ANNEX C1: Twinning Fiche

Project title: Support in strengthening of the capacities of relevant institutions within the substances of human origins (SoHO) system

Beneficiary administration: The Ministry of Health

Twinning Reference: SR 18 IPA HE 01 20

Publication notice reference: EuropeAid/170893/ID/ACT/RS

EU funded project

TWINNING TOOL

(It is recommended that the complete Twinning Fiche should not exceed 10 pages, excluding annexes)

ABBREVIATIONS, ACRONYMS AND EXPLANATIONS

BC	Beneficiary country
BE	Blood Establishments
CARDS	Community Assistance for Reconstruction, Development and Stabilization
CFCU	Department for Contracting and Financing of EU Funded Programs
CL	Component Leaders
EC	European Commission
EU	European Union
EUD	European Union Delegation to the Republic of Serbia
HBB	Hospital Blood Banks
HE	Health and consumer protection
HRSD	Human Resources and Social Development
IO	Induced output
IPA II	The Instrument for Pre–accession Assistance for the period from 2014 to 2020
IPA 2013 TWL project	The IPA programme – Action Plan (a Road-map), prepared by Twinning light project "Strengthening the national institutional capacities in the field of SoHO, for the improvement of blood quality in transfusion and transplantation"
NAD	National Priorities of the Republic of Serbia for International Assistance
NCA	the National Competent Authority
NPAA	National Programme for Adoption of the Acquis
MAK-SYSTEM	Software to manage Blood, Plasma, Tissue, and Cells
MS	Member State
OPO	Organ Procurement Organization
PAR	Public Administration Reform
PL	Project Leader
PSC	Project Steering Committee
PLAC	Policy and Legal Advice Centre
RS	Republic of Serbia
RTA	Resident Twinning Advisor
SAR/E	Serious adverse reactions and events
SEE	South East Europe
SoHO	Substance of Human Origins
SPO	Senior Programming Officer
STE	Short-term experts
TAIEX	Technical Assistance and Information Exchange instrument of the European Commission
TFEU	The Treaty on the Functioning of the European Union
TNA	Training needs analysis/assessment
ToR	Terms of Reference
TW	Twinning
TWL	Twinning light

1. Basic Information

1.1 Programme: Annual Action Programme for Republic of Serbia 2018, indirect management with ex-ante control

"For UK applicants: Please be aware that following the entry into force of the EU-UK Withdrawal Agreement[1] on 1 February 2020 and in particular Articles 127(6), 137 and 138, the references to natural or legal persons residing or established in a Member State of the European Union and to goods originating from an eligible country, as defined under Regulation (EU) No 236/2014[2] and Annex IV of the ACP-EU Partnership Agreement[3], are to be understood as including natural or legal persons residing or established in, and to goods originating from, the United Kingdom [4]. Those persons and goods are therefore eligible under this call".

1.2 Twinning Sector: Health and consumer protection (HE)

1.3 EU funded budget (€): 1.500.000

2. Objectives

2.1 Overall Objective:

To contribute to the strengthening of the legislative framework and institutional capacities for fulfilling the requirements of EU membership in the area of public health.

2.2 Specific objective:

To support and strengthen the National Competent Authority (NCA) and Substance of Human Origins (SoHO) institutions to successfully implement EU quality and safety requirements to meet the needs of citizens in the area of biomedicine.

2.3 The elements targeted in strategic documents i.e. National Development Plan/Cooperation agreement/Association Agreement/Sector reform strategy and related Action Plans:

According to the Stabilisation and Association Agreement, Serbia has to take the necessary measures to guarantee cooperation with the European Commission through development of adequate structures and capacity in the field of health protection and biomedicine. Successful implementation of this twinning project through the IPA indirect management system will also improve government effectiveness. The Budget System Law has provisions related to co-financing of the EU funded programs - **The European Partnership for Serbia 2008/213/EC, the Stabilisation and Association Agreement, the Enlargement Strategy, the Strategy Paper for Serbia, the SEE 2020, A credible enlargement perspective for and enhanced EU engagement with the Western Balkans**.

This Twinning project will directly contribute to the further development of an integrated and coherent system in the area of biomedicine in Serbia by supporting enforcement of legislation aligned with the Union acquis in accordance with the better regulation approach, and by enhancing capacities and improving cooperation among all institutions' in the SoHO defined priorities. The major concepts of key European Directives in the field of biomedicine (2002/98/EC, 2010/53/EU and 2004/23/EC) have been fully transposed through the adopted of four new laws governing the SoHO area - **The National Program for the Adoption of the**

[1] Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community.

[2] Regulation (EU) No 236/2014 of the European Parliament and of the Council of 11 March 2014 laying down common rules and procedures for the implementation of the Union's instruments for financing external action.

[3] Annex IV to the ACP-EU Partnership Agreement, as revised by Decision 1/2014 of the ACP-EU Council of Ministers (OJ L196/40, 3.7.2014).

[4] Including the Overseas Countries and Territories having special relations with the United Kingdom, as laid down in Part Four and Annex II of the TFEU.

Acquis (NPAA) - Third revision (2018-2021)/3.28.2. Health protection; Indicative Strategy Paper for Serbia 2014-2020.

The central coordinating and regulatory institutions in the area of biomedicine in Serbia are the Ministry of Health with its the Directorate for Biomedicine, as the NCA, both responsible for further transposition, enforcement and monitoring of health-related EU regulations, including dissemination of quality and safety standards and raising the capacities of inspection services - **The National Priorities for International Assistance (NAD) 2014-2017, with projections until 2020/Priority 4/Measure 4.2; The EU-Western Balkan Strategy;** draft **NAD 2019-2025, Measure 2.3**.

Improvement in the field of SoHO requires reform and a lot of engagement and effort to meet the EU's SoHO quality and safety standards under Chapter 28 of the accession negotiations. Serbia is encouraged to use the IPA as a means of cooperation with relevant EU Member States and gain practical experience. Efforts should be directed towards the implementation and application of legislations in practice. More specifically, the common challenges in all three sectors of the SoHO (organ, tissue, cell) are the implementation of a unified information system, the establishment of a National quality system, the strengthening of the capacities of procurement organizations/tissue establishments, and awareness raising of the population on the benefits and importance of donations of cells and tissue - **Screening report Serbia: Chapter 28 - Consumer and Health Protection**.

Continuous improvement of the quality of health care and patient safety are one of the specific objectives that require the regulations of quality standards for all activities at all levels of health care, as well as the continuous development of health care professionals. In order to improve efficiency, more efforts is needed on Health Technology Assessment (medicines, medical equipment, devices and procedures) and development of the guidelines for good clinical practice - **The Public Health Strategy 2018-2026/ Specific objective 4.5.2, 4.5.3**.

In order to tackle the challenges regarding infertility, Serbia shall provide professional assistance related to infertility - raising awareness, developing guidelines for good clinical practice, continuing medical education, institutional capacity building, improving the quality of service, and establishing the Registrar and the Bank of reproductive cells, tissues and embryos - **The Birth Promotion Strategy**.

