Terms of Reference (ToR) for a Short-Term assignment

Technical assistance requested:	1 (one) Senior and 1 (one) Junior Non-Key Expert in the area of Ch. 28 – Consumer and Health protection, Biomedicine, Transplantation of Cells and Tissues
Project Title:	Policy and Legal Advice Centre (PLAC III), Serbia
Ref:	EuropeAid/139295/DH/SER/RS
Service Contract No.:	(CRIS) 2018/404-529
Main beneficiary:	Ministry of European Integration of the Republic of Serbia and the Negotiating Team
Target Beneficiaries:	Negotiating Group Ch. 28; Ministry of Health
Budget Line / Expert Category:	One Senior and One Junior Non-Key Expert
Duration of the assignment:	35 working day (20 WD for NKSE and 15 WD for NKJE); the assignment period from June 2019 – October 2019

1. Relevant background information

The scope of PLAC III project is to provide support to relevant national institutions in charge of alignment of national legal acts with the EU acquis and to contribute to further building of capacities of relevant national structures for successful carrying out of accession negotiations.

The PLAC III project should achieve two results:

RESULT 1 - Enhanced compatibility of national legislation with EU legislation and its effective implementation

RESULT 2 - Enhanced capacities of the relevant national structures for successful carrying out of accession negotiations

In general, the project aims at fostering the process of accession negotiations of the Republic of Serbia by supporting the effective alignment of national legislation with the Union *acquis* and its implementation and by further building the capacities of involved carriers of the EU integration process in the Republic of Serbia. After completion of screening process in 2015, Serbian public administration has entered into much more demanding and obliging exercise of accession negotiations, whereby each step and every decision should result in approaching actual membership in the EU. For this scenario to happen in accordance with planned dynamics, preparedness, adequate institutional capacity of public administration with highly competent staff is of crucial importance. In the core period of the negotiations, PLAC III Project shall support domestic line institutions and the negotiating structures both in performance of quality operational work in relation to harmonisation process and in the effective coordination during various stages and phases in the process for different negotiation chapters.

2. Background information in relation to Chapter 28 – Health protection - Blood, tissues, cells and organs

Ministry of Health conducted the activities that are directed towards the adoption of legislation in the field of Biomedicine. In order to fully comply with the acquis of the EU the Law on Biomedically Assisted Fertilization (Official Gazette of the RS No 40/17) and the Law on Transfusion Medicine (Official Gazette of the RS No 40/17) , Law on the Transplantation of Cells and Tissues (Official Gazette of the RS No 57/18), Law on Human Organ Transplantation (Official Gazette of the RS No.57/18), were adopted.

Law on Biomedically Assisted Fertilization (Official Gazette of the RS No 40/17) covers the regulations of the EU as follows: Directive 2010/45/EC; Directive 2012/39/EC; Commission Directive 2012/39/EU, Directive 2015/565/EC; Directive 2015/566/EC). In order to organise healthcare institutions operating in the field of cells and tissues according to the EU Directives, and in order to regulate this area, the new Law on Biomedically Assisted Fertilization firstly establishes who may perform the activity of biomedically assisted fertilization and makes a clear distinction between the centres for biomedically assisted fertilization and the bank for reproductive cells, tissues and embryos which performs at least activities for the purpose of obtaining, processing, preservation, storage and distribution of reproductive cells and tissues for heterologous fertilization, as well as the activity of storage and distribution of embryos for heterologous fertilization. After the entry into force of the mentioned law, the Implementation Plan was made, covering numerous activities which refer primarily to adoption of bylaws, analysis and introduction of the information systems in the field of Biomedically Assisted Fertilization analysis and establishment of the Bank of donated reproductive cells and tissues.

Law on Human Organ Transplantation it is harmonized with the Directive 2010/53/EU and Directive 2012/25/EC which lays down information procedures for the exchange, between Member States, of human organs intended for transplantation (these two Directives were adopted after the adoption of the existing Act on Organ Transplantation).

