<u>Standard Summary Project Fiche – IPA decentralised National programmes</u> (maximum 12/<u>15</u> pages without the annexes)

1. Basic information

1.1 CRIS Number: TR080215

1.2 Title: Strengthening the Blood Supply System1.3 Sector: 03.28 – Consumer and Health Protection

1.4 Location: Turkey

Implementing arrangements:

1.5 Implementing Agency:

The CFCU will be Implementing Agency and will be responsible for all procedural aspects of the tendering process, contracting matters and financial management, including payment of project activities. The director of the CFCU will act as Programme Authorizing Officer (PAO) of the project.

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Söğütözü/Ankara Turkey

1.6 Beneficiary (including details of SPO):

Ministry of Health; General Directorate of Curative Services

MDr. Alaattin Dilsiz (Deputy General Director of Curative Services)

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Turkey

1.7 Overall cost:

€3,217,000

1.8 EU contribution:

€2,776,800

1.9 Final date for contracting:

2 years after the signature of the Financing Agreement

1.10 Final date for execution of contracts:

2 years following the end date for contracting

1.11 Final date for disbursements:

3 years following the end date for contracting.

2. Overall Objective and Project Purpose

2.1 Overall Objective:

The overall objective of the project is to contribute to the implementation of the EU *acquis communautaire* in the area of public health, specifically focusing on the strengthening and effective functioning of blood supply system in Turkey.

2.2 Project purpose:

To develop a national blood programme that is regional blood centre based and that is underpinned with legislation, national guideline, human resources as an experts committee and trainers and a data management system.

2.3 Link with AP/NPAA / EP/ SAA:

Council Decision of 23 January 2006 on the principles, priorities and conditions contained in the Accession Partnership with Turkey (2006/35/EC), emphasizes alignment with the acquis under the chapter of consumer and health protection as a significant priority.

In this regard, this project aims to ensure effective implementation of the following EU legislation in Turkey:

- 1. Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments.
- 2. Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events.
- 3. Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components.
- 4. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC

5. The Council of Europe's Guide to the preparation, use and quality assurance of blood components - 13th edition (2007), for alignment with standard requirements in terms of quality, safety and adequacy.

The new blood law (Law on Blood and Blood Products, No: 5624, OJ No: 26510, 02.05.2007) published in May 2007 describes a centralized system composed of regional blood centres, transfusion centres and donation centres as blood establishments

A draft by-law has been prepared by the MoH and will be published upon receiving opinions from relevant stakeholders.

2.4 Link with MIPD:

The MIPD for Turkey 2008-2010 includes "ability to assume the obligations of membership and adoption and implementation of the acquis communautaire" as priority axis 2. This project aims to ensure effective implementation of blood and blood product related EU Acquis in Turkey.

2.5 Link with National Development Plan (where applicable):

Priority No. 240 of the 9th Development Plan sets "improvement of health information systems" as a priority. This project will set up an information system that will include all necessary data as regards institutional capacity of MoH in the field of managing regional blood centre based blood banking and transfusion system.

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

Result 7 of the project is related with the specific objective of "Citizen Focused Service Provision" plan prepared by the State Planning Organization "sharing of stocks in blood banks and single point searching for blood with the help of electronic channels (SMS, the internet, etc.)" defined under the "Article 33: Data Sharing In the Blood Banks".

3. Description of project

3.1 Background and justification:

Blood is a very critical therapeutic material, the source of which is only human. Therefore it is the subject of multidisciplinary science. During the last decades acquired immunodeficiency virus and other infectious agents transmitted by blood directly affected the safety of blood supply and led to a set of requirements for blood banks.

To provide safe, efficient and adequate blood and blood components to all citizens is the primary responsibility of the Ministry of Health (MoH). The Ministry is expected to fulfil this responsibility through a well established national blood policy.

