Abbreviations and Acronyms

BAAI - Biomedical Assisted Artificial Insemination

BC – Beneficiary Country

BE – Blood Establishments: in Belgrade, Niš, Kragujevac, Novi Sad

BTI's - Blood Transfusion Institutes

CARDS - Community Assistance for Reconstruction, Development and Stabilisation

CFCU – Department for Contracting and Financing of EU Funded Programs

DG SANTE - Directorate general for health and food safety

EC – European Commission

EU – European Union

EUD – European Union Delegation to the Republic of Serbia

HBTS's - Hospital Blood Transfusion Services

IPA- Instrument for Pre-Accession Assistance

NCA - Directorate of Biomedicine i.e. National Competent Authority

PLAC - Policy and Legal Advice Centre

PL - Project Leader

PSC - Project Steering Committee

RS - Republic of Serbia

SoHO - Substance of Human Origins

TWL – Twinning Light

ANNEX C1[1]

STANDARD LIGHT TWINNING PROJECT FICHE

1. Basic Information

1.1 Programme: IPA 2013

1.2 Twinning Number: SR 13 IPA HE 02 17 TWL

1.3 Title: Strengthening national institutional capacities in the field of Substance of Human Origins (SoHO) to improve the safety of blood in transfusion and transplantation

1.4 Sector: Health and consumer protection

1.5 Beneficiary country: Republic of Serbia

2. Objectives

2.1 Overall Objective(s):

Developing sustainable system for the Substance of Human Origins (hereinafter: SoHO) in the Republic of Serbia by strengthening of the surveillance and inspectorate system and establishing a National Quality System (hereinafter: NQS) within the Ministry of Health as well as within the institutions in the area of SoHO.

2.2 Project purpose:

The Twinning fiche is financed from the IPA 2013 unallocated envelope as per BC request. It aims to map the activities and provide action-oriented guidelines to fully implement EU directives in the field of transfusion and transplantation and, therefore, improve the surveillance and inspectorate system and improve and increase the sustainable institutional capacities in accordance with the relevant *aquis*.

It is important to point out the fact that the activities to be carried through the Twinning light (hereinafter: TWL) will be a precondition as well as a strong foundation for any further EU funding support for SoHO system. With this in mind, this TWL will focus on the following:

- Assessing the capacities of relevant institutions in the field of SoHO which include: relevant institutions in the field of transfusion medicine; relevant institutions in the field of organ tissue and cells; relevant institutions for BAAI-biomedical assisted artificial insemination.
- Strengthening the human, technical, administrative and physical/infrastructural capacities of Directorate of Biomedicine i.e. National Competent Authority (hereinafter: NCA) within the Ministry of Health in the Republic of Serbia to ensure proper surveillance in the field of SoHO ;

[1]For Twinning light the Project fiche should be detailed as it will form an annex to the Twinning light contract together with the selected Member State proposal.

- Gaining valuable recommendations regarding the implementation of the IT system and other technical conditions for securing safe blood transfusion and transplantation services.

2.3 Contribution to National Development Plan/Cooperation agreement/Association Agreement/Action Plan

In 2008, a **European Partnership for Serbia** was adopted setting out priorities for the country's membership application, and Serbia formally applied for accession in 2009. In March 2012, Serbia was granted EU candidate status. In September 2013, the **Stabilisation and Accession Agreement (SAA)** between the EU and Serbia entered into force.

In June 2013, by the decision of the European Council negotiations to open accession with Serbia, the Council adopted the negotiating framework in December 2013 and agreed to hold the 1st Intergovernmental Conference with Serbia in January 2014.

On 21stJanuary 2014, the 1st Intergovernmental Conference took place, signalling the formal start of Serbia's accession negotiations. The explanatory and Bilateral Screening Meetings on Chapter 28 - Consumer and Health Protection - Public Health started at the end of 2014. On the Bilateral Screening Meeting with officials from the Ministry of Health (hereinafter: MoH) and European Commission it was emphasized that SoHO is one of the most important area within the chapter 28 that will require a lot engagement and reforms from the Serbian side. At the same time, Serbian representatives were encouraged to use the Instrument for pre-accession assistance (hereinafter: IPA) as a tool for cooperating with the relevant EU member states and gaining practical experience in management of EU funds.

Serbia started with transposition of the relevant EU *acquis* in the field of biomedicine in 2009. The Ministry of Health adopted the Law on the Organ Transplantation, Law on Cells and Tissues Transplantation, Law on Infertility Treatment with the Procedures of Biomedical Assisted Fertilization and Law on the Transfusiology (Official Gazette No. 72/09). These laws were partially harmonised with EU *acquis* but further harmonisation with EU legislation is needed. With the assistance provided through EU PLAC, these laws were re-drafted to be fully harmonised with relevant EU directives with positive feedback from DG SANTE. The Law on Transfusion Medicine and the Law on Infertility Treatment with the Procedures of Biomedical Assisted Fertilization successfully passed public debate and are now in processed for adoption by the Government/Parliament. The Law on Cell and Tissue Application and the Law on Organ Transplantation underwent public debate on 24/1/17 to be processed for further adoption by the Government and by the Parliament.

The Screening Report on Chapter 28, in the field of SoHO underlined that efforts are needed towards implementation and application of the legislation. More specifically, the implementation of a unified information system; the establishment of a National Quality System; strengthening the capacities of institutions and establishments dealing with tissues in Republic of Serbia; raising awareness among the population about the benefits and the importance of cell and tissue donation are identified as common challenges in all three sectors of SoHO. The EU's Annual Report also underlines that for SoHO it is necessary to achieve alignment of the Serbian legislation with the Acquis on the blood, tissues, cells and organs, including the administrative capacity of relevant institutions are in an early stage.

The administrative and technical capacity of the Directorate for Biomedicine, National Competent Authority (NCA) needs to be strengthened. The legislative framework that outlines the

competences and responsibilities of the sector needs to be established. Overall, quality and safety standards based on EU practice and proper inspection services of the sector need to be developed.

In February 2015, during the Bilateral Screening Meeting with the officials from the Ministry of Health (hereinafter: MoH), the Serbian Delegation informed the European Commission that the Serbian SoHO sector had been prioritised by the Ministry of Health as one of the most important sector for improvement due to shortcomings which have been identified, particularly in the critical area of blood transfusion services. It was stated that improvements in blood transfusion services would be an important component of the Serbian efforts towards meeting the EU SoHO quality and safety standards in the framework of Chapter 28. Thus, DG SANTE was officially invited to visit Serbia in order to assess the situation and give recommendations for improvements and assistance. The referenced visit was organized by five TAIEX-funded missions including EU Member State experts who assessed various elements of the Serbian SoHO sector between November 2014 and April 2015.

3. Description

This Twinning Light project represents initial phase of a much broader accomplishment which will aim to improve the sustainable SoHO system, establishing the National Quality System and increase and improve the quality of transfusion and transplantation system in the Republic of Serbia. The main purpose of this Twinning Light is to establish and build the preconditions for a sustainable SoHO system and to improve capacities of the National Competent Authority (NCA) and all other relevant institutions in SoHO from a technical, infrastructural, institutional and human resources perspective; develop measures for implementation of the information system; assess the gaps in the practices and develop a unique parameter system and, finally, develop a roadmap which will help to overcome the identified challenges and enable as well as place the Directorate of Biomedicine in the position to perform the tasks of the NCA.

Having in mind the above mentioned, this Twinning Light will lay a solid foundation which will, therefore, help overcome the aforementioned challenges by relying heavily on the experience and expertise of the EU member state partners selected for this project. Namely, the Twinning Light EU partner will be indispensable and functional to the elaboration of defined gaps between the EU standards and the Serbian legislation in order to the implement and harmonize the data and give recommendations for improving and strengthening the information system for safe blood transfusion and transplantation.