The existence of a national or regional strategic policy framework for health within the limits of Article 168 TFEU[5] shall ensure economic sustainability. The national or regional strategic policy framework for health should include coordinated measures to improve access to health services, measures to stimulate efficiency in the health sector through the deployment of service delivery models and infrastructure, as well as the monitoring and review system – **The Europe 2020 strategy, the Pillar of Social Rights/Chapter III/Key principle 16, the Common Provisions Regulation - ex-ante conditionalities/Thematic Objective 9/9.3. Health.**

3. Description

The IPA II[6] assistance shall support strengthening capacities and competences, as well as improve the functioning of relevant institutions within the SoHO system, with specific emphasis on the surveillance and inspectorate system. Building managerial, institutional, administrative and technical capacity of the Ministry in charge of health/the Directorate for Biomedicine ought to qualify Serbia to implement EC directives that set standards for the quality assurance and safety testing, processing, donation, procurement, preservation, storage and distribution of human blood and blood components, organs, tissues and cells. This leads Serbia to become

[5] The Treaty on the Functioning of the European Union
[6] The Instrument for Pre–accession Assistance for the period from 2014 to 2020

eligible for exchange of organs with other countries by meeting the conditions that the international foundation Eurotransplant sets for new members. This will also reduce the rising healthcare expenditures by performing more organ transplantations in-country.

3.1 Background and justification:

Strengthening the **capacity** of relevant institutions within the SoHO system is one of the highest priorities in the area of public health in Serbia, which will affect the progress of the EU negotiation process in relation to Chapter 28.

The four new laws regulating the area of SoHO - the Law on Transfusion medicine, the Law on Organ Transplantation, the Law on Cell and Tissue Transplantation and the Law on Infertility Treatment with the Procedures of Biomedical Assisted Fertilization have been adopted. Serbia is committed to the implementation of national legislation aligned with the Union acquis in order to ensure full enactment of the EU quality and safety requirements in the area of biomedicine. **The bylaws** that closely regulate the field of human cells, tissues and organs transplantation were also adopted. Beside implementation of legislation, a number of activities that relate primarily to the raising awareness of health care professionals and citizens, developing guidelines for good clinical practice, continuing medical education, institutional capacity building, improving the quality of service, etc. shall commence.

With the aim to develop and improve the **transplantation** of organs, cells and tissues and establish the EU standards, after the adoption of the by-lays which closely regulate these fields, the plan is to adopt the National Transplantation Programme.

Fulfilling the EU's safety and quality requirements also implies a substantial **reorganization** of the Serbian Transfusion and Transplantation Services, as well as the upgrading of the medically assisted reproduction technology. This activity shall support the improvement of the competences and functioning of the NCA with a special focus on the surveillance and inspection system, and the increase of institutional capacities and technical conditions of the most relevant institutions of SoHO. Specifically, the Ministry of Health has programmed and started activities toward the reorganisation of blood transfusion services, i.e. reducing the number of blood transfusion services and hospital banks. It is necessary to establish 7 transfusion centres in order to preserve the blood donation, primarily due to balanced territorial distribution, in terms of timely and safe blood supply. This reduction should take place in stages.

Pursuant to the Law on biomedical assisted fertilization, the Bank of reproductive cells, tissues and embryos was established at the Gynaecology and Obstetrics Clinic of the Clinical Centre of Serbia and 10 rulebooks[7] have been written that closely regulate the field of biomedical assisted fertilization.

In the area of **transfusion**, this activity will contribute to the further implementation of the priority activities identified under the IPA programme – Action Plan (a Road-map), prepared by the Twinning light project "Strengthening the national institutional capacities in the field of SoHO, for the improvement of blood quality in transfusion and transplantation" (IPA 2013 TWL project). Activities carried out by this TW light resulted with 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 acquis. Also, the goal of the activities was to fulfil the preconditions and lay the basis for SoHO sector for further EU funding support. Implementation of a unique **MAK** information system for the field for transfusion medicine is ongoing and in connection with the centralisation of transfusion activity on the national level. The plan is to introduce an information system for keeping the national registry of donors of reproductive cells. In parallel

[7] Published in the Official Gazette number 27, since 12 April 2019

with the implementation of the new Law on organ transplantation, an information system covering the field of human organ transplantation will be introduced. The information system in the field of biomedicine will be part of a unique health information system in Serbia.

The EU-Western Balkan Strategy indicate that "much remains to be done across the board to align with the EU's acquis, to establish or build up the related institutions, and to ensure implementation capacity, whether in terms of single market rules, social policy, energy and transport acquis or EU environmental law", hence the proposed intervention is focused on strengthening the capacities of relevant SoHO institutions to implement requirements related to aligning with the acquis on blood, tissues, cells and organs. In the coming year, Serbia should in particular strengthen the overall managerial capacity, human resources.

Although the progress made in consumer and health protection in Serbia in 2018 was rated as moderate[8], in the area of harmonisation of legal and regulatory recruitments "some progress was made including with the adoption of the Law on the transplantation of cells and tissues and the Law on human organ transplantation". Compared to the previous report's[9] assessment when it was estimated as limited, some progress was made with the adoption of the laws on transfusion medicine and biomedical assisted fertilization. The overall administrative and technical capacities of the Directorate for Biomedicine to perform oversight of the sector as the NCA must be further improved ("still very limited") and reach the EU-level of quality, safety standards and inspection services. Interventions will contribute to the EC Progress Report 2019 recommendation that Serbia still needs to invest more efforts to "strengthening of the overall administrative and technical capacity of the Directorate for Biomedicine to perform oversight" and to further develop "safety standards and inspection services for the sector" in line with the EU requirements and quality.

In the field of transfusion Serbia has not yet 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") that was emphasized as one of the priorities of the "Strategy for providing adequate quantities of safe blood and blood product in the Republic of Serbia" which was adopted in 2009. Blood collection in several blood establishments (BE) is still based on replacement donations, nevertheless, some BE that have invested in voluntary non-remunerated blood donation programs (in collaboration with Red Cross), showed good results (Observation assessment EU/TAIEX recommendations).

In accordance with EC's DG SANTE priority findings for SoHO, clear definition of the competences and responsibilities of the NCA (oversight the SoHO sector, authorise and inspect BE, to operationalize the national vigilance and annual reporting systems and national registries, and coordinate international cooperation) is needed. The NCA has to be fully equipped, resourced and empowered to ensure implementation of the SoHO acquis on the basis of a long-term development plan. The responsibility of the inspection is also a question. Prerequisites for timely reorganization of blood services nationwide should be set. In the area of organ, tissue and cells deceased and live donation and transplantation rates has to be improved. Serbia has to put in place a fully functioning national transplant agency (The 2015 EC DG SANTE Serbia Mission Report for SoHO report).

