working tasks and duties:

- Performing tasks in accordance to the instructions of the head of Unit provide documents, administrative and technical support and participate in the work of the working group preparing the project documentation;
- Collect information and data needed for analyze and development of the projects;
- provide information to the Public Relation Unit on the status of the projects;

- create and maintain data base for the projects;
- participate in organization and keep evidence on performed project management trainings;
- participate in preparation of the documents for technical meetings, organize meeting, and other events, prepare minutes and perform other tasks in accordance with the instructions given by the Head of the Unit.

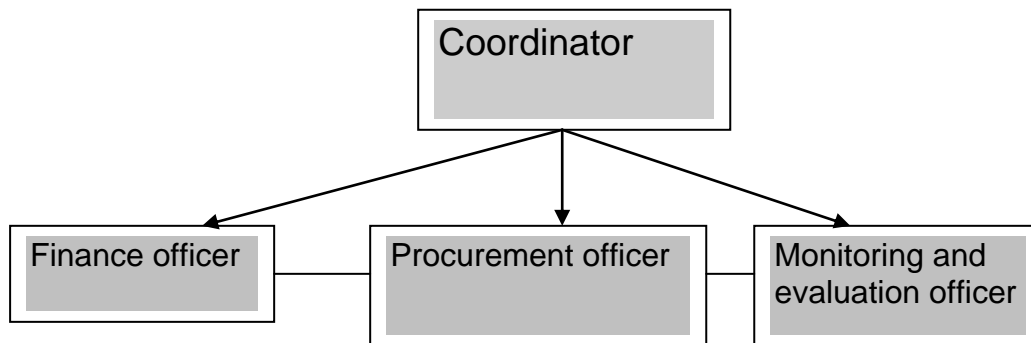
- **Junior Associate for Monitoring and evaluation**

Goals: monitoring and evaluation of the implementation of the Operational programme and IPA projects

Working tasks and duties:

- in accordance to the instructions of the head of Unit, participate in preparation of the plans for Operational programme and IPA projects;
- provide documents needed for monitoring the level of project implementation and for preparation of reports;
- assist in preparation of the annual and final sectorial reports;
- monitoring of the programming and realisation of the training programme for human capacity building in the fields of M&E, and realisation of the training programmes related to EU, maintain evidence for trainings;
- participate in the preparation of the technical meetings of the MoH working groups, as well as for the inter-ministerial working groups in the relevant fields and prepare minutes from the meetings;
- Monitor and distribute information and reports related to the status of IPA projects and keep evidence;
- continuously cooperate with Secretariat for European Affairs, Ministry of Finance, as well as with other departments in the Ministry of Health.
- Introduction of the Project Management and Administration (Steering Committee)

## Organigramme of the Project Management and Administration (Steering Committee)



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For the purpose of this project a **Project Management and Administration (Steering Committee)** will be established. The leading beneficiary institution is the Ministry of Health. The co-beneficiary is National Institute for Transfusion Medicine, Skopje, the former Yugoslav Republic of Macedonia .

The SPO from the Ministry of Health for implementation of the project is Mrs. Snezana Cicevalieva, Head of the Sector for European integration.

The Steering Committee for implementation of the project will be consisted of:

- Prim Dr. Risto Dukovski, as a program coordinator;
- Prof. Dr. Olga Todorovska, as a monitoring and evaluation officer;
- Mr. Adelon Latifi, as a finance officer;
- Mr. Bobi Bozinovski, as a procurement officer.



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

### **Referent List of relevant laws and regulations**

Key laws and the regulations in the field of blood safety are:

- Law for health protection, Official Gazette No. 38/91, 46/93, 55/95, 10/2004, 111/2005, 65/2006, 5/2007 and 77/2008);
- Law for health protection of the population from communicable diseases (Official Gazette No. 66/04 and 139/08);
- Law for safety of blood and blood components, (Official Gazette No. 110/2007).

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

Reference to **SAA** (2001): The program will contribute towards the implementation of the SAA Article 68 on approximation of legislation.

**Reference to NPAA:** The National Plan for Adoption of Acquis includes several short term and medium term priorities in the field of blood safety, as it follows: to further legal development and harmonization of legislation with the Acquis, to strengthen administrative and technical capacity in order to implement the legislation and EU standards, especially the following ones: 32002L0098, 32004L0033, 32005L0061, 32005L0065 and Council Recommendation 98/463.