3.1 Background and justification:

In terms of the current legislation, there are four laws that regulate the area of SoHO in the Republic of Serbia: the Law on Organ Transplantation, the Law on Cell and Tissue Transplantation, the Law on Infertility Treatment with the Procedures of Biomedical Assisted Fertilization and the Law on Transfusiology Activity. Having this in mind, it could be said that the legislation was partially harmonized with the relevant EU directives and, therefore, new legislation, or, amendments of the existing legislation will be drafted in order to achieve full harmonization.

Although with the new changes of the legislation in the Republic of Serbia regulating SoHO the major concepts of relevant EU Directives will be transposed, in practice there is a necessity to implement those legal, regulatory and technical requirements. More concretely, when it comes to transfusion rules and procedures, Ministry of Health in the Republic of Serbia has not up till now

ended the process of reorganization of the blood transfusion service (initiated in 2003 through the EU funded project "Support of the European Union to the National Blood Transfusion Service in Serbia"). Therefore this was emphasized as one of the priorities in the "Strategy for providing adequate quantities of safe blood and blood product in the Republic of Serbia" adopted in 2009. In several Blood Establishments (hereinafter: BE) collection of the blood is merely based on replacement donations. Nevertheless, several Blood Establishments have invested in voluntary non-remunerated blood donation programs (in collaboration with Red Cross) which showed very good results. (Observation assessment of EU/TAIEX recommendations).

SoHO as one of the highest priority public health issue was discussed on the Bilateral Screening. European Commission was emphasized that SoHO is one of the most important area within the chapter 28 that will require a lot engagement and reforms from the Serbian side. Having in mind that we should harmonise all SoHO national legislations with EU acquis, our negotiation process opening and closing chapter 28 mostly depends of developments of this field of public health)
Furthermore, findings from The 2015 EC DG SANTE Serbia Mission Report for SoHO indicate the need for change in the following:

Legislation - to clearly outline the competences and responsibilities of the Competent Authority in the terms of supervision of the SoHO, including establishment of the authorisation and inspection system, setting-up and running national vigilance, annual reporting systems and national registries and coordination of international cooperation.
National Competent Authority **-** to become fully equipped and empowered for successful implementation of the SoHO acquis on the basis of a long-term plans. The responsibility of inspections is one that needs to be clearly defined and described and broader understanding as well as the role of a Competent Authority should be defined and a roadmap indicating how to implement this system should be developed.
Blood Sector **-** to set the preconditions for timely implementation and reorganization of blood services nationwide.
Tissue and Cells **-** to decease donation rates for tissues.
Organ Sector **- establish** a national transplant agency in order to improve donation and transplantation rates in the Republic of Serbia.

Priorities in SoHO refer to:

In the field of transfusion, SoHO is responsible for securing a sufficient number of unique and high quality blood and blood products from voluntary and non-remunerated blood donors in order to meet the needs of all patients in regular and emergency situations. The safe blood will be provided as part of sustainable and modern blood transfusion service and the establishment of a unique national information system database within the existing health care system. The software for the system has been developed through the Reorganization of Blood Transfusion Services - CARDS 2005. However, it is necessary to upgrade and customize this software in order to be in line with the current procedures and recommendations of EU and also to fulfil the current needs of Serbian transfusion system. It has been identified that one of the main problems in transfusion services are the underdeveloped decentralised transfusion system and lack of modern equipment, which would provide a sufficient amount of safe blood as well as standardised and safe production of blood components. The abovementioned project supported the national blood transfusion service through Blood Transfusion Institute in Belgrade, Novi Sad and Nis and resulted in the development of the National Strategy orientation which should centralise the activities in the blood

segment. There is still a need to implement recommendations derived from the CARDS project and strategy.

In the field of organ, cells and tissue transplantation, it is of fundamental importance to establish an appropriate organizational structure for transplantation of organs, cells and tissues and particularly to improve hematopoietic stem cell transplantation, by regulating the following:

- Establishment of National Quality Standards related to national policy, processes, procedures and standard operating procedures increasing number of donor hospitals, organ donors and organ transplantations;
- Acquisition of standardized level of quality for transplantation of organs, cells and tissues in RS;
- Develop an on-going educational program that will enable additional transplantation teams.

Also, it is important to mention that the lack of adequate equipment for transplantation is a major problem as well.

Moreover, according to the findings from the Serbia Mission Report and the latest EC Progress report, TAIEX expert missions identified the main challenges that this twinning light could address:

1. Lack of capacities of the National Competent Authority (NCA) and the necessity to establish SoHo Inspectorate, with educate and license SoHO inspectors with in the NCA. The TAIEX expert mission's recommendations highlight the necessity to strengthen the capacities of the Serbian Competent Authority, Directorate of Biomedicine (or NCA) within the Ministry of Health of the Republic of Serbia to oversight the work of all relevant actors and processes. In order to achieve high quality standards of SoHO system (organs, cells and tissues), it is necessary to establish an inspectorate for all three areas as well as to educate and license SoHO inspectors.

2. The lack of a unified transfusion information system which leads to several additional issues:

a) The absence of communication and information system network(s) between blood establishments in Belgrade, Novi Sad, Niš, Kragujevac and HBTS's (hospital blood transfusion services (hospital blood banks));

b) Lack of documentation for software development and existing information system;

c) Lack of common data models and functionalities for the information system;

d) Inability to trace the unit of blood from the donor to the patient;

e) Outdated hardware and software technology along with the absence of proper maintenance function and limited IT technical manpower resources;

f) Lack of a procedure with appropriate documentation for quality control system;

g) Lack of adequate data protection (protection of all data collected and used in the IT system for transfusion and transplantation) and accessibility to the data. The systems for vigilance and traceability are not in place but are planned in the future. Their implementation is conditioned by the adoption of a national IT system, and the development of proper transfusion confirmation procedures.

3. Lack of necessary medical devices for effective transfusion practice. Many health facilities lack the necessary medical devices, particularly for transfusion practices. Equipment for collecting, processing, storage and transportation of blood and blood components is in most cases outdated

or missing. At the same time, technical requirements for development of unique information system is lacking.

3.2 Linked activities *(other international and national initiatives)*:

In cooperation with the Ministry of Health, a TAIEX workshop was organized - "Multi-country Workshop on the Role and Functioning of Competent Authorities in the Field of Substances of Human Origin" in Podgorica, Montenegro from June 20-22, 2016. The aim of the workshop was to provide the participants from the **Ministries of Health, competent authorities and inspectorates** in the field of **substance of human origin (blood, tissues & cells, and organs)** with information on the set-up and functioning of competent authorities in the SoHO sector.

In cooperation with the Ministry of Health, the following TAIEX expert missions were realized and the experts reported identified gaps in practices and underlined especially the lack of surveillance and quality control institutional capacities, mechanisms and information system:

- "National System in the area of organ donation and Transplantation" in February 2015 to provide support and recommendations to the Serbian Competent Authority (Inspectorate of Biomedicine) for the implementation of successful model for organ donation and transplantation in the Republic of Serbia, in line with Directive 2010/53/EC;
- "National system in the area of Transplantation of Cells and Tissues" in March 2015 to provide support and recommendations to the Serbian Competent Authority for tissues and cells (Directorate for Biomedicine), in the process of implementation of requirements of Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, in the Republic of Serbia.
- "Establishment of National Center for Fractionation of Republic of Serbia"
- "Establishment of National Haemovigilance System in the Area of Blood Transfusion in Republic of Serbia"
- "Establishment of National Quality System in the Area of Blood Transfusion in Republic of Serbia"

With the assistance provided through EU PLAC project existing laws covering the area of SoHO have been re-drafted in order to fully harmonise them with the relevant EU directives and positive feedback was received from Directorate-General for Health and Food Safety (DG SANTE). The Law on Transfusion Medicine and the Law on Infertility Treatment with the Procedures of Biomedical Assisted Fertilization have passed public debate and are in the process of preparation for the adoption by the Government and by the Parliament, while the Law on Cell and Tissue Application and the Law on Organ Transplantation and are preparing for a public debate.