According to the findings from the Serbia Mission Report, the latest EC Progress report 2019 TAIEX expert mission's recommendations, IPA 2013 TWL project outputs, and EU-Western Balkan Strategy, following major challenges have been identified in the SoHO field:

1) Insufficient administrative and human capacities and competencies of the NCA and lack of inspectors with education, skills and competencies in the SoHO field;

2) Lack of technical capacities in the relevant SoHO institutions, necessary to meet EU

[8] EC Serbia 2019 Report
[9] EC Serbia 2018 Report

safety and quality standards;

3) Lack of a common coding system and unified information system in national transfusion service;
4) Lack of national bio vigilance system to ensure proper SAR/E management;
5) Lack of proper Database Management system to ensure adequate data protection and traceability in all SoHO fields, and
6) Lack of national blood (organs, tissues and cells) quality management system to ensure the same quality and safety standards of blood components and other SoHO, countrywide.

The Ministry in charge of Health/Directorate for Biomedicine is the key institution responsible for establishment of the SoHO system and acts as the NCA in this field. In addition, relevant health institutions (hospitals, institutes) in the field of transfusion, transplantation and medically assisted reproduction technology are called SoHO institutions, and will be targeted during the implementation of this intervention.

In the previous period, the Ministry of Health conducted the activities that were directed towards the adoption of legislation in the field of SoHO.

The area of *blood transfusion and blood components* is regulated by the Law on Transfusion Medicine ("Official Gazette of the RS" No.40/17) which entered into force on May 5, 2017, and whose implementation began on January 1, 2019. According to the Work Plan of the Government of Republic of Serbia, Ministry of Health prepared and published Rulebooks which more closely define Law on Transfusion Medicine:

- Rulebook on donors of blood or blood components ("Official Gazette of the RS" No.6/19),
- Rulebook on notification and consent for the receipt of blood and blood components ("Official Gazette of the RS" No.6/19),
- Rulebook on quality in the field of transfusion medicine ("Official Gazette of the RS" No.6/19),
- Rulebook on the traceability system and the manner of notification of a serious adverse reaction, or a serious adverse event ("Official Gazette of the RS" No.6/19).

The law and bylaws that are currently in force are fully aligned with the EU directives in the field of blood transfusion.

The field of *reproductive cells* is regulated by the new Law on Biomedical Assisted Fertilisation ("Official Gazette of the RS" No. 40/17), which entered into force on May 5, 2017. Also, the Rulebooks specifying Law on Biomedical Assisted Fertilisation the Rulebooks specifying Law on Biomedical Assisted Fertilisation were published:

- Rulebook on the content of the form of donor's declaration on the withdrawal of the statement on donation and use of reproductive cells and embryos in the process of biomedically assisted fertilization and the form of Certificate of withdrawal of the donation and use of reproductive cells and embryos in the process of biomedically assisted fertilization and the form of Certificate of destruction of donated reproductive cells and embryos ("Official Gazette of the RS" No.27/19),
- Rulebook on the content of the application form stating further procedure in treating reproductive cells, i.e. unused early embryos ("Official Gazette of the RS" No.27/19),
- Rulebook on the detailed conditions, criteria and manner of selection, testing and assessment of the donors of reproductive cells and embryos ("Official Gazette of the RS" No.27/19),
- Rulebook on detailed conditions regarding space, medical - technical equipment, personnel,

and the manner of submission of requests for carrying out the procedures of biomedically assisted fertilization ("Official Gazette of the RS" No.27/19),

- Rulebook on a single registry of procedures for biomedically assisted fertilization ("Official Gazette of the RS" No.27/19)
- Rulebook on the content of the notification form for persons subject to the process of biomedically assisted fertilization ("Official Gazette of the RS" No.27/19),
- Rulebook on how to communicate information to the donor about the legal consequences and content of the form of the donor's declaration on the donation and use of reproductive cells or embryos in the process of biomedically assisted fertilization ("Official Gazette of the RS" No.27/19),
- Rulebook on detailed conditions for performing activities of import and export of reproductive cells, as well as the manner of evaluating the quality and safety requirements ("Official Gazette of the RS" No.27/19),
- Rulebook on detailed conditions for performing activities of import and export of reproductive cells, as well as the manner of evaluating the quality and safety requirements ("Official Gazette of the RS" No.27/19).

The law and bylaws that are currently in force are fully aligned with the EU directives in the field of Biomedical Assisted Fertilisation.

The *cells and tissues* transplantation area is regulated by the new Law on the Transplantation of Cells and Tissues ("Official Gazette of the RS" No. 57/18), which entered into force on July 24, 2018, is fully aligned with the acquis.

The area of *organ* transplantation is regulated by the new Law on Human Organ Transplantation ("Official Gazette of the RS" No.57/18) which entered into force on July 24, 2018, is fully aligned with the acquis.

As one of the preventive measures and acting in accordance with Serbian Anticorruption agency`s recommendations, Ministry of Health conducted self-assessment of institution`s exposure to risk of corruption and professionally unrespectable acts, in line with its the Integrity plan adopted in 2017. Ministry recommended to all health care institutions to do the same in order to make mechanisms for prevention of corruption and unethical and unprofessional acts in all areas of institution`s work.

3.2 Ongoing reforms:

Overall, the Human Resources and Social Development (HRSD) sector policies aim at raising the country's human capital as a foundation for economic growth, improving living standards and the dignity of every citizen. Quality and inclusive health services are essential to combat poverty and promote economic development since healthier people are more autonomous and productive. The HRSD sector therefore places emphasis on the coordination and integration of policy responses to combat social exclusion and promote the well-being of Serbia's citizens.

The Serbian government is engaged in a wide range of reforms to address these challenges. Reforms of social protection and social inclusion policies are also progressing, aiming at increasing the coverage and targeting on the neediest groups and individuals, with better links between employment, education, housing, health and social policies and a greater use of community-based social services at the local level. In the health sector, the quality and accessibility of health services is being promoted, most recently through structural reforms to establish a legislative framework and measures to raise efficiency.

Efforts are needed on strengthening the governance of the health sector to improve the quality and efficiency of health systems and services. Serbia should implement more vigorous health

promotion and disease prevention policies in line with the EU acquis.

In addition to strengthening service delivery, with a view to promote a more balanced regional development and greater social cohesion it is necessary to ensure the availability of inclusive, safe and accessible social infrastructure across the country, including healthcare facilities.

With regards to the health sector the proposed Action will provide support to strengthening of the capacities of relevant institutions within the SoHO system, as envisaged in IPA II Regulation[10] i.e. to strengthen the ability at all levels to fulfil the obligations towards progressive alignment with, and adoption, implementation and enforcement of the Union acquis, including preparation for management of Union Structural Funds and the Cohesion Fund. Interventions in this area shall aim at enhancing access to affordable, sustainable and high-quality services, such as health care services of general interest.