The national blood policy should address the following issues:

• Supply of safe and adequate blood, blood components and blood products

- Strengthening the structure and organisation of blood establishments throughout the country
- Strengthening the functional capacity of blood establishments
- Technical support for the blood establishments in line with current global standards
- Organisation of voluntary, non-remunerated and regular blood donors with national donor programmes
- Optimal use of blood, blood components and blood products
- Strengthening the human resources in blood banking and transfusion services
- Provision of supervision, inspection and auditing for blood banking and transfusion services
- Organisation of research in blood banking and transfusion

National blood policy should be a part of the national health programme. Blood establishments are key elements both in the national health care system in the country and in the implementation of the national blood policy. With the adoption of the "safe blood" strategy in the national blood policy and the introduction of a well-functioning system of transfusion services; adequate, safe and efficient supply of blood components can be guaranteed.

The Ministry of Health of Turkey is the main authority regulating and auditing the services related with blood and blood products throughout the country. The Directorate General for Curative Services of the MoH is responsible for:

- Preparation of legislation related with quality, safety and adequacy of the blood supply and transfusion system;
- Training and certificating the personnel working in blood establishments;
- Supervising and inspecting the blood establishments;
- Collecting and analysing the data from the blood establishments;
- Providing the data related with blood transfusion system to the international bodies; is the General Directorate of Curative Services under the Ministry of Health.

Blood Banking and Transfusion Society of Turkey (BBTST), founded in Istanbul in 1996, is the primary nongovernmental organisation in the country that has the specific objectives of producing training materials and related documents, organising courses, national congresses and publishing books in close cooperation with the MoH. BBTST has organised nine national courses so far, mostly with two levels as basic and advanced, one international congress in 2003 (Regional Congress of ISBT), two national congresses in 2000 and 2007.

There are different models of blood supply systems worldwide. Blood supply system in Turkey has long been a hospital based and decentralized one. According to the previous law published in 1983, all the hospitals that is around 800-1500 in number are obliged to organise blood supply and transfusion services on their own and it is very hard to

standardise and control such a system composed of small blood centres, all collecting blood less than 1.000 annually.

In Turkey hospital blood banks collect approximately 70 % of the annual blood supply and Turkish Red Crescent (TRC) blood banks collect the rest. The main donor type is replacement in hospital blood banks although TRC has put donor education, recruitment programmes into its strategic plans. Turkish Red Crescent blood banks are in a reorganisation plan; yet they are far from fulfilling the national needs.

The new blood law (Law on Blood and Blood Products, No: 5624, OJ No: 26510, 02.05.2007) published in May 2007 describes a centralized system composed of regional blood centres, transfusion centres and donation centres as blood establishments. Switch from a hospital based system to a centralized system based on regional blood centres is required. The organisation of the blood supply system and the transfusion system according to the new law requires to review the current system and to reorganise it with a strategic plan and an activity plan.

A by-law has been prepared by the chairmanship of the MoH and is about to be published. There is still need to adopt the following EU legislations:

- Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components
- Directive 2005/62/EC implementing Directive 2002/98/EC as regards Community standards and specifications relating to a quality system for blood establishments
- Directive 2005/61/EC implementing Directive 2002/98/EC as regards traceability requirements and notification of serious adverse reactions and events
- Directive 2004/33/EC implementing Directive 2002/98/EC as regards certain technical requirements for blood and blood components

There is no national guideline of blood banking and transfusion in Turkey. The Council of Europe's Guide to the preparation, use and quality assurance of blood component-9th edition has been translated into Turkish by BBTST. There is still need to adopt 13th edition (2007) as a national guideline.

In Turkey the blood supply and transfusion statistics are obtained from the blood centres by the MoH as paper work in a limited adequacy. The statistics form is filled monthly by the responsible person in the blood centre and is sent to the MoH by a formal letter through the provincial health directorate.