In the area of blood transfusion service, most relevant EU funded programs include: Reorganization of Blood Transfusion Services - CARDS 2005 that supported the reforming/ upgrading the existing transfusion system, harmonization with the *acquis* and providing relevant equipment and works. This project established Blood Transfusion Service and the further equipping of the BE in Nis, Belgrade and Novi Sad. EU assistance effectively supported the development of legislative and regulatory acts as well as the National Strategy for providing adequate quantities of safe blood and blood product in the Republic of Serbia. While the significant progress was made in harmonization of the relevant legislation with the EU *acquis*, challenges remain in the implementation of directives, regulations and legislation.

3.3 Results:

For all proposed Results and Indicators the MS will in its offer, present a detailed list of indicators and milestones towards achieving the required outputs of the Project.

Component 1 - Assessment and analysis of gaps, needs and situations related to legal, institutional, administrative, infrastructural and technical capacities of the relevant abovementioned institutions in the area of SoHO.

Result 1.1 - Prepared assessment of the gaps, needs and the situation for the Directorate of Biomedicine (National Competent Authority) in the area of SoHO in order to match the practices and legislation with the EU

Indicators for Result 1.1

- Questioners and surveys for the gap assessment approved by beneficiary
- Document which defined gaps and needs for the Directorate of Biomedicine (National Competent Authority in the area of SoHO in order to match the legislation with the EU with recommendations for bylaws and laws for Directorate for biomedicine in order to be harmonized with acquis approved by beneficiary

Result 1.2. Prepared assessment of the capacities of **relevant institutions in the area of SoHO beside of NCA**, in terms of staff and administration, management structure, technical conditions and infrastructure.

Indicators for result 1.2

- Questioners and surveys for the SoHO Institutions approved by beneficiary
- At least one workshop related to performed assessment in duration of one day delivered (at least 50 participants)
- Assessment report document which defined current capacities of relevant institutions in the area of SoHO beside of NCA, in terms of staff and administration, management structure, technical conditions and infrastructure approved by NCA

Result 1.3. Gap assessment for weakness of system for sharing and protection of data in IT system for transfusion and transplantation prepared, recommendations for use of information system on national level between the institutions in the field of SoHO prepared

Indicators for result 1.3.

- Questionnaires for gap assessment of weakness of system for sharing and protection of data in IT system for transfusion and transplantation approved by beneficiary
- Document with gap assessment - of the current situation in regards to development of information system at national level in the area of blood transfusion and organ tissue and cells transplantation approved by beneficiary
- One workshop in duration of two days, with representatives of relevant institutions in the area of SoHO in order to present results of assessment and to discuss of data set and parameters of unified IT system (at least 20 participants) performed

Result 1.4. Need assessment of specific capacities of the National Competent Authority and the future inspectorate system prepared

Indicators for result 1.4.

- Questioners for assessment of capacities related to establishing future inspectorate system within Directorate of Biomedicine approved by beneficiary
- Assessment report of the specific capacities of the Directorate of Biomedicine in terms of the functioning, human resources, work load and future inspectorate within the Directorate as a NCA approved by beneficiary
- One training in duration of two days delivered to employees at the Directorate of Biomedicine preparing them for conducting surveillance of SoHO system on national level with at least 20 participants

Component 2 - Development of Roadmap to improve the human, technical, administrative and physical/infrastructural capacities of relevant institutions in the area of SoHO

Result 2.1 – Concrete measures defined in order to improve capacities (human, technical, administrative and physical/infrastructural), highlighting the roles and organisation of work, milestones and targets, budget and financing sources for future projects.

Indicators for Result 2.1

- The roadmap as a reference document, with definition of scope of work; roles and competences; procedures; quality standards and criteria; administration, recommendations for National Parameters System (set of mandatory data for SoHO System), coordination and management skills of relevant institutions in the area of SoHO approved by beneficiary
- Delivered at least two workshops in duration of two days (with at least 40 participants in total) for measures/action for strengthening capacities of relevant institutions in the field of SoHO,

Result 2.2 - Proposal for reorganization of health institutions in the area of SoHO according to the EU regulations and legislation in SoHO field

Indicators for Result 2.2

- Approved document with proposals for:
  - enforcement/implementation of the roles and functions of all relevant institutions in the area of SoHO
  - roles and functions of the Directorate of Biomedicine as a NCA
  - organization of inspectorate and surveillance system
  - merging of Blood Establishment (BE) (now total of 44) leading to a new structure with 4 Blood Establishment (BE)
- Delivered at least two educational trainings in duration of one day for administration, management, and implementation and monitoring skills (at least 20 participants per training)

Result 2.3. - Proposed measures for the improvement of IT system related to blood transfusion and transplantation

Indicators to result 2.3

- Document with proposal of the measures for implementation of information system and implementing mechanisms which will secure the fully application of the information system
- Delivery of one educational training in duration of two day for build unique and unified IT system (at least 20 participants)

Result 2.4. Preparation of proposal for future interventions in the field of SoHO which will be included in IPA II programming documentation

Indicators to result 2.4.

- Draft concept of Action document to be used as a basis for IPA II programing cycle IPA 2018 in order to secure support in the implementation of the priorities related to relevant findings of the assessments and recommendations from previous activities (activities under result 1 and 2)

Component 3 - Preparation of technical documentation for the purchase of mandatory equipment to perform SoHO procedures in health institutions

Result 3.1 – Preparation of Elaborate of necessary medical equipment for SoHO procedures with draft of technical specification and tender documentation according to PRAG rules

Indicators for Result 3.1

- Elaborate of necessary medical equipment for SoHO procedures
- Prepared technical specification and tender dossier for necessary medical equipment according to PRAG rules approved by beneficiary

3.4 Activities:

Component 1 - Assessment and analysis of gaps, needs and situations related to legal, institutional, administrative, infrastructural and technical capacities of the relevant abovementioned institutions in the area of SoHO.

Activities to achieve Result 1.1

The focus of this group of activities relates to the assessment of the situation in the area of SoHO so as to get a better understanding of what needs to be done in order to match the practices and legislation with the EU. The assessment aims to: analysis of the situation and capacities of the Directorate of Biomedicine and elaboration of capacity building measures to enable the Directorate to fully and successfully perform its role of NCA; analysis of the overall situation throughout institutions in the area of SoHO, including current implementation of EU directives in the field of transfusion and transplantation; setting up rules and procedures regarding the communication between the institutions; data collection and transfer of the data between the institutions etc.

1.1.1- Reviewing relevant documentation and preparing questionnaires, interviewing methods (on-the-spot checks), focus groups, and templates for gap assessment report.

Desk review of all relevant national documents and legislation will be entailed in terms of public health with emphasis on SoHO. All technical assessment reports from EC mission, TAIEX, ECDC etc. will be reviewed together with legislation, relevant laws and regulations of the Republic of Serbia and comparison should be made with the EU legislation. Preparation of questionnaires, tools for recording relevant data (database), interviewing methods (on-the-spot checks), focus groups, and templates for gap assessment document.

1.1.2 -Development of gap assessment document

Preparation of the gap assessment document with recommendations to the beneficiary for further improvement on the basis of EU *acquis* requirements and EU standards.

Activities to achieve Result 1.2.

This set of activities refers to the implementation of the assessment throughout relevant institutions in the area of SoHO. The assessment methodology will be aimed to provide a complete overview of the situation that will enable development and elaboration of adequate measures with set of priorities, guidelines and recommendations. This will provide precondition for more comprehensive intervention and further support (including through additional EU funding). In particular, the assessment will include the analysis of facilities, equipment, personnel and quality management system, parameters, labelling system and practices in blood traceability and prepare recommendation in line with EU acquis.

Specifically, activities at this stage will be the following:

1.2.1- Preparation of questionnaires and surveys for the SoHO institutions
1.2.2- Conducting of at least one workshop with relevant health institutions in the area of SoHO on the methodology, standards and criteria of data collection and reporting system between health institutions and NCA
1.2.3- Conducting of assessment and collection of relevant data in the field of management of SoHO in accordance with EU Directives, such as number of transplanted organs, cells and tissues; number of BMPO; number of blood donors and others information.
1.2.4-Preparation of the current assessment report document which defined current capacities of relevant institutions in the area of SoHO beside of NCA, in terms of staff and administration, management structure, technical conditions and infrastructure with recommendations for further improvement of the SoHO system

Activities to achieve Result 1.3.