3.3 Linked activities:

In relation to the health, significant progress was made in harmonization of the relevant legislation with the Union acquis. However, challenges remain in the human, technical and administrative capacities for implementation of adopted legislation. So far, the EU has significantly supported the reform process in SoHO through provision of expert assistance in different analysis, studies, legislative acts preparation by **TAIEX** and **PLAC project** experts (**TAIEX Multi-country Workshop** on the Role and Functioning of Competent Authorities in the Field of Substances of Human Origin 2016, **TAIEX expert missions** - National System in the area of organ donation and Transplantation 2015, National system in the area of Transplantation of Cells and Tissues 2015, Establishment of National Centre 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 be fully harmonised with relevant EU directives, and positive feedback was received from **DG SANTE**. In addition, support was provided in the field of transfusion through **CARDS 2005** project for Reorganization of Blood Transfusion Services that supported the reforming/upgrading the existing transfusion system, harmonization with the acquis and providing relevant equipment and works. The **IPA 2013 TWL project** has provided broader experts assistance in conducting gap assessment analysis of the current Serbian overall capacities in the area of SoHO and identifying their needs and priorities in terms of staff and administration, management structure, technical conditions and infrastructure. The NCA has been provided with set of recommendations for improvement in the SoHO defined priorities. The Plan for reorganisation of the National blood transfusion service has been designed, in close collaboration with BC experts, in order to facilitate reform of National transfusion service in line with EU requirements, and to ensure optimal supply of the blood components of the same quality and safety for all citizens of the Republic of Serbia. A comprehensive *Roadmap document and technical specification for procurement of most critical equipment for SoHo institutions* have been prepared in order to support Serbia in strengthening of their institutional capacities within the SoHO system. The road map document laid down major goals, objectives and priority actions and grounded basis for the IPA II action plan programming. The Activity proposed under this Action will support the NCA and SoHO institutions in implementing the Roadmap. In the frame of **PLAC 3** (2019), the Ministry in charge of health/the NCA has been awarded an EU-funded project to fully align legislation in the SoHO defined priorities areas with EU Directives, in particular bylaws on the Law on Cell and Tissue Transplantation and the Law on Organ Transplantation.

[10] REGULATION (EU) No 231/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 March 2014 establishing an Instrument for Pre-accession Assistance (IPA II)

The Serbian Government/The Office for Cooperation with Civil Society has established an institutional mechanism to involve other parties, such as representatives of civil society, private and professional sectors' organisations into working groups for drafting and public debates on public policy documents and regulations, all published on their website.

HRSD – PUBLIC ADMINISTARTION REFORM: In the context of the state administration reform and the improvement of administrative procedures (PAR), the public administration system optimization, creating the opportunities for professional development of employees and enabling sustainable budgetary planning and execution will empower the efficiency, effectiveness and good governance of the HRSD/Health sector institutions at all levels. Improving accountability, E-government services and quality assurance system contribute to better performance of services for people and simplification of administrative procedures in accessing HRSD/Health sector services and benefits. Continuous training, mutual communication and cooperation with stakeholders are ongoing. Improvement of the system of managing administrative statistics enables the content and formal evaluation of work quality and decision making. The E-inspector will increase efficiency of data and electronic documents exchange in the field of planning and implementation of inspection supervision. The PAR sector reform contributes to increasing legal security, improving the business environment and the quality of public services provision, and improvement of the regulation drafting process. PAR sector is partly supported by the national budget and IPA funds specially allocated for PAR sector.

In this context, the new Rulebook from 2019 on the internal organization and systematization of jobs of Ministry of Health, introduce reorganization of Directorate for Biomedicine. In line recommendation of TW light and relevant Union acquis, 4 inspectors in the filed od biomedicine are included in the systematization. Human capacities are strengthened and number of employees are increased from 9 to 13. From January 2020 one inspector has started to work while three more inspectors are planned to fully cover Inspection Affairs. Whole system of transplantation and transfusion have been reorganized. There are currently five centres for organ transplantation in Serbia, three of which are in the Belgrade area, one in Nis and one in Novi Sad. In the field of transfusion practice, activities are performed by 3 major institutes (Belgrade, Novi Sad, and Nis) and the Military Medical Academy, as well as organizational units of different health institutions (3 clinical centres, 4 clinical/hospital centres, 37 general hospitals). 70 healthcare facilities with or without clinical blood departments are exclusively users of blood and blood products. The Ministry of Health has programmed and initiated activities toward the reorganisation of blood transfusion services, i.e. establishment of 7 transfusion centres with a balanced territorial distribution and timely and safe blood supply.

3.4 List of applicable *Union acquis*/standards/norms:

The list of applicable Union acquis/standards/norms is presented as Annex 2.

3.5 Components and results per component:

Result 1 - Component 1 – Institutional and administrative capacities of the NCA strengthened

The process of authorization, inspection, monitoring, reporting and biovigilance will be improved by scaling-up the NAC's managerial, human, administrative, technical and physical/infrastructural capacity for alignment with EC Directives and standards for quality and safety assurance - emphasizing roles and organisation of work, milestones and targets, budget and financing sources, etc.

The following indicative sub-results will be achieved:

Sub-result 1.1 Operational procedures and tools, Need Assessment related to institutional, administrative, infrastructural and technical capacities of the NCA for biomedicine developed.

Sub-result 1.2 Institutional and administrative capacities of the NCA for biomedicine regarding the process of authorization, inspection, monitoring, reporting and biovigilance enhanced.

Sub-result 1.3 Assessment report with draft documents critical for establishment of NCA functionalities (IT, Quality System, staff capacities…) according EU regulations and the best practices submitted.

Sub-result 1.4 Training for all NCA personnel in NCA's responsibilities (the OPO functions, authorization, monitoring, inspection, reporting, and bio vigilance) designed.

Result 2 - Component 2 – Transposition of the EU requirements related to SoHO field into national legislation enhanced

The aim is to make more effective utilization of EU requirements in the field of SoHO by detailed presentation of national legislation at workshops to health care professionals by the NCA staff.

The following indicative sub-results will be achieved:

Sub-result 2.1. Implementation of by-laws and law implementing acts/rulebooks among health care professionals of SoHO institutions introduced.

Sub-result 2.2 Awareness on the EU standards and requirements to healthcare professionals raised.

Sub-result 2.3 Amendments of legislation recommended.

Result 3 - Component 3 – Institutional capacities and quality of technical conditions in SoHO institutions improved

In order to meet the safety and quality conditions of the requirements of the EU Directive, the focus will be on improving knowledge, skills and practices, development of technical specifications of critical equipment to SoHO institutions, i.e. improving their institutional capacities and quality of technical conditions in SoHO institutions.

The following indicative sub-results will be achieved:

Sub-result 3.1 Quality system and technical conditions reviewed.

Sub-result 3.2 Procurement plans for SoHo institutions in line with TW Light recommendation defined.

Sub-results 3.3 Training capacities for SoHo personnel improved.