**Reference to the Progress Report (2008):** The latest progress report makes the following evaluation: “Progress was made in the field of public health. Implementing of the blood safety and quality strategy was postponed owing to insufficient financial resources. Preparations in this field have started. “

### **Reference to the MIPD:**

Ability to assume the obligations of membership and approximation to European standards /harmonise quality infrastructure standards with EU standards:

- This Project is responding to priorities 28. Consumer and Health Protection, Public Health;
- Improved risk assessment will provide for improved safety of blood and blood components and will provide for improved application of international (EU) and harmonized national standards for blood safety.

### **Reference to the National Development Plan**

It stipulates **strengthening and improvement of health, prevention of the diseases and insurance of quality of the health services**, as well as reducing of at least 1/3 of the existing differences in the health status of the population of the former Yugoslav Republic of Macedonia and population from the EU countries.

### **Reference to national / sectorial plans**

Links with national plans refer especially to:

- National Health Strategy;
- National Strategy on Prevention and Control of HIV/AIDS; and
- Law for Safety of Blood and Blood Components (Official No. 110/2007).

## **ANNEX 5: Details per EU funded contact (\*) where applicable**

### **Management and contracting arrangements**

Project Management and Administration (Steering Committee) will be established, that will consist of 1 project coordinator, 1 M&E officer, 1 procurement and 1 finance officer.

A program coordinator will be responsible for overall program management, representation (co-ordination with the EU and other international bodies) as well as reporting, and financial management, coordination with international and national bodies and reporting. Internal protocol for performing of duties and responsibilities of Steering Committee and its staff will be written and implemented. The co-ordination of activity is significantly important. The program coordinator is responsible for an appropriate management of resources. During the inception phase of the project, a detailed deployment plan will be developed.

The detailed project management and implementation structure, with full descriptions of roles and responsibilities will be proposed during the preparation of ToRs.

### **The expected contracting arrangements are:**

- 1 service contract will be concluded following an open international tender process. The contract has an expected duration of 12 months, and is expected to be signed in the 1st quarter 2011 and have a budget of EUR 482 000 (IPA funds of EUR 433 800 and national co-financing of EUR 48 200)
- 1 supply contract will be concluded following an open international tender process. The contract has an expected duration of 12 months, and is expected to be signed in the 1st quarter 2011 and have budget of EUR 617 800 (IPA funds of EUR 463 350 and national co-financing of EUR 154 450)

### **Estimated budget breakdown by activity:**

Activity 1 - Book of regulations on blood safety developed and adopted EUR 14 400.

Activity 2 - Guidelines on blood safety developed and printed EUR 6 720.

Activity 3 - Practitioners' guide on blood safety developed and printed EUR 12 800.

Activity 4 - Strengthening of the blood safety system through development and implementation of training programs for health professional EUR 108 600.

Activity 5 - Training provided, according to the requirements for continuous medical education for implementation of quality assessment standards, of standard operational procedures, of good laboratory practice, of separation processes, as well as components processing, for the health professionals, 30 in total (external training) EUR 135 000.

Activity 6 - On-site training provided, in blood transfusion institution in EU country for the period of 3 months, for 12 health professionals EUR 168 000.

Activity 7 - Strengthening of the blood safety system through provision of equipment IT supplies, including laboratory. Equipment EUR 617 800.

Activity 8 - Project Management and Administration (Steering Committee) EUR 36 480.

**Appendix 1a: Indicative list of equipment for the supply contract**

<b><u>Blood Transfusion Service (BTS)</u></b>	<b><u>Type of equipment</u></b>							
	Blood bags cold centrifuges	Refrigerators on - 40° C	Refrigerators on - 80° C	Refrigerators on + 4° C	Platelet incubators	IT Server	Personal Computer	Lap top
Skopje	2	2	2	4	2	1	11	6
Bitola	1	1	1	1	1		3	1
Stip	1	1		1	1		3	1
Tetovo	1	1		1	1		3	1
Ohrid				1			1	
Prilep				1			1	
Struga				1			1	
Strumica				1			1	
Kocani				1			1	
Gevgelija				1			1	
Delcevo				1			1	
Gostivar				1			1	
Kicevo				1			1	
Veles				1			1	
Kumanovo				1			1	
Kavadarci				1			1	
Negotino				1			1	
Kriva Palanka				1			1	
<b>TOTAL</b>	<b>5</b>	<b>5</b>	<b>3</b>	<b>20</b>	<b>5</b>	<b>1</b>	<b>33</b>	<b>9</b>