According to the statistics of the MoH; total number of blood donors is 1.177.209 and total number of donations is 1.282.526 in the year 2005 and total number of blood donors 1.300.932 and donations 1.327.234 in the year 2006. Of the 1.177.209 donors 430.312 are voluntary, 16.530 are paid, 625.778 are replacement and 104.589 are insignificant in 2005. Same figures for the year 2006 are 567.421 (43.6 %), 30.358 (2.3 %) and 703.153 (54.1%) respectively. Concerning the separation of whole blood to its components; in the year 2005 814.337 units were separated to erythrocyte whereas 738.342 units of erythrocyte suspensions were prepared for the year 2006. Total number of aphaeresis thrombocytes prepared in 2005 is 44.708 units and in 2006 56.747 units.

A questionnaire distributed by BBTST in 2004 revealed that of the 227 blood centres that responded the questionnaire 88.1 % have blood storage refrigerators, 27.2% use

temperature controlled transport system for transfer of blood components, 30.2 % run a quality system, 4.3 % provide external proficiency samples and 25.4 % collect autologous donations.

This project is expected to contribute primarily to the institutional capacity of the Ministry of Health to regulate, supervise, inspect and audit blood banking and transfusion system in the country.

The achievements planned to be attained in the project are;

- To review the current system with sufficient detail to have the data required for reorganisation plan. This is planned to be performed in province and district level all around the country which enables to have the inventory of all centres with their capacity, equipment, buildings, list of personnel, processes etc.,
- To make a reorganisation plan for the blood banking and transfusion system enabling EU legal alignment together with the planning of regional blood centre locations, numbers, linked transfusion centres again with capacities, buildings, equipment, functions, structure, personnel, processes etc.
- Organisation of an experts committee (medical doctors of five years experience in management of blood centres), training of the committee to have a further capacity on national and international issues related with centralization and management of regional blood centres,
- Establishment of lacking regulation in terms of EU legal alignment,
- Establishment of national blood banking and transfusion standard
- Training of trainers (medical doctors of one year experience in blood banking) and organisation of a supervision model for the system and
- Acquisition of a data management system with software, hardware and network for the blood banking and transfusion services including the central authority, regional blood centres, transfusion centres and donation centres.
- **3.2** Assessment of project impact, catalytic effect, sustainability and cross border impact (where applicable)

Project impact: Blood is a unique therapeutic material the source of which is only human. It is essential for the treatment of a number of diseases; on the other hand it carries major risks for adverse events foremost the infectious, haemolytic and alloimmunisation complications. Blood and all activities related with blood carry important consequences related with health promotion. This project is expected to increase the safety and quality of this unique therapeutic material and have an impact on the health promotion by decreasing the infectious and other complications.

Catalytic effect: By improving the quality, safety and adequacy of the blood transfusion system, infectious burden in the population is expected to decrease concerning the pathogens transmitted by blood. The reorganization of the blood supply system helps citizens to have safe blood when needed. The decrease in infectious

burden sourcing from transmission through blood in Turkey would decrease the infectious burden in the region concerning viral agents like hepatitis viruses, HIV, bacterial agents like Treponema and parasitic agents like malaria etc.

Sustainability: The sustainability of the project in large depends on political decisions of the governments concerning resources (both financial and human) and institutions. Organisation of a national audit system for the blood establishments, developing a training model for blood banking and transfusion and finally voluntary donor organisation are the critical steps required to follow for the sustainability of the outputs of the project.

Cross border impact:

N/A

3.3 Results and measurable indicators:

Results and measurable indicators in relation with activity 1 Results and measurable indicators in relation with activity 2

. . . .