Result 4 - Component 4 – Awareness-raising in the population about the voluntary donations (blood, organ, tissue and cells) enhanced

The project will develop documents and perform activities aimed to increase public trust in the field of SoHO. The NCA should be seen as a trustworthy and reformed institution that operates in accordance to the EU standards, rules and procedures. The project should enable citizens to understand and advocate for voluntary unpaid donations (blood, organs, tissues and cells), adequate implementation of European standards and practices and to recognize their own role and responsibilities.

The following indicative sub-results will be achieved:

Sub-result 4.1 Needs for voluntary donations assessed.

Sub-result 4.2 Public awareness on voluntary unpaid donations (blood, organ, tissues and cells) raised.

Sub-results 4.3 Public awareness on the NCA reform and alignment with EU standards raised.

3.6 Means/input from the EU Member State Partner Administration(s)*:

The project will be implemented between the final beneficiary country and EU Member State(s). The implementation of the project requires one Project Leader (PL) with responsibility for the overall coordination of project activities and one Resident Twinning Adviser (RTA) to manage implementation of project activities, Component Leaders (CLs) and pool of short-term experts (STEs) within the limits of the budget. It is essential that the team has sufficiently broad expertise to cover all areas included in the project description.

Proposals submitted by Member State shall be concise and focused on the strategy and methodology and an indicative timetable underpinning this, the administrative model suggested, the quality of the expertise to be mobilised and clearly show the administrative structure and capacity of the Member State entity/ies. Proposals shall be detailed enough to respond adequately to the Twinning Fiche, but are not expected to contain a fully elaborated project. They shall contain enough detail about the strategy and methodology and indicate the sequencing and mention key activities during the implementation of the project to ensure the achievement of overall and specific objectives and mandatory results/outputs.

The interested Member State(s) shall include in their proposal the CVs of the designated PL and the Resident Twinning Advisor, as well as the CVs of the potentially designated component Leaders-CLs.

The Twinning project will be implemented by close co-operation among the partners aiming to achieve the mandatory results in sustainable manner.

The set of proposed activities will be further developed with the Twinning partners when drafting the initial work plan and successive rolling work plan every three months, keeping in mind that the final list of activities will be decided in cooperation with the Twinning partner. The components are closely inter-linked and need to be sequenced accordingly.

The Project Leader (PL) and RTA (Resident Twinning Adviser) will provide support to the responsible Serbian authorities in strengthening their capacities as well as in implementation of this project. During the implementation of this project RTA will be positioned in the premises of the Ministry in charge of health/Directorate of Biomedicine.

3.6.1 Profile and tasks of the PL:

The MS Project Leader will manage the project team of selected member state(s) and co-ordinate the implementation of activities.

Tasks of the Project Leader:

- Overall management and coordination of the project with MS and cooperation with the BC;
- Project reporting and supervises the RTA;
- Ensuring backstopping and financial management of the project in the MS;
- Ensuring timely, effective and efficient implementation of the project and achievement of results, through proposed activities;

- Coordination of deployment and work of short-term experts;
- Coordination with RTAs, from the Member State side, the Project Steering Committee meetings, which will be held in Serbia every three months;
- Participation at the Steering Committee meetings (every three months);
- Assuring compatibility with EU requirements;
- Overall responsibility and direction of the MS Twinning partner inputs and proposing corrective measures, if needed.

Profile of the Project Leader:

Requirements:

- High ranking official/senior civil servant currently working in the MS administration;
- Proven contractual relations to public administration or mandated body;
- University degree or equivalent professional experience of 8 years in the field of medicine;
- 3 years of professional working experience in the field of SoHO (organs, tissues, blood and cells);
- Project management experience;
- Working knowledge of English language;
- Computer literacy.

Assets:

- Experience in implementation of EU Directives and standards for blood and/or organs, tissues and cells;
- Experience with EU funded project/Twinning rules and procedures;
- Experience in managing implementation of at least 1 similar project.

3.6.2 Profile and tasks of the RTA:

The RTA works on a daily basis with the BC staff to implement project, support and coordinate activities in the beneficiary country.

The RTA should have adequate experience and knowledge in the field of SoHO (organs, tissues, blood and cells) which will enable him/her to organize interdisciplinary team for successful implementation of the project. She/he should be an employee of the governmental competent authority for SoHO (organs, tissues, blood and cells) in the Ministry or Agency in an EU Member State.

He/she will liaise with the BC Project Leader and will report to the MS Project Leader. The RTA will also be responsible for ensuring that experts' input and distribution of their working days will be used in the most efficient and effective way and in line with the agreed work plan to enable timely completion of project results. Duration of his/her secondment will be 24 consecutive months.

Tasks of the RTA:

- Responsible for monitoring project implementation and proposing corrective management actions if required;
- Project management and coordination of the activities of the team members in line with the agreed work plan to enable timely completion of project results;
- Selection, mobilisation and supervision of the short-term experts, together with the Project

Leader;

- Facilitation of the contacts with peer institutions in EU member states in order to stimulate a proper exchange of information, data and experience;
- Organization of visibility events (kick-off and final event);
- Advice on related EU policies, regulation and best practice;
- Establish and maintain cooperation with all beneficiaries involved in the implementation of the project and other related projects (ensuring the avoidance of overlapping), in close coordination with the Project Leader;
- Responsible for the organisation of the Project Steering Committee meetings and reporting on the project progress in cooperation with the Project Leader;
- Identifying and reporting to the Contracting authority, at early stage, all difficulties that may jeopardize the implementation of the project and the achievement of its results.

Profile of the RTA:

Requirements:

- University degree or equivalent professional experience of 8 years.
- At least 3 years of working experience in the field of in the field of SoHO (organs, tissues, blood and cells) in the public administration of a Member State or Mandated body;
- Project management experience;
- Working knowledge of English language;
- Computer literacy.

Assets:

- Experience in implementation and/or managing of at least 1 similar project.
- Experience with EU funded project/Twinning rules and procedures;
- Experience in analysing and developing procedures in the field of in the field of SoHO (organs, tissues, blood and cells)
- Experience in context of public administration reform
- Experience in conducting trainings.

3.6.3 Profile and tasks of Component Leaders*:*

The Twinning partner will decide on the profile, number and involvement of the short-term experts during the drafting of the project work plan. Component Leaders should be identified by the Project Leader/RTA and have to be agreed with the beneficiary institutions in the course of designing and delivery of the expected project outputs. Main areas of expertise required by the team of short-term experts should cover the following fields of SoHO (organs, tissues, blood and cells) (the list of fields is non exhaustive): Law harmonization and enforcement, Analysing needs and developing operational procedures, Procurement and Supply management, Training design and delivery, and Media and communication.

Tasks of Component Leaders:

Component Leaders will provide specialized know-how for the individual tasks in this project. Therefore, the experts should have a relevant professional experience in administration and minimum qualifications required, as well as specific skills needed for individual task. As a general approach, the Component Leaders will take the responsibility for the implementation of the Project

and the achievement of the results, each for his/her individual mission tasks, as defined by individual ToR. They will also prepare the required reports and the output described.