The surveys will be conducted in order to map weakness of system for, collection, sharing and protection of data in IT system for transfusion and transplantation in SoHO sector and provide structured assessment. A comprehensive map of the situation including all data on institutions will be provide through the delivered surveys and questionnaires collected data will be analysed, compared and evaluated resulting into a comprehensive assessment and needs report. This will allow mapping of structural and infrastructural conditions along with staff competences and capacities as well as technical capacities (including IT literacy and proficiency) in institutions dealing with transfusion and transplantation and elaboration and development of measures in guidelines for relevant services.

Specifically, activities will consist of:

1.3.1- Preparation and delivery of questionnaires for gap assessment for weakness of system for sharing and protection of data in IT system for transfusion and transplantation
1.3.2- Conduction of assessment and collection of data of the current situation in regards to development of information system at national level in the area of blood transfusion and organ tissue and cells transplantation

1.3.3-Organisation of workshop with representatives of relevant institutions in the area of SoHO in order to present results of assessment and to discuss of data set and parameters of unified IT system (at least 20 participants)

Activities to Result 1.4.

This set of activities refers mainly to the map and assess the capacities of the Directorate of Biomedicine as NCA and future inspectorate system within and propose adequate measures to strengthen performance and role of NCA. Specifically, activities will consist of:

1.4.1- Preparation and dissemination of questionnaires for assessment of capacities related to establishing future inspectorate system within Directorate of Biomedicine and data collection

1.4.2- Assessment of the capacities of the Directorate of Biomedicine to oversee management and coordination of transfusion, organ donation and transplantation activities; to support donor hospitals and transplant centres to meet EU requirements to implement relevant directives with proposal with definition of the scope of work; roles and competences; quality standards and criteria; administration, coordination and management skills needed to the Directorate of Biomedicine as a NCA

1.4.3 Providing of educational training to employees at the Directorate of Biomedicine with scope to prepare them for conduct the surveillance of SoHO system on national level

Component 2 - Development of Roadmap to improve the human, technical, administrative and physical/infrastructural capacities of relevant institutions in the area of SoHO

Activities to achieve Result 2.1

Roadmap development will entail concrete skill and capacity building activities throughout health institutions in the area of SoHO in order to guarantee the basis for implementation of roadmap by the end of the twinning light project and to lay the ground for further EU assistance in the structured steps towards a more sustainable SoHO system. The workshops and education trainings will be designed and delivered according to the mapped capacities and situation throughout the institutions in the area of SoHO. Training needs analysis for health professional throughout the SoHO system, including the Directorate of Biomedicine, will be specified in order to secure continuous education for all health institutions in the area of SoHO as a priority to build up and update key competences of staff securing safe blood transfusion and high quality transplantations. Education and training will also be essential to build national quality standards and enhance the quality control system.

The activities listed below will lead to elaborated roadmap, defined scope of work and structured unified and unique IT system. They will also contribute to increased capacities for implementation of the roadmap and for the fulfilment of duties of institutions in the area of SoHO in securing safe blood for transfusion and transplantation. Specific activities in this phase are:

2.1.1- Development of roadmap document which define scope of work; definition of the roles and competences; procedures; quality standards and criteria; administration, recommendations for National Parameters System (set of mandatory data for SoHO System), coordination and management skills of relevant institutions in the area of SoHO

2.1.2-Delivery of at least two workshops to health professionals from health institutions in the area of SoHO as a priority to build and update key competences of staff in securing safe blood for transfusion and transplantation

Activities to achieve Result 2.2

The results from the assessment of the situation in terms of capacities will provide the necessary information for the reorganization of health institutions in area of SoHO. The assessment analysis will comprise of a complete analytical report on the state of the BE, underlying their functioning, inter-communication, activity rate and service delivery and other relevant data that will be used to evaluate the modalities in which the network of BE is to be strengthened to become more effective and efficient including their streamlining/merging. The reorganization will significantly contribute to increased quality and effectiveness in the implementation of safe blood practices and procedures. It will create the structure enabling the tracking of collection, processing and testing of blood throughout the SoHO system. Additional outputs will consist in: identification of blood establishments to be merged; the planning of phases of reorganization leading to the final structure with the identified optimal number of blood establishments; functional organigram; elaboration of system functioning including management structure, communication, exchange of digital data, description of the roles, competence of staff needed and foreseen number of health professionals. An action plan with specific roles in the implementation of the reorganized structure will be elaborated in the Roadmap. This will be inclusive of the specific and concrete role of the Directorate of Biomedicine as NCA. As such, specific steps will be developed to strengthen the management and administration of the Directorate of Biomedicine through the elaboration of its scope of work; roles and competences; relevant by-laws, rulebooks and procedures; administration, coordination and management skills to be employed in the supervision of the functioning of institutions in the area of SoHO.

The activities listed below are to result in the proposed reorganization/optimisation of institutions in the area of SoHO underlying the role, function and capacity of the NCA for the implementation of the regulations in SoHO sector.

2.2.1-Development of proposal for establishing the network of institutions in the area of SoHO with functional analysis and definitions of roles and functions especially as related to the Directorate of Biomedicine as NCA

2.2.2- Preparation of the recommendations for new reorganization of health institutions in the area of SoHO in order to create more functioning and effective SoHO system with proposal for phases structuring and subsequent merging of the present 44 BE into a final number of 4 BE

2.2.3-Delivery of educational trainings to develop administration, management, and implementation and monitoring skills, inspectorate and information flow of the Directorate of Biomedicine in quality standards and control

Activities to achieve Result 2.3

This set of activities will include specific steps in order to propose measures for implement the best practices in using information system related to blood transfusion. These will be the result of the assessment in the identified practice gaps in terms of current lack of implementation of a unified transfusion information system including: a) absence of communication and information system network(s) between blood establishments, and hospital blood banks; b) lack of documentation on the development of the software packages or the existing information system; c) lack of common data models and functionalities; d) inability to completely trace the unit of blood from the donor to the patient; e) outdated hardware and software technology, with absence of proper maintenance function and limited IT technical manpower resources; f) lack of a documented quality environment; g) lack of adequate data protection and accessibility.

2.3.1-Preparation of Recommendations on how to expand the best practices of the implementation of the information system related to blood transfusion and transplantation

2.3.2 -Training and education of the staff to apply and use software functionalities in accordance with recommendations for advanced functionalities of unified IT system

Activities to achieve Result 2.4

2.4.1 Preparation of draft concept of Action document to be used as a basis for IPA II programing cycle

This activity will entail the preparation of a draft concept of the Action document to be used as a basis for IPA II programming cycle (IPA 2018) in order to secure support in the implementation of the priorities identified in the roadmap. The draft concept of the Action document will be elaborated on the basis of the most relevant findings of the assessments and recommendations from previous activities

Component 3 - Preparation of technical documentation for the purchase of mandatory equipment to perform SoHO procedures in health institutions

Activities to achieve Result 3.1

3.1.1-Preparation of Elaborate of necessary medical equipment for SoHO procedures in health institutions

3.1.2 -Preparation of technical specification for medical and technical equipment in order to equip BE and HBB as well as recommendations for equipping the institutions and centres for transplantation with the adequate tools, instruments and equipment in order to be able to operate efficiently and effectively under national and EU quality standards in line with the acquis.

3.1.3 -Preparation of tender dossier for necessary equipment according to the PRAG

Draft technical specification of medical equipment will enable the planning of procurement in order to:

- Contribute to securing sufficient unique quality of blood and blood products from voluntary non-remunerated blood donors to meet the needs of all patients in regular and emergency situations. The safe blood will be provided as part of sustainable and modern blood transfusion service within the existing health care system.
- Implement high quality system standards for collecting, testing, processing, storage, distribution and system of haemovigilance and traceability in blood establishments ensuring

systematic approach toward unique quality of blood and blood products, as well as safety standards for blood and blood products through implementing automatic system for testing, collection, processing, storage, transport and distribution of blood and blood products of donors. This will allow uniformity, precision, and standard quality of work.