| Results | Objectively verifiable indicators |
|---|---|
| 1. Turkish blood legislation harmonized with that of EU. | Legislation for blood banking and transfusion published by the end of the project. |
| 2. Database necessary to develop a national blood program formed. | Situation analysis report published by third quarter of 2010. |
| 3. A reorganisation model for blood banking and transfusion for the whole country in line with requirements envisaged by relevant EU legislation developed and | National blood program adopted by first quarter of 2011. |
| reorganization plan published | Existing regional blood centres started to operate in line with the requirements set by the National Blood Program by the end of the project. |
| 4. Legal base and technical infrastructure | Standards of blood transfusion |
| for effective implementation of the standards of blood transfusion chain | communicated to blood |
| established. | establishments by last |

| | quarter of 2010. |
|--|--|
| 5. Human resources necessary for effective operation of a national supervisory body that would supervise and/or manage regional blood centres developed. | Experts committee of 20 professionals and 10 MoH staff further trained in managerial skills by the end of the project. |
| 6. Human resources necessary for an adequate, efficient, safe and high quality blood supply system that would operate in line with EU standards created. | At least 3 blood centre physicians from each of the 25 "health regions of the Ministry of Health" and 10 MoH – Directorate General for Curative Services staff certified as trainers for BCPT. |
| | At least 25 blood centre personnel from each of the 25 "health regions of the Ministry of Health" certified by BCPT. |
| 7. Regular flow of information between the blood establishments and national authority enabled. | Accurate information on blood supply available by the end of project. |

3.4 Activities:

Activity 1 (including **inputs** = precise list of **contracts** to be deployed in relation to it / including where applicable national-funded contracts concurring to the activity as well as identification of source of co financing funding and its availability)

Activity 2

. . . .

Turkish Ministry of Health, Directorate General for Curative Services will provide the national co-financing for the project, which amount to €440,200. This

amount has already been included in the 2009, 2010 and 2011 budget planning of the above mentioned Directorate General.

The project includes **one service contract** and **one supply contract**. Activities 1.1 to 7.1 and software development related part of activity 7.2 will be carried out through the service contract, whereas hardware purchase related part of the activity 7.2 will be carried out through a supply contract.

Details of project activities are as follows:

Activities 1.1-1.4 aim to make a systematic and detailed analysis of the gap between the current legislation in Turkey and the European Union; and then to prepare the additional legislation accordingly. These activities will be performed through experts committee meetings.

Activities 2.1-2.4 aim to review the existing system in detail in province and district level and to provide a database accordingly. These are performed through a service contract by people with proven experience in the field of blood banking and transfusion.

Activities 3.1-3.4 aim to develop a reorganisation plan for blood banking and transfusion system in the country in light of the data provided by activities 2.1-2.5. These are performed through a service contract by people with proven experience in the field of blood banking and transfusion.

Activities 4.1-4.3 aim to develop a national guideline for blood banking and transfusion. These are performed by experts committee meetings.

Activities 5.1-5.6 aim to build up an experts committee of 20 professionals and 10 MoH staff in the country at national and international level. These are performed through a service contract by people with proven experience in the field of blood banking and transfusion.

Activities 6.1-6.8 aim to build up a team of trainers of 75 people in blood banking and transfusion in the country and 10 MoH staff. These are performed through a service contract by people with proven experience in the field of blood banking and transfusion.

Activities 7.1-7.2 aim to develop a national data management system including the software, network and the hardware connecting MoH, regional blood centers, transfusion centers and donation centers. These are performed through a supply contract.

| Activities | Means |
|------------|-------|
| | |

- 1.1 EU legislation on blood translated into Turkish, current translated versions revised.
- 1.2 Gap analysis between blood related Turkish legislation in force and EU legislation conducted.
- 1.3 Draft texts of Turkish blood legislation in conformity with relevant EU legislation prepared and
- 1.4 Legal procedures for official publication of draft legislation initiated.
- 2.1 Data collection team of 50 experts (2 experts for each of the 25 health regions of Turkey) composed.
- 2.2 Data to be analysed determined.
- 2.3 Materials and methods for data collection and analysis determined
- 2.4 Data collected and analysed
- 3.1 EU member country national blood programmes examined 3.2 Study visits to EU member countries performed to examine well-functioning systems in place 3.3 Taking the situation analysis report (see result 2) into consideration, the number and locations of the regional blood centers to be established throughout the country determined
- 3.4 The requirements for prospective regional blood centres, their planning in terms of buildings and infrastructure; personnel management system; equipment, consumables and technical sufficiency; total quality management system and data management system determined