Profile of Component Leaders:

Requirements:

- University degree in the relevant field depending of the area of expertise or equivalent of 8 years of professional experience;
- At least 3 years of specific working experience in the field of SoHO (organs, tissues, blood and cells) or other relevant field depending of the area of expertise;
- Experience in providing assistance in the capacity building initiatives in the area of SoHO (organs, tissues, blood and cells);
- Working knowledge of English language;
- Computer literacy.

The concrete assignments will be subject to the preparation of the Twinning Contract and the recommendations of the Twinning partner(s).

3.6.4 Profile and tasks of other short-term experts*:*

The Twinning partner will decide on the profile, number and involvement of the short-term experts during the drafting of the project work plan. STEs should be identified by the Project Leader/RTA and have to be agreed with the beneficiary institutions in the course of designing and delivery of the expected project outputs.

Main areas of expertise required by the team of short-term experts should cover the following fields (the list of fields is non exhaustive): SoHO (organs, tissues, blood and cells), Law harmonization and enforcement, Analysing needs and developing operational procedures, Procurement and Supply management, Training design and delivery, and Media and communication. If needed, short-term expertise may also be requested to support with (regulatory/budgetary) impact assessments.

Tasks of the short- term experts:

STEs will provide specialized know-how for the individual tasks in this project. Therefore, the experts should have a relevant professional experience in administration and minimum qualifications required, as well as specific skills needed for individual task. As a general approach, the STEs will take the responsibility for the implementation of the Project and the achievement of the results, each for his/her individual mission tasks, as defined by individual ToR. They will also prepare the required reports and the output described.

Detailed profiles and tasks of short - term experts and including the duration of their assignments will be subject to the preparation of the TW Twinning Contract and the recommendations of the TW Twinning partner(s).

Profile of the short- term experts:

Requirements:

- University degree in relevant field depending of the area of expertise or equivalent of 8 years of professional experience;
- At least 3 years of specific working experience in the field of SoHO (organs, tissues, blood and cells) or other relevant field depending of the area of expertise;
- Proven contractual relations to public administration or mandated body;

- Working knowledge of English language;
- Computer literacy.

4. Budget

IMPLEMENTATION MODALITIES "SUPPORT IN STRENGTHENING OF THE CAPACITIES OF RELEVANT INSTITUTIONS WITHIN THE SUBSTANCES OF HUMAN ORIGINS (SOHO) SYSTEM"	BUDGET (€)			TIMELINE	
	EU contribution	**National contribution**	**Total**	**Launch of procedure**	**Contract signature[11]**
TWINNING	1.500.000	-	1.500.000	Q4 2020	Q2 2021

5. Implementation Arrangements

5.1 Implementing Agency responsible for tendering, contracting and accounting (AO/CFCE/PAO/European Union Delegation/Office):

The Implementing Agency of the project is the Department for Contracting and Financing of EU Funded programmes (CFCU). The CFCU will be the Contracting Authority and it will be responsible for publishing tenders, concluding contracts and authorizing the Treasury to make contract related payments.

Ministry of Finance

Department for Contracting and Financing of EU Funded programmes (CFCU)

Sremska St, No. 3-5

11000 Belgrade, Serbia

Mr. Marko Jovanović, Acting Assistant Minister/Head of CA

Phone: +381 11 20 21 115

E-mail: marko.jovanovic@mfin.gov.rs

Mr. Darko Vasić, Twinning National Contact Point

Phone: +381 11 2021 412

E-mail: twinnning@mfin.gov.rs

5.2 Institutional framework

The **beneficiary administration** responsible for organizing and coordinating project implementation:

The Ministry of Health is responsible for implementing legislation in the field of SoHO: transfusion medicine, biomedically assisted fertilization, transplantation of human organs for the treatment and application of human cells and tissues. It is also responsible for the nomination of the competent authority, the inspection control of the implementation of the law and other actions defined by the Law on Ministries.

The Directorate of Biomedicine was established within the Ministry in charge for health in 2010.

Timeline: QUARTER (Q1, Q2, Q3, Q4) YEAR

According to the Law on Organ transplantation, the Directorate of Biomedicine is the NCA responsible for SoHO, organized into 3 main areas: Blood and Blood components; Tissue, Cells and Biomedical Assisted Fertilization; Organs. As the NCA, the Directorate is responsible to oversight the work of all relevant actors involved in the areas, activities and processes mentioned above, as well as the conditions of the facilities in which the activities and processes are performed. The work of the NCA should be supported and complemented by the licensed SoHO inspectors. At present, one inspector is employed.

There are currently **five centres for organ transplantation** in Serbia, three of which are in the Belgrade area, one in Nis and one in Novi Sad. All five centres perform kidney transplantation, three perform liver transplantation and only one centre performs heart transplantation. There is a total of 14 donor hospitals, including 5 transplant centres. When it comes to organ transplantation, Serbia lags behind the EU, not only in the types of the organs that could be transplanted, but in terms of organ donation at an Annual Rate of p.m.p 2014 of 3.1. In addition, there are 5 institutions that perform haematopoietic stem cells transplantation and 8 institutions that perform tissue transplantations.

In the field of **transfusion** practice, activities are performed by **3 major institutes** (Belgrade, Novi Sad, and Nis) and the Military Medical Academy, as well as organizational units of different health institutions (3 clinical centres, 4 clinical/hospital centres, 37 general hospitals). 70 healthcare facilities with or without clinical blood departments are exclusively users of blood and blood products. In order to comply with the Directive 2002/98/EC and to meet all the necessary requirements to ensure the quality and safety of the collection, testing, processing, storage and distribution of human blood and blood components, it is necessary to segregate competences, which includes defining the number of institutions to be responsible for any aspect of the collection and testing of human blood or blood components, whatever their purpose, and their processing, storage and distribution when intended for transfusions (BE) and to define the hospital unit responsible for storage and distribution (Hospital Blood Banks, HBB). Following an assessment that included field visits, the Ministry of Health has programmed and initiated activities toward the reorganisation of blood transfusion services, i.e. establishment of 7 transfusion centres with a balanced territorial distribution and timely and safe blood supply.

5.3 Counterparts in the Beneficiary administration:

5.3.1 Contact person:

Danijela Urošević, MD, MPH, Acting Assistant Minister / Senior Project Officer (SPO)
Nemanjina St, No. 22-26
11000 Belgrade, Serbia

5.3.2 PL counterpart

Vesna Rakonjac, MD, Director of Directorate for Biomedicine
Pasterova St, No. 1
11000 Belgrade, Serbia

The BC Project Leader will manage and lead a project team from the Serbian side and will ensure that the decision makers at the national level will be informed accordingly on the implementation and evolution of the project. He/she will ensure close cooperation and supervision of the project and he/she will also be responsible for drafting and signing reports and other documents related to project management from the Serbian side and will chair PSC meetings.