At least two major visibility events with not less than 30 participants will be organized in the course of the implementation of the project: Kick-off meeting at the start of the implementation process and the Final meeting at the end of project implementation activities.

The MS will propose additional visibility actions as standalone or associated with training workshops etc.

3.5 Means/ Input from the MS Partner Administration:

3.5.1 Profile and tasks of the Project Leader/Coordinator

Requirements:

- University level education or equivalent professional experience of 10 years in the field of health
- 5 years of professional working experience in the field of SOHO (organs, tissues, blood and cells)
- Experience in project management
- Working level of English language
- Proven contractual relations to public administration or mandated body in line with point 5.4.5 of Twinning Manual
- Computer literacy

Assets:

- Experience in implementation of EU Directives and standards for blood and/or organs, tissues and cells
- Experience in EU funded project

Tasks of the Project Leader:

- Overall management and coordination of the whole project and particular activities, in cooperation with RS PL
- Co-ordination of MS experts work and availability
- Project reporting
- Organization of study visits
- Participation in Steering Committee Meetings
- Mobilizing short - term experts
- Ensuring backstopping and financial management of the project in the MS
- Overall responsibility and direction of the MS Twinning partner inputs and proposing corrective measures, if needed

3.5.3 Profile and tasks of the short-term experts

Profile of the Short-term expert 1 (STE 1) – Expert for organisational aspects in the transplantation and transfusion filed

Requirements:

- University level education or equivalent professional experience of 8 years in the health system
- 3 years of working experience in the field of SoHO
- Experience in developing, building or restructuring national blood and national transplantation systems in line with EU Directives
- Working level of English language
- Proven contractual relations to public administration or mandated body in line with point 5.4.5 of Twinning Manual
- Computer literacy

Asset:

- Experience in providing trainings on organisational model in the health system

Tasks of the Short-term expert 1:

- Reviewing RS organisational model and capacities for transfusion and transplantation medicine service
- Reviewing RS CA organisational model and capacities for SoHO field
- Preparing relevant review reports with recommendations
- Conducting gaps and needs analysis and preparing assessment report with recommendations for future projects
- Close cooperation with the RS experts in undertaking all activities
- Participating in all relevant project activities in cooperation with other short-term experts

Profile of the Short-term expert 2 (STE 2) – Expert for EU legislation in the SOHO field

Requirements:

- University level education or equivalent professional experience of 8 years in the health system
- 3 years of working experience in the inspection for the SoHO
- Experience in developing proper inspection system in the field of SoHO in line with EU Directives requirements
- Working level of English language
- Proven contractual relations to public administration or mandated body in line with point 5.4.5 of Twinning Manual
- Computer literacy

Asset:

- Experience in building inspections capacities and providing trainings on the inspection system in the SOHO field in accordance of EU legislation

Tasks of the Short-term expert 2:

- Reviewing RS CA capacities related to the inspection system in the SoHO field
- Preparing relevant review reports with recommendations for reorganization of health

institutions in the area of SoHO
- Preparation of recommendations for National Parameters System
- Conducting gaps and needs analysis and trainings for health professionals to develop administration, management, and implementation and monitoring skills, inspectorate and information flow of the Directorate of Biomedicine in quality standards and control
-Close cooperation with the RS experts in undertaking all activities
-Participating in all relevant project activities in cooperation with other short-term experts

Profile of the Short-term expert 3 (STE 3) – Expert for transfusion

Requirements:

- University level education or equivalent professional experience of 8 years in the field of transfusion medicine
- 4 years of experience in the field of transfusion medicine
- Experience in the implementation of national blood policy
- Working level of English language
- Proven contractual relations to public administration or mandated body in line with point 5.4.5 of Twinning Manual

-Computer literacy

Assets:

- Working experience in providing trainings related to the national or EU blood policy development, implementation or reorganisation of transfusion systems

Tasks of the Short-term expert 3:

- Assessing needs for the reorganisation of the national blood service in line with the National transfusion Strategy and preparing assessment report with action needed and road map
- Conducting consultations with BE and workshop(s) related to the national blood strategy Close cooperation with the RS experts in undertaking all activities
- Participating in all relevant project activities in cooperation with other short-term experts

Short-term experts 4 (STE 4) – Expert for the implementation of the information system for transfusion medicine service

Requirements:

- University level education or equivalent professional experience of 8 years in the field of ICT or medical or technical science
- 4 years of ICT experience in the field of health
- Experience in transfusion services system
- Working level of English language
- Proven contractual relations to public administration or mandated body in line with point 5.4.5 of Twinning Manual

-Computer literacy

Assets:

- Experience in providing trainings in the field of IT system for transfusion medicine
- Experience in project preparation in the health sector under national or EU funds

Tasks of the Short-term expert 4:

- Conducting gaps and needs analysis for the implementation of the national common IT system in the transfusion medicine services
- preparing assessment report with recommendations for RS CA and future projects
- Preparation of Elaborate of necessary medical equipment for SoHO procedures in health institutions
- Preparation of technical specification for medical and technical equipment prepared to equip BE and HBB as well as recommendations for equipping the institutions and centres for transplantation with the adequate tools, instruments and equipment in order to be able to operate efficiently and effectively under national and EU quality standards in line with the acquis.
- Preparation of tender dossier for necessary equipment according to the PRAG

4. Institutional Framework

Ministry of Health is responsible for implementation of the Laws regulation the following in the area of SoHO: Transfusion Medicine, Biomedically Assisted Fertilisation, Transplantation of Human Organs for the purpose of treatment, Application of human cells and tissues. It is also responsible for the nomination of Competent Authority, inspection control of the Laws implementation and other actions defined by the Law on Ministries.

Directorate of Biomedicine is established as a directorate within the Ministry of Health in 2010. According to the "Law on Organ transplantation" the Directorate of Biomedicine is the National Competent Authority within the MoH of Republic of Serbia responsible for SoHO. The Directorate is organized in 3 main areas: Blood and blood components; Tissue, cells and Biomedical Assisted Fertilization; Organs. As being the NCA, the Directorate is responsible to oversight the work of all relevant actors dealing with above mentioned areas, activities and processes, as well as the conditions of the facilities in which the activates and processes are performed. The work of the NCA should be supported and complemented by the licensed SoHO inspectors. At present, although foreseen by relevant laws, inspectors are not employed.

There are presently **five centres for organ transplantation** in Serbia, three of them in the Belgrade area, one in Nis and one in Novi Sad. All five centres perform kidney transplantation, three of them perform liver transplantation and just one centre performs heart transplantation. There are in total 14 donor hospitals, with these 5 transplant centres included. When it comes to organ transplantation, Serbia is lagging behind the EU, not just in the types of the organs which could be transplanted but also on the organ donation rates that in 2014 amounted 3,1 pmp. In addition, there are 5 institutions that perform hematopoietic stem cells transplantation and 8 institutions that perform tissue transplantations.

In the field of transfusion practice the activities are performed by **3 major institutes** (Belgrade, Novi Sad, Nis) and Military Medical Academy, as well as organizational units of different health institutions (3 clinical centres, 4 clinical/hospital centres, 37 general hospitals). Seventy health institutions with departments for clinical use of blood or without specific departments are exclusively users of blood and blood products. In order to comply with the Directive 2002/98/EC and fulfil all necessary requirements for enabling quality and safety of the collection, testing, processing, storage and distribution of human blood and blood components there is a necessity to conduct the segregation of competence that includes defining the number of institutions that will be responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage, and distribution when intended for transfusion (Blood Establishments) and to define hospital units responsible for storage and distribution (Hospital Blood Banks). In order to make a decision on precise number of BE and HBB, there is an assessment on-going, which includes field visits.