1 Service Contract €2,427,000 1 Supply Contract €790,000

- 4.1 EU country guidelines and implementation procedures of these guidelines in EU member countries analysed.
- 4.2 National guideline(s) for blood banking and transfusion services that supports the implementation of 2002/98/EC, 2004/33/EC, 2005/61/EC, 2005/62/EC directives developed.
- 4.3 National guidelines published.
- 5.1 The number and qualifications of the Experts Committee, which would form the basis of future supervisory body, determined.
- 5.2 Members of Experts Committee selected.
- 5.3 Training needs of the Experts Committee determined
- 5.4 Training program established
- 5.5 Expert Committee training performed
- 5.6 Training certified.
- 6.1 Training needs analysis (TNA) for "blood centre personnel training (BCPT)" conducted.
- 6.2. TNA for "training of trainers (ToT)" conducted. 6.3 Qualifications and number of trainees for BCPT and ToT determined in accordance with TNA.
- 6.4 Training programs and schedules for BCPT and ToT determined.
- 6.5 ToT performed.
- 6.6 ToT measured and certified
- 6.7 BCPT performed by trainers certified by ToT.
- 6.8 BCPT measured and certified.
- 7.1 Data sets to be transferred among blood establishments and national authority formed.
- 7.2 Software and hardware necessary for data transfer and analysis(National Blood Program Information System) established at the MoH premises.

3.5 Conditionality and sequencing:

The tender for this project can be launched on the condition that, by submitting a formal Declaration of Assurance, showing that the beneficiary has sufficient staff in a list for technical implementation and monitoring of the contract(s)

3.6 Linked activities:

National haemovigilance and transfusion risk mapping system- The Scientific and Technological Research Council of Turkey (Project is at the approval stage). The purpose of this project is to establish a national haemovigilance system. The duration of project is proposed to be three years. Since the project is in proposal phase, the budget of the project is not prepared yet.

The specific objective of haemovigilance project is affirmative with the specific objective of this project.

3.7 Lessons learned

Depending on previous experience of the MoH on Implementation of IPA/Financial Cooperation projects, the Ministry decided to set up a project coordination team composed of 5 MoH staff that would elaborate on coordination and technical implementation of project activities. This project coordination team will include experts on both blood supply system and European Union experts, thus it aims to prevent possible delays during implementation period that may arise from lack of technical and procedural information and knowledge on the side of the beneficiary institution.

4. Indicative Budget (amounts in €)

| | | | | | | SOURCES OF FUNDING | | | | | | | |
|---|-----------|------------|--------------------|---------------------------|------------|---|---------------------------------|----------|-----------------------|----------------------------------|-------------------------|------------|----------|
| | | | TOTAL EXP.RE | TOTAL PUBLIC EXP.RE | | A COMMUNITY ONTRIBUTION 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) | % (3) |
| Activity 1: Technical Assistance to Ministry of Health for Strengtheni ng the Blood Supply System | | | | | | | | | | | | | |
| Contract 1: Service Contract | X | _ | 2,427,000 | 2,427,000 | 2,184,300 | 90 | 242,700 | 10 | 242,700 | 0 | 0 | 0 | 0 |
| Activity 2: Purchase of Equipment for Upgrading MoH Database Servers for the purposes of Data transfer between blood establishme nts and the MoH. | | | | | | | | | | | | | |
| contract 2: Supply | _ | X | 790,000 | 790,000 | 592,500 | 75 | 197,500 | 25 | 197,500 | 0 | 0 | 0 | 0 |

| Contract | | | | | | | | | | | |
|---------------|-----------|-----------|-----------|----|---------|----|---------|---|---|---|---|
| TOTAL IB | 2,427,000 | 2,427,000 | 2,184,300 | 90 | 242,700 | 10 | 242,700 | 0 | 0 | 0 | 0 |
| TOTAL INV | 790,000 | 790,000 | 592,500 | 75 | 197,500 | 25 | 197,500 | 0 | 0 | 0 | 0 |
| TOTAL PROJECT | 3,217,000 | 3,217,000 | 2,776,800 | 86 | 440,200 | 14 | 440,200 | 0 | 0 | 0 | 0 |