5.3.3 RTA counterpart

Assistant / Deputy Director of Directorate for Biomedicine
Pasterova St, No. 1
11000 Belgrade, Serbia

6. Duration of the project

Duration of the project is 24 months.

7. Management and reporting

7.1 Language

The official language of the project is the one used as contract language under the instrument (English). All formal communications regarding the project, including interim and final reports, shall be produced in the language of the contract.

7.2 Project Steering Committee

A project steering committee (PSC) shall oversee the implementation of the project. The main duties of the PSC include verification of the progress and achievements via-à-vis the mandatory results/outputs chain (from mandatory results/outputs per component to impact), ensuring good coordination among the actors, finalising the interim reports and discuss the updated work plan. Other details concerning the establishment and functioning of the PSC are described in the Twinning Manual.

7.3 Reporting

All reports shall have a narrative section and a financial section. They shall include as a minimum the information detailed in section 5.5.2 (interim reports) and 5.5.3 (final report) of the Twinning Manual. Reports need to go beyond activities and inputs. Two types of reports are foreseen in the framework of Twining: interim quarterly reports and final report. An interim quarterly report shall be presented for discussion at each meeting of the PSC. The narrative part shall primarily take stock of the progress and achievements via-à-vis the mandatory results and provide precise recommendations and corrective measures to be decided by in order to ensure the further progress.

8. Sustainability

The capacity building of the NCA through institutional capacity building, and further support mechanisms, lays the basis for the NCA to implement the legislation in accordance with 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. Financing of operating and maintenance costs of the technical equipment will be provided through the budget of the Republic of Serbia. Final beneficiaries of equipment will be health care institutions, which are under the jurisdiction of the Ministry in charge of Health. Annually, the Ministry in charge of Health provides funds for investment and maintenance of health facilities.

Financing of operating and maintenance costs of the technical equipment will be provided through the budget of the Republic of Serbia. Final beneficiaries of equipment will be health care institutions, which are under the jurisdiction of the Ministry in charge of Health. Annually, the Ministry in charge of Health provides funds for investment and maintenance of health facilities. Therefore, every health institution, upon recording of the equipment in the fixed assets, will be able to justify all the funds necessary for the reliable functioning. Financial sustainability will be secured through continuous education and training of healthcare professionals. It is of great importance to have training courses for installation, validation and adequate maintenance of the equipment. Also, sustainability will be provided through the process of harmonising national legislation with EU acquis as well through adequate enforcement of harmonised legislation.

9. Crosscutting issues *(equal opportunity, environment, climate, etc.)*

Cross-cutting issues will be addressed in the project so as to comply with the best EU standards and practice in that area and in a way which demonstrates how they will be dealt with within the project's framework, its activities and outputs. Support to the antidiscrimination and gender equality policies are the core of the specific objectives in the HRSD/Health care sector and respective measures, while a sustainable development principle is integrated and promoted where applicable. Improving the system for high quality, access and effective health care services will have impact on empowering population most in need to take active participation in society. Efficient and effective design and provision of quality healthcare services and health promotion will foster all citizens with equal access to healthcare. Progress will be measured though official disaggregated statistics on unmet healthcare needs, Blood utilisation in different medical and surgical settings (Analyse blood use in cardiovascular surgery, transplants, etc.), Number of donors and donor reactions of submitted samples/request forms during the study period, Adequacy of the red cell reserves related to the medical or surgical procedure, Compliance with hospital transfusion guidelines, Relationship with the Regional Blood establishment, Breaches of stock (Number of times the transfusion service cannot supply a blood product), Performance of the Haemovigilance system (Speed of communication, case solving and corrective action, etc.), Adverse effects of apheresis or whole blood donation, Performance in external quality controls, mortality from diseases that require transfusion and / or transplantation of cells, tissues and organs.

The project will be implemented in a way which provides equal opportunities for participation for those within the NCA and SoHO institutions. No discrimination will be made on the basis of gender and activities such as training needs analysis, trainings will be organised in a way which makes them accessible for both men and women. The number of men and women participating in training events will be monitored during the project and this information will be used to identify any potential discrimination. Principle of gender equality will be implemented in all project activities and procedures. The project will result in procedures and measures that will implement this principle and by no means will not endanger it throughout the project implementation and upon its completion. For all the activities recycling of paper and the reduction of paper-based activities is recommended. As a general principle, sensitivity towards minorities and vulnerable groups, where meaningful, should be reflected in the improved provision of public services.

The last but not least, the intervention implies equal opportunities and treatment for the entire population, i.e. it is non-discriminatory in relation to gender, ability, belonging to minorities and / or vulnerable groups. When appropriate, professional associations will be included. During the preparation and implementation of the activities, special attention will be paid to location, resources, potential pollution, waste, land-based requirements and transports related to the intervention.

10. Conditionality and sequencing

Conditionality:

The implementation of this TW has the following conditions:

1. Necessary number of SoHO inspectors employed in the NCA, in line with the recommendations of the TW light project;
2. Unique information system (MAK - ISBT128) introduced and operational for all BE (centres as defined by the Law on Transfusion medicine);
3. Providing support for financing the procurement of equipment for the health sector, through the fulfilment of national co-financing of app. € 1 million (indicative budget for equipment € 2.5 million, EU contribution for the purchase of equipment € 1.5 million).

There are no special requirements for sequencing between the results, but certain need for sequencing between the activities within the same result should be respected:

- Needs analysis in regards to critical equipment and IT system, and procurement plan of critical equipment precedes supply of critical equipment for transfusion and transplantation for SoHO institutions.

11. Indicators for performance measurement

Result 1:

1.1 Number of inspected and authorized SoHO institutions according to the EU requirements (2017: 0; 2022: 30; 2025: 38)

1.2 Operating procedures and templates for all functionalities of the NCA prepared (2017: No; 2022: Yes; 2025: Yes)

1.3 % of the NCA staff capacitated to successfully fulfil their roles and responsibilities (2017: 0; 2022: 80%; 2025: 90%)

Result 2:

2.1 % of SoHO institutions staff know the requirements of EU directives and national legislation in the field of SoHO (2017: 0; 2022: 80%; 2025: 90%)

Result 3:

3.1. Number of designated staff in selected SoHO institutions capacitated and trained to successfully implement EU Directives requirements, as a result of the action (2017: 0; 2022: 100; 2025: 200)

Result 4:

4.1 % of blood voluntary unpaid donation (2017: 90%; 2022: 100%; 2025: 100%)

4.2 Rate of deceased organ donors (2017: 5 donors PMP; 2022: 8 donors PMP; 2025: 10 donors PMP)

4.3 Number of tissues and cells donors (2017: 7200 registered HPC donors, 1700 patients on the waiting list for cornea transplantation; 2022: 8000 HPC donors; 1000 waiting for cornea transplantation; 2025: 9000 HPC donors; 500 waiting for cornea transplantation)

12. Facilities available

The beneficiary will provide the MS Twinning partner with adequate office space for RTA and experts, meeting rooms and equipment necessary for relevant everyday activities and training foreseen in TW fiche.