5. Budget

The total budget for this Twinning project is EUR 250.000.

Strengthening national institutional capacities in the field of Substance of Human Origins (SoHO) to improve the safety of blood in transfusion and transplantation	IPA Community Contribution	National Co-financing	TOTAL
Twinning Light Contract	€ 225.000	€ 25.000	€ 250.000

The MoH will cover the costs of the following provisions:

-MoH will provide the Twinning light partner with adequate office space for experts, meeting rooms and office equipment necessary for relevant activities foreseen in the Twinning light fiche

-Adequate conditions for the STEs to perform their work while on mission to the BC.

-Training and conference venues, costs of catering, as well as presentation and interpretation equipment.

Provisions for visibility costs and expenditure verification costs must be included in the budget.

Source for the co-financing is planned in the budget of MoH for 2017 as the 10% of total amount of the project.

6. Implementation Arrangements

6.1 Implementing Agency responsible for tendering, contracting and accounting

Ministry of Finance
Department for Contracting and Financing of EU Funded programmes (CFCU)
Sremska St, No. 3-5
11000 Belgrade, Serbia

Mr. Dušan Čarkić, Programme Authorising Officer (PAO)/Head of CFCU
E-mail: dusan.carkic@mfin.gov.rs

Mr. Darko Vasić, Twinning National Contact Point
E-mail: twinnning@mfin.gov.rs
Phone No: +981 11 202 14 12

6.2 Main counterpart in the BC:

Ministry of Health, Nemanjina 22-26 str. 11 000 Belgrade

Senior Programme Officer (SPO)

dr Danijela Urošević, Senior Adviser

Project leader:

dr Nenad Milojičić, director of Directorate for Biomedicine

The BC Project Leader will manage a project team at the Serbian side and will assure that the decision makers at the national level will be informed properly on the implementation of the project. He will ensure close co-operation and overall steering and coordination of the project. He will also be responsible for drafting reports and other documents, related to project management at the Serbian side and will chair PSC meetings.

6.3 Contracts

The project will be implemented through one Twinning Light Contract.

6.4 Language

The working language is English.

7. Implementation Schedule (indicative)

7.1 Launching of the call for proposals: February 2017

7.2 Start of project activities: Jun 2017

7.3 Project completion: December 2017

7.4 Duration of the execution period: 6 + 3 months

8. Sustainability

The achievements of Twinning light project (mandatory results) shall be maintained as a permanent asset to the beneficiary even after the completion of the project implementation.

The development and improvement of sustainable system in the fields of organ, cell and tissue transplantation as well as blood transfusion service is a priority of the reform process in health care system. In order to establish a sustainable system in the area of SoHO, it is of priority importance to build the capacities of the Directorate of Biomedicine to be enabled to perform its functions ad roles as NCA and of all relevant institutions in the area of SoHO. This Twinning Light addresses this priority through institutional capacity building, mapping resources and further support mechanisms, thus laying the basis for the NCA to implement the legislation in accordance to the *acquis*. The capacity building of the NCA will guarantee ownership of institutions, healthcare professionals and an overseeing and supervision role to secure implementation of transfusion and transplantation legal framework. In addition, the introduction of a unique national parameters system and the implementation of digital information system will set the conditions for sustainable information flow.

In terms of technical equipment, financing for operating and maintenance costs will be provided through the budged of Republic of Serbia. Final beneficiaries of equipment will be health care institutions, which are under the jurisdiction of the Ministry of Health. Annually, the Ministry of Health provides funds for investment and maintenance of health facilities. Therefore, every health institution, upon registration of the equipment in the basic means, will be able to justify all the funds necessary for the smooth functioning.

9. Crosscutting issues

Based on the Fundamental principles of promoting equality and combating discrimination, participation in the project will be guaranteed on the basis of equal access regardless of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation.

Civil society

The cooperation with CSOs is facilitated by the Government's commitment as part of its European Agenda. Regarding mechanisms for dialogue, two official mechanisms exist: (i) Office for Cooperation with Civil Society; and (ii) Sectoral Civil Society Organisations - SECO for the processes of IPA programming. Both are examples of good practices in terms of CSO representation in general.

The Government Office for Cooperation with Civil Society still is the main institutional mechanism for the support of developing the dialogue between the Government and CSOs through offering support to its institutions in understanding and recognizing the role of CSOs in policy shaping and decision making processes.

Office for Cooperation with Civil Society also established the mechanism that allows involvement of CSOs in negotiations on the accession of the Republic of Serbia to the European Union. During 2013 and 2014, Office for Cooperation with Civil Society in cooperation with the Negotiating team for the accession and relevant institutions for different negotiation chapters included CSOs in negotiations. CSO participation in this process so far included monitoring of explanatory

screenings, participation in the preparation of the bilateral screening for some negotiating chapters and participation in briefing meetings that followed bilateral screenings.

In addition, NIPAC TS - SEIO established a consultation mechanism with the civil society organization (CSOs)[2]. This mechanism is based on the consultative process with Sectoral Civil Society Organizations (SECOs) and serves as a platform that enables exchange of information and contribution of CSOs in relation to planning development assistance, particularly programming and monitoring of the Instrument for Pre-Accession Assistance (IPA). Extensive consultations with CSOs have been undertaken in drafting Sector Planning Document (2015 – 2017) for HRSD sector, whereas support to Health sub-sector has been envisaged and particularly support to improvement of surveillance on CDs.

Equal Opportunity

The project will be implemented according to the regulations of the national legislation providing equal opportunities for men and women. Twinning partners will be expected to comply with EU Equal Opportunity policies.

Enforcement of equal opportunity principles will be ensured through specific administrative procedures applied in accordance with the Law on non-discrimination. No discrimination on the basis of racial or ethnic origin, religion or belief, disability, sex or sexual orientation or on any other grounds.

Environmental considerations

The project does not involve activities with an environmental impact.

10. Conditionality and sequencing

The implementation of this twinning light project fulfils the pre-condition to apply for broader assistance in the implementation of SoHO legislation in the establishment of a sustainable system in the area of SoHO. Due to lack of necessary feasibility studies and needs assessments regarding the current functioning of the health institutions in the area of SoHO, the first phase reiterated in this twinning light, will cover activities related to assessing the needs, identifying the gaps and mapping interventions aimed at improving institutional capacities in compliance with EU *acquis* and EU standards.

The broader Action (second phase) will be the subject of the IPA II programming (most probably IPA 2018) including supply of equipment based on the gaps identified and roadmap developed in the first stage.

ANNEXES TO PROJECT FICHE

1. Logical framework matrix in standard format (compulsory)
2. Relevant National and EU legislation
3. Indicative work-plan