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))

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

| Contracts | Start of Tendering | Signature of contract | Contract Completion |
|------------|--------------------------------|--------------------------------|--------------------------------|
| Contract 1 | 2009 – 1 st Quarter | 2009 – 4 th Quarter | 2011 – 4 th Quarter |
| Contract 2 | 2010 – 2 nd Quarter | 2010 – 4 th Quarter | 2011 – 4 th Quarter |

Duration of the project: 39 months

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

6. Cross cutting issues (where applicable)

6.1 Equal Opportunity:

The project will apply the policy of equal opportunities for all groups.

6.2 Environment:

This project has no negative impact on environment.

6.3 Minority and vulnerable groups:

According to the Turkish Constitutional System, the word "minorities" encompasses only groups of persons defined and recognized as such on the basis of multilateral or bilateral instruments to which Turkey is a party. This project has no negative impact on minority and vulnerable groups.

ANNEXES

- 1- Log frame in Standard Format
- 2- Amounts contracted and Disbursed per Quarter over the full duration of Programme
- 3- Institutional Framework
 - * Role and responsibilities of the SPO
 - * frequency of project management meetings,
 - * who chairs, who attends and in what role
 - * coordination mechanisms for multi-beneficiary projects
 - * monitoring (roles, responsibilities of all actors)
- 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 Project Fiche | Programme name and number Strengthening the Blood Supply System – TR 080215 | |
|--|---|------------------------------|
| | Contracting period) expires 2 years after the signature of the Financing Agreement Total budget: €3,217,000 | in 3 years following the end |

| Overall objective | Objectively verifiable | Sources of Verification | |
|---|---------------------------------------|-------------------------|--------------------------------|
| To contribute to the implementation of the EU | indicators Turkish blood banking and | EU progress reports | _ |
| acquis communataire in the area of public health, | transfusion system is | Le progress reports | |
| specifically focusing on the strengthening and | operational in line with EU | Activity and progress | |
| effective functioning of blood supply system in | standards. | reports of the project. | |
| Turkey | | G 077 100 11 | |
| Project purpose | Objectively verifiable indicators | Sources of Verification | Assumptions |
| To develop a national blood programme that is | Blood supply system based on | MoH legislations | The Turkish government is |
| based on regional blood centres and underpinned | regional blood centres is | EU progress report | committed to sustain |
| with legislation, national guidelines, human | effective. | Project report | sufficient financial resources |

| resources and a data management system | | MoH statistics | |
|--|---|---|-------------|
| Results | Objectively verifiable indicators | Sources of Verification | Assumptions |
| 1. Turkish blood legislation harmonized with that of EU. | Legislation for blood banking and transfusion published by the end of the project. | Official Gazette | |
| 2. Database necessary to develop a national blood program formed. | Situation analysis report published by third quarter of 2010. | Semi – annual progress reports of the project. | |
| 3. A reorganisation model for blood banking and transfusion for the whole country in line with requirements envisaged by relevant EU legislation developed and reorganization plan published | National blood program adopted by first quarter of 2011. | Official declaration by the MoH on adoption of the National Blood Program. | |
| | Existing regional blood centres started to operate in line with the requirements set by the National Blood Program by the end of the project. | Activity reports of Regional Blood Centres. Inspection reports of the MoH. | |
| 4. Legal base and technical infrastructure for effective implementation of the standards of blood transfusion chain established. | Standards of blood transfusion communicated to blood establishments by last quarter of 2010. | Official records of Blood Services Department. Official letters to blood establishments. | |
| 5. Human resources necessary for effective operation of a national supervisory body that would supervise and/or manage regional blood centres developed. | Experts committee of 20 professionals and 10 MoH staff further trained in managerial skills by the end of the project. | Semi-annual progress reports of the project. Official records of the Ministry of Health. | |
| | | Meeting reports/minutes of | |