MoH will dedicate all necessary human and institutional resources in order to guarantee an effective implementation of the respective project. In particular, the beneficiary institution will insure the availability of the following provisions: Adequately equipped office space for the RTA and the RTA assistants.

Component Leaders and short-term experts for the entire duration of their secondment (in particular a desk, a telephone line, PC with e-mail account and internet access, possibility to use fax & copy services) will have adequate conditions to perform their work while on mission to the BC, training and conference venues as well as presentation and interpretation equipment.

The availability of the BC human resources (BC experts) during the implementation of the activities.

ANNEXES TO PROJECT FICHE

1. The Simplified Logical framework matrix as per Annex C1a (compulsory)
2. List of applicable Union acquis/standards/norms

Annex 1: Simplified Logical Framework

	Description	Indicators (with relevant baseline and target data)	Sources of verification	Risks	Assumptions (external to project)
Overall Objective	To contribute to the strengthening of the legislative framework and institutional capacities for fulfilling the requirements of EU membership in the area of public health	Progress made towards meeting the accession criteria under chapter 28, specifically in the area of SoHO • Some progress achieved in chapter 28 (2016) • Very good progress achieved in chapter 28 (2022) • Very good progress achieved in chapter 28 (2025)	• Progress assessment / European Commission Annual Progress Report for Serbia, published on yearly basis		
Specific (Project) Objective	To support and strengthen the National Competent Authority (NCA) and Substance of Human Origins (SoHO) institutions to successfully implement EU quality and safety requirements to meet the needs of citizens in the area of biomedicine	1. NCA and SoHO institutions operating in accordance with the EU Directives and requirements in the field of biomedicine • No (2016) • Yes (2022) • Yes (2025)	• Annual report of the Ministry of Health • European Commission Annual Progress Report for Serbia		Continuous financing for the NCA and SoHO institutions is secured and sustained.
Mandatory results/outputs by components	R1: Institutional and administrative capacities of the NCA for biomedicine regarding the process of authorization, inspection, monitoring, reporting and biovigilance enhanced	1.1 Number of inspected and authorized SoHO institutions according to the EU requirements (2017: 0; 2022: 30; 2025: 38) 1.2 Operating procedures and templates for all functionalities of the NCA	• Annual report of the Ministry of Health • NPAA implementation reports • Official Gazette of the Republic of Serbia		All health care institutions in the field of SoHO are willing to collaborate and have reached consensus on the priorities to be achieved by accession

		prepared (2017: No; 2022: Yes; 2025: Yes)			
	R2: The EU requirements in the field of biomedicine and SoHO and fully aligned national legislation among healthcare professionals promoted	1.3 % of the NCA staff capacitated to successfully fulfil their roles and responsibilities (2017: 0; 2022: 80%; 2025: 90%)			
		2.1 % of SoHO institutions staff know the requirements of EU directives and national legislation in the field of SoHO (2017: 0; 2022: 80%; 2025: 90%)			
	R3: Institutional capacities and technical conditions of SoHO institutions enhanced	3.1. Number of designated staff in selected SoHO institutions capacitated and trained to successfully implement EU Directives requirements, as a result of the action (2017: 0; 2022: 100; 2025: 200)			
	R4: Public awareness on voluntary unpaid donations (blood, organ, tissues and cells) raised	4.1. % of blood voluntary unpaid donation (2017: 90%; 2022: 100%; 2025: 100%)			
		4.2. Rate of deceased organ donors (2017: 5 donors PMP; 2022: 8 donors PMP; 2025: 10 donors PMP)			
		4.3. Number of tissues and cells donors (2017: 7200 registered HPC donors, 1700 patients on the waiting list for cornea transplantation; 2022: 8000 HPC donors; 1000 waiting for cornea transplantation; 2025: 9000 HPC donors; 500 waiting for cornea transplantation)			

Sub-results per component (optional and indicative)					

Results / Induced outputs	Objectively verifiable indicators	Baseline	Targets	
		2017	2022	2025
R1: Institutional and administrative capacities of the NCA for biomedicine regarding the process of authorization, inspection, monitoring, reporting and biovigilance enhanced	1.1 Number of inspected and authorized SoHO institutions according to the EU requirements	0	30	38
	1.2 Operating procedures and templates for all functionalities of the NCA prepared	No	Yes	Yes
	1.3 % of the NCA staff capacitated to successfully fulfil their roles and responsibilities, as the result of the Action	0	80%	90%
R2: The EU requirements in the field of biomedicine and SoHO and fully aligned national legislation among healthcare professionals promoted	2.1. % of SoHO institutions staff know the requirements of EU directives and national legislation in the field of SoHO	0	80%	90%
R3: Institutional capacities and technical conditions of SoHO institutions enhanced	3.1. Number of designated staff in selected SoHO institutions capacitated and trained to successfully implement EU Directives requirements, as a result of the action	0	100	200
	3.2. Selected SoHO institutions provided with critical equipment to meet safety and quality EU Directives requirements, as a result of the action	No	Yes	Yes
R4: Public awareness on voluntary unpaid donations (blood, organ, tissues and cells) raised	4.1. % of blood voluntary unpaid donation	90%	100%	100%
	4.2. Rate of deceased organ donors	5 donors PMP (per million population)	8 donors PMP	10 donors PMP
	4.3. Number of tissues and cells donors	7200 registered HPC donors 1700 patients on the waiting list cornea transplantation	8000 registered HPC donors 1000 patients on the waiting list cornea transplantation	9000 registered HPC donors 500 patients on the waiting list cornea transplantation

Annex 2: List of applicable Union acquis/standards/norms

National	**EU**
Law on Human Organ Transplantation	• Directive 2010/53/EU • Directive 2012/25/EC
Law on the Transplantation of Cells and Tissue	• Commission Directive 2004/23/EC • Commission Directive 2006/17/EC • Commission Directive 2006/86/EC • Commission Decision 2010/453/EC • Commission Directive 2012/39/EC • Commission Directive 2015/565/EC • Commission Directive 2015/566/EC • Commission Decision C (2015)4460
Transfusion	• Commission Directive 2002/98/EC • Commission Directive 2004/33/EC • Commission Directive 2005/61/EC • Commission Directive 2005/62/EC • Commission Directive 2009/135/EC • Directive 2011/38/EU • Directive 2014/110/EU • Directive (EU) 2016/1214
Law on Biomedically Assisted Fertilization	• Commission Directive 2004/23/EC • Commission Directive 2006/17/EC • Commission Directive 2006/86/EC • Commission Decision 2010/453/EC • Commission Directive 2012/39/EC • Commission Directive 2015/565/EC • Commission Directive 2015/566/EC