2 Introduced in 2011

Annex 1 - Logical framework matrix in standard format

LOGFRAME PLANNING MATRIX		**Total budget:** **€ 250 000**	**IPA budget:** **€ 225 000**
Overall objective	**Objectively verifiable indicators**	**Sources of Verification**	**Assumptions**
To improve the sustainable SoHo (Substance of Human Origins) system in the Republic of Serbia, by strengthening the surveillance, inspectorate system and establishing the national quality system	Progress made towards meeting accession criteria in Chapter 28	EC Progress Report	
Project purpose	**Objectively verifiable indicators**	**Sources of Verification**	**Assumptions**
Map the activities and provide action-oriented guidelines to fully implement EU directives in the field of transfusion and transplantation in order to: improve the surveillance and inspectorate system and build the sustainable institutional capacities, in accordance with relevant *aquis*. Departing from relevant EU directives, the activities to be carried forward through the TWL will fulfil the preconditions and lay the basis for SoHO sector to be able to access further EU funding support. The TWL will focus on: • The overall assessment of the capacities of relevant institutions in the area of SoHO • The strengthening of the capacities of NCA to ensure quality of surveillance • The implementation of the IT system and fulfilment of technical conditions for securing safe blood in transfusion services	• The roadmap, as a reference document outlining the organisation of the work, the specific activities/initiatives, milestones and targets to be achieved and framework for mobilising, harnessing and leveraging resources (both national and international) developed by the end of the project. The roadmap specifically spells out interventions aimed at: • Reorganization of institutions in the SoHO system and service; implementing core functions and roles of the NCA; implementing IT system;	• TWL final report • Annual EC progress report	• The relevant necessary legislative, administrative, technical and financial set up to implement road-map is in place
Results	**Objectively verifiable indicators**	**Sources of Verification**	**Assumptions**
Component 1. Assessment and analysis of gaps, needs and situations related to legal, institutional, administrative, infrastructural and technical capacities of the relevant abovementioned institutions in the area of SoHO.			
Result 1.1. - Prepared assessment of the gaps, and needs for the **Directorate of Biomedicine (National Competent Authority**)in the area of SoHO in order to match the practices and legislation with the EU	• Questionnaires and surveys for the gap assessment approved by beneficiary • Document which defined gaps and needs for the Directorate of Biomedicine (National Competent Authority in the area of SoHO in order to match the legislation with the EU with recommendations for bylaws and laws for Directorate for biomedicine in order to be harmonized with acquis and approved by beneficiary	• Questinnares for gap assesment • document with gap analysis and needs assessment • TWL reports	• Decision makers and all relevant actors are timely informed about progress during project implementation

Result 1.2. Prepared assessment of the capacities **of relevant institutions in the area of SoHO beside of NCA**, in terms of staff and administration, management structure, technical conditions and infrastructure prepared.	• Questioners and surveys for the SoHO Institutions approved by beneficiary • At least One workshop in duration of one day related to performe assessment delivered (at least 50 participants) Assesment report document which defined current capacities of relevant institutions in the area of SoHO beside of NCA, in terms of staff and administration, management structure, technical conditions and infrastructure approved by NCA	• Questioners • Assessment • report/document • Workshop reports and attendance list	
Result 1.3. Gap assessment for weakness of system for sharing and protection of data in **IT system for transfusion and transplantation** prepared with recommendations for use of information system on national level between the institutions in the field of SoHO prepared	• Questionnaires for gap assessment of weakness of system for sharing and protection of data in IT system for transfusion and transplantation approved by beneficiary • • Document with gap assessment - of the current situation in regards to development of information system at national level in the area of blood transfusion and organ tissue and cells transplantation approved by beneficiary • One workshop in duration of two days with representatives of relevant institutions in the area of SoHO in order to present results of assessment and to discuss of data set and parameters of unified IT system (20 participants) performed	• questioners • Assessment document with gap analysis report • Workshop reports and attendance list	Sufficient knowledge of the EU and national legislation in the field of SOHO and comprehensive recommendations
Result 1.4. Need assessment of **specific capacities of the National Competent Authority and the future inspectorate system prepared**	• Questioners for assessment of capacities related to establishing future inspectorate system within Directorate of Biomedicine prepared and approved by beneficiary • Assessment report of the specific capacities of the Directorate of Biomedicine in terms of the functioning, human resources, work load and future inspectorate within the Directorate as a NCA approved by beneficiary • One training in duration of two days delivered to employees at the Directorate of Biomedicine preparing them for conducting surveillance of SoHO system on national level with at least 20 participants	• Questioners • Assessment report/document • Workshop reports and attendance list	
Component 2. – Development of Roadmap to improve the human, technical, administrative and physical/infrastructural capacities of relevant institutions in the area of SoHO Result			
Result 2.1. Concrete measures defined in order to improve capacities (human, technical, administrative and physical/infrastructural), highlighting the roles and organisation of work, milestones and targets, budget and financing sources for future projects	• The roadmap as a reference document, with definition of scope of work; roles and competences; procedures; quality standards and criteria; administration, recommendations for National Parameters System (set of mandatory data for SoHO System), coordination and management skills of relevant institutions in the area of SoHO approved by beneficiary • Delivered at least two workshops in duration of two days (with at least 40 participants in total) for measures/action for strengthening capacities of relevant institutions in the field of SoHO,	• Road map document • Workshop reports and attendance list	• Decision makers and all relevant actors are timely informed about progress during project implementation

Result 2.2. Proposal for reorganization of health institutions in the area of SoHO according to the EU regulations and legislation in the field of SoHO	• Approved document with proposals for: - enforcement/implementation of the roles and functions of all relevant institutions in the area of SoHO - roles and functions of the Directorate of Biomedicine as a NCA - organization of inspectorate and surveillance system - merging of Blood Establishment (BE) (now total of 44) leading to a new structure with 4 Blood Establishment (BE) • Delivered at least two educational trainings in duration of one day for administration, management, and implementation and monitoring skills (at least 20 participants per training)	• Document with proposals of reorganization of health institutions in the area of SoHO (roles and functions of Directorate of Biomedicine and organization of inspectorate and surveillance system and proposal for merging of BE on National level • Training materials, reports and training attendance list	Attendance of all relevant employees on training sessions
Result 2.3. Proposed measures for the improvement of IT system related to blood transfusion	• Document with proposal of the measures for implementation of information system and implementing mechanisms which will secure the fully application of the information system • Delivery of one educational training in duration of two days for build unique and unified IT system (at least 20 participants) •	• Document with proposals for implementation of information system • Training materials, reports and training attendance list	• Attendance of all relevant employees on training sessions
Result 2.4. Proposal for future interventions in the field of SoHO which will be included in IPA II programming documentation	• Concept of the Action document to be included in IPA II programming prepared	• Action document prepared	• Approval of draft of the Action document for the IPA II programing period conducted by SPO of MoH
Component 3. Preparation of technical documentation for the purchase of mandatory equipment to perform SoHO procedures in health institutions			
Result 3.1. Preparation of Elaborate of necessary medical equipment for SoHO procedures with draft of technical specification and tender documentation according to PRAG rules	• Elaborate of necessary medical equipment for SoHO procedures • Prepared technical specification and tender dossier for necessary medical equipment according to PRAG rules approved by beneficiary	• Elaborate of necessary medical equipment for SoHO procedures • Technical specification • Draft of tender dossier	All relevant findings about SoHO system presented to the decision makers to MoH Technical specifications should be prepared in accordance with PRAG rolls and with EU country origin of goods
Activities	**Means**	**Specification of costs**	**Assumptions**
Component 1 - Assessment and analysis of gaps, needs and situations related to legal, institutional, administrative, infrastructural and technical capacities of the relevant abovementioned institutions in the area of SoHO. **Activities to achieve Result 1.1**	TWL WD Premises –office for experts Venues for workshops Translation Interpretation/translation Printing	TWL Consultant/expert fees 145 WD Premises –office for experts Translation of documents Interpretation/translation	• Relevant documentation available

1.1.1- Reviewing relevant documentation and preparing questionnaires, interviewing methods (on-the-spot checks), focus groups, and templates for gap assessment report. 1.1.2 -Development of gap assessment document **Activities to Result 1.2.** 1.2.1- Preparation of questionnaires and surveys for the SoHO institutions 1.2.2- Workshop with relevant health institutions in the area of SoHO on the methodology, standards and criteria of data collection and reporting system between health institutions and NCA 1.2.3- Conduction of assessment and collection of relevant data in the field of management of SoHO in accordance with EU Directives, such as number of transplanted organs, cells and tissues; number of BMPO; number of blood donors and others information. 1.2.4-Preparation of the current assessment report document which defined current capacities of relevant institutions in the area of SoHO beside of NCA, in terms of staff and administration, management structure, technical conditions and infrastructure prepared with Recommendations for further improvement of the SoHO system **Activities to Result 1.3**. 1.3.1- Preparation and delivery of questionnaires for gap assessment for weakness of system for sharing and protection of data in IT system for transfusion and transplantation 1.3.2- Conduction of assessment and collection of data of the current situation in regards to development of information system at national level in the area of blood transfusion and organ tissue and cells transplantation 1.3.3-Organisation of workshop with representatives of relevant institutions in the area of SoHO in order to present results of assessment and to discuss of data set and parameters of unified IT system (at least 20 participants) **Activities to Result 1.4.** 1.4.1- Preparation and dissemination of questionnaires for assessment of capacities related to establishing future inspectorate system within Directorate of Biomedicine and data collection 1.4.2- Assessment of the capacities of the Directorate of Biomedicine to oversee management and coordination of transfusion, organ donation and transplantation activities; to support donor hospitals and transplant centres to meet EU	Travel costs	Printing- Travel cost	