| 6. Human resources necessary for an adequate, efficient, safe and high quality blood supply system that would operate in line with EU standards created. 7. Regular flow of information between the blood establishments and national authority enabled. | At least 3 blood centre physicians from each of the 25 "health regions of the Ministry of Health" and 10 MoH – Directorate General for Curative Services staff certified as trainers for BCPT. At least 25 blood centre personnel from each of the 25 "health regions of the Ministry of Health" certified by BCPT. Accurate information on blood supply available by the end of project. | Experts Committee meetings. Training attendance sheets and reports. Semi-annual progress reports of the project. Official records of the Ministry of Health. Semi-annual progress reports of the project. Official records of the Ministry of Health/ National Blood Program Information System | |
|---|--|--|-------------|
| Activities | Means | Costs | Assumptions |
| 1.1 EU legislation on blood translated into Turkish, current translated versions revised. 1.2 Gap analysis between blood – related Turkish legislation in force and EU legislation conducted. 1.3 Draft texts of Turkish blood legislation in conformity with relevant EU legislation prepared and 1.4 Legal procedures for official publication of draft legislation initiated. | 1 Service Contract 1 Supply Contract | €2,427,000 €790,000 | |

| 2.1 Data collection team of 50 experts (2 experts for each of the 25 health regions of Turkey) composed.2.2 Data to be analysed determined.2.3 Materials and methods for data collection and analysis determined2.4 Data collected and analysed | | |
|---|--|--|
| 3.1 EU member country national blood programmes examined 3.2 Study visits to EU member countries performed to examine well-functioning systems in place 3.3 Taking the situation analysis report (see result 2) into consideration, the number and locations of the regional blood centers to be established throughout the country determined 3.4 The requirements for prospective regional blood centres, their planning in terms of buildings and infrastructure; personnel management system; equipment, consumables and technical sufficiency; total quality management system and data management system determined | | |
| 4.1 EU country guidelines and implementation procedures of these guidelines in EU member countries analysed. 4.2 National guideline(s) for blood banking and transfusion services that supports the implementation of 2002/98/EC, 2004/33/EC, 2005/61/EC, 2005/62/EC directives developed. 4.3 National guidelines published. | | |

| 5.1 The number and qualifications of the Experts | | |
|---|--|--|
| Committee, which would form the basis of future | | |
| supervisory body, determined. | | |
| 5.2 Members of Experts Committee selected. | | |
| 5.3 Training needs of the Experts Committee | | |
| determined | | |
| 5.4 Training program established | | |
| 5.5 Expert Committee training performed | | |
| 5.6 Training certified. | | |
| 6.1 Training needs analysis (TNA) for "blood centre | | |
| personnel training (BCPT)" conducted. | | |
| 6.2. TNA for "training of trainers (ToT)" conducted. | | |
| 6.3 Qualifications and number of trainees for BCPT | | |
| and ToT determined in accordance with TNA. | | |
| 6.4 Training programs and schedules for BCPT and | | |
| ToT determined. | | |
| 6.5 ToT performed.6.6 ToT measured and certified | | |
| 6.7 BCPT performed by trainers certified by ToT. | | |
| 6.8 BCPT measured and certified. | | |
| 7.1 Data sets to be transferred among blood | | |
| establishments and national authority formed. | | |
| 7.2 Software and hardware necessary for data | | |
| transfer and analysis(National Blood Program | | |
| Information System) established at the MoH | | |
| premises. | | |

Pre – Conditions

The tender for this project can be launched on the condition that, by submitting a formal Declaration of Assurance, showing that the beneficiary has sufficient staff in a list for technical implementation and monitoring of the contract(s)