requirements to implement relevant directives with proposal with definition of the scope of work; roles and competences;; quality standards and criteria; administration, coordination and management skills needed to the Directorate of Biomedicine as a NCA 1.4.3 One training in duration of two day for employees at the Directorate of Biomedicine with scope to prepare them for conduct the surveillance of SoHO system on national level (at least 20 participants)			
Component 2 - – Development of Roadmap to improve the human, technical, administrative and physical/infrastructural capacities of relevant institutions in the area of SoHO **Activities to achieve Result 2.1** 2.1.1- Development of road map document which define scope of work; definition of the roles and competences; procedures; quality standards and criteria; administration, recommendations for National Parameters System (set of mandatory data for SoHO System), coordination and management skills of relevant institutions in the area of SoHO 2.1.2-Delivery of 2 workshops to health professionals from health institutions in the area of SoHO as a priority to build and update key competences of staff in securing safe blood for transfusion and transplantation **Activities to achieve Result 2.2** 2.2.1-Development of proposal for establishing the network of institutions in the area of SoHO with functional analysis and definitions of roles and functions especially as related to the Directorate of Biomedicine as NCA 2.2.2- Preparation of the recommendations for new reorganization of health institutions in the area of SoHO in order to create more functioning and effective SoHO system with proposal for phases structuring and subsequent merging of the present 44 BE into a final number of 4 BE 2.2.3-Delivery of educational trainings to develop administration, management, and implementation and monitoring skills, inspectorate and information flow of the Directorate of Biomedicine in quality standards and control **Activities to achieve Result 2.3**	TWL WD Venues for workshops Travel costs Translation Interpretation Printing	TWL Consultant/expert fees 90 Venues for workshops Travel costs Translation Interpretation Printing	• Organisation, selection and appointment of staff to participate in field visits • Collaboration of all relevant institutions in the area of SoHO

• Document with proposal of the measures for implementation of information system and implementing mechanisms which will secure the fully application of the information system • Delivery of educational trainingin duration of two day for build unique and unified IT system for at at least 20 participants **Activities to Result 2.4** Preparation of a draft concept of the Action document to be used as a basis for IPA II programming cycle			
Component 3 - Preparation of technical documentation for the purchase of mandatory equipment to perform SoHO procedures in health institutions **Activities to achieve Result 3.1** Act. 3.1.1 Preparation of Elaborate of necessary medical equipment for SoHO procedures in health institutions Act. 3.1.2 Preparation of technical specification for medical and technical equipment prepared to equip BE and HBB as well as recommendations for equipping the institutions and centres for transplantation with the adequate tools, instruments and equipment in order to be able to operate efficiently and effectively under national and EU quality standards in line with the acquis. Act. 3.1.3 Preparation of tender dossier for necessary equipment according to the PRAG	• Consultant fees • Translation	Maximum contract value: 250.000 EUR	
Preconditions: • Appointment of counterpart in the beneficiary before launching the tender procedure; • Allocation of working space and facilities by the beneficiary for technical assistance before launching the tender procedure; • Relevant legislation/regulations regulating this field is in place • Collaboration of all relevant institutions in the area of SoHO			

Annex 2 Relevant National and EU legislation

In terms of the current legislation, there are four laws that regulate the area of SoHO:

The Law on Organ Transplantation,
The Law on Cell and Tissue Transplantation,
The Law on Infertility Treatment with the Procedures of Biomedical Assisted Fertilization and
The Law on Transfusiology Activity.

Annex 3 Indicative work-plan

Indicative work-plan	M 1				M 2				M 3				M 4				M 5				M 6			
Component 0 - Coordination and Visibility																								
Act. O.1.1 Kick off meeting																								
Act 0.1.2. Project Steering Committee meetings																								
Act. 0.1.3 Final Event																								
Component 1																								
Act. 1.1.1 Reviewing relevant documentation and preparing questionnaires, interviewing methods (on-the-spot checks), focus groups, and templates for gap assessment report																								
Act 1.1.2. Development of gap assessment document																								
Act 1.2.1 Preparation of questionnaires and surveys for the SoHO institutions																								
Act 1.2.2 Workshops with relevant health institutions in the area of SoHO on the methodology, standards and criteria of data collection and reporting system between health institutions and NCA																								
Act 1.2.3 Conducting of assessment and collection of relevant data in the field of management of SoHO in accordance with EU Directives, such as number of transplanted organs, cells and tissues; number of BMPO; number of blood donors and others information																								
Act 1.2.4 Preparation of the current assessment report document which defined current capacities of relevant institutions in the area of SoHO beside of NCA, in terms of staff and administration, management structure, technical conditions and infrastructure prepared with recommendations for further improvement of the SoHO system																								
Act 1.3.1Preparation and delivery of questionnaires and surveys for gap assessment for weakness of system for sharing and protection of data in IT system for transfusion and transplantation																								

Act 1.3.2 Conduction of assessment and collection of data of the current situation in regards to development of information system at national level in the area of blood transfusion and organ tissue and cells transplantation																									
Act 1.3.3 Organisation of workshop with representatives of relevant institutions in the area of SoHO in order to present results of assessment and to discuss of data set and parameters of unified IT system																									
Act 1.4.1Preparation and Dissemination of questionnaires and surveys within Directorate of Biomedicine and data collection																									
Act 1.4.2 Assessment of the capacities of the Directorate of Biomedicine to oversee management and coordination of transfusion, organ donation and transplantation activities; to support donor hospitals and transplant centres to meet EU requirements to implement relevant directives																									
Act 1.4.3 Educational training delivered to employees at the Directorate of Biomedicine with scope to prepare them for conduct the surveillance of SoHO system on national level																									
Component 2																									
Act. 2.1.1Development of road map document which define scope of work; definition of the roles and competences; procedures; quality standards and criteria; administration, recommendations for National Parameters System (set of mandatory data for SoHO System), coordination and management skills of relevant institutions in the area of SoHO																									
Act. 2.1.2 Delivery of workshops to health professionals from institutions in the area of SoHO as a priority to build and update key competences of staff in securing safe blood for transfusion and transplantation																									
Act. 2.2.1 Development of proposal for establishing the network of institutions in the area of SoHO with functional analysis and definitions of roles and functions especially as related to the Directorate of Biomedicine as NCA																									
Act. 2.2.2 Preparation of the recommendations for new reorganization of health institutions in the area of SoHO to create more functioning and effective SoHO system																									

with proposal for phases structuring the subsequent merging of the now 44 BE into a final number of 4 BE																							
Act. 2.2.3Delivering of educational trainings to develop administration, management, and implementation and monitoring skills, inspectorate and information flow of the Directorate of Biomedicine in quality standards and control																							
Act. 2.3.1 Preparation of Recommendations on how to expand the best practices of the implementation of the information system related to blood transfusion and transplantation																							
Act. 2.3.2 Training and education of the staff to apply and use software functionalities in accordance with recommendations for advanced functionalities of unified IT system																							
Act. 2.4.1. Preparation of a draft concept of the Action document to be used as a basis for IPA II programming cycle																							
Component 3																							
Act. 3.1.1 Preparation of Elaborate of necessary medical equipment for SoHO procedures in health institutions																							
Act. 3.1.2 Preparation of technical specification for medical and technical equipment prepared to equip BE and HBB as well as recommendations for equipping the institutions and centres for transplantation with the adequate tools, instruments and equipment in order to be able to operate efficiently and effectively under national and EU quality standards in line with the acquis.																							
Act. 3.1.3 Preparation of tender dossier for necessary equipment according to the PRAG																							