Law on the Transplantation of Cells and Tissue, included the following EU regulations as follows: Directive 2010/45/EC; Directive 2012/39/EC; Commission Directive 2012/39/EU, Directive 2015/565/EC; Directive 2015/566/EC, Directive 2004/23/EC, Directive 2006/17/EC, Directive 2006/86/EC. In order to organise healthcare institutions operating in the field of cells and tissues according to the EU Directives, and in order to regulate this area, a clear distinction was made between the Bank of tissues and the healthcare institution to perform the activity of testing of cells and tissues, and the healthcare institutions to perform the activity of obtaining cells and tissues. In addition to that, donor hospitals are defined as inpatient healthcare institutions with an intensive care unit.

The Ministry of Health has established a Working Group for the preparation of regulations in the field of transplantation of cells and tissues. At the moment, it is not precisely defined how many rulebooks will be prepared but the preliminary estimate is about 4 (four).

At present, there is no on-going and/or planned assistance projects for the activities covered by this ToR.

3. Description of the assignment:

3.1 Specific objectives

The specific objective of this assignment is to provide the support to the Ministry of Health - Directorate of Biomedicine in drafting harmonised legislation (regulations, by-laws) in the field of Transplantation of Cells and Tissues in accordance with the Union acquis in order to be fully harmonised and to accurately anticipate implications of its implementation.

3.2 Requested services

3.2.1 The Senior NKE in the area of biomedicine is expected to provide the following services:

a) Perform a short gap analysis of the existing legislation of the Republic of Serbia in the area of biomedicine within the scope of this assignment

b) Draft text of up to four Rulebooks according to the Law Transplantation of Cells and Tissues

c) Draft a report on recommendations highlighting the most important issues regarding the further implementation of the law on the transplantation of cells and tissues

d) Hold workshop presenting the drafts of the new legislation.

3.2.2 The Junior NKE in the area of biomedicine is expected to provide the following services:

a) Draft Table of Concordance of the level of compliance of draft Rulebooks with EU regulations (Directive 2010/45/EC; Directive 2012/39/EC; Directive 2012/39/EU, Directive 2015/565/EC; Directive 2015/566/EC, Directive 2004/23/EC, Directive 2006/17/EC, Directive 2006/86/EC)

b) Holding workshop presenting the results of the work

3.3 Outputs

The **Senior NKE** are expected to deliver the following outputs:

a) A draft report on the gap analysis and on recommendations regarding the further implementation of the law on the transplantation of cells and tissues

b) Rulebooks drafted

c) Workshop held

The Junior NKE are expected to deliver the following outputs:

a) ToCs drafted

b) Workshop held

3.4 Reporting

The SNKE shall provide the following reports by using the templates of the Project:

- **Final Mission Report**, no later than 1 week after completion of tasks under this assignment. This report will include description of all activities and outputs provided by both NKEs in the context of this assignment.
- A brief interim report - only upon a request of the PLAC III team: TL and/or KE2.

Submission of reports:

- Draft mission report shall be submitted to the Team Leader of the Project for a review and comments at the completion of the mission.

- Final version of the mission report prepared in the agreed quality shall be submitted to the Team Leader of the Project for a review, comments and the final approval at the agreed time, but not later than 7 days after the TL comments on the draft mission report have been submitted to the expert.
- The reports shall be signed by the SNKE and the Team Leader, who is responsible for endorsing the reports.
- The mission report and all prepared documents shall be submitted in a hard copy and in an electronic version to the Team Leader of the project.

3.5 Specifics

Both NKEs shall work under the guidance and follow the instructions of the Team Leader. The NKEs shall collaborate with the project team, other experts involved and representatives of the relevant beneficiary institutions.

Each of the short-term missions, the timing and duration shall be agreed with the Beneficiary and the PLAC team prior to each mission.

3.6 Expert input

3.6.1 Total working days

20 working days (WDs) in total have been planned for Senior Non-Key expert and 15 working days for Junior Non-Key expert for this assignment

3.6.2 Period of the assignment and Starting day

It is expected that the work will be performed during several missions in the period from June 2019 – October 2019. The exact starting date will be agreed at later stage.

3.6.3 Location/Place of assignment

The SNKE and JNKE has to deliver 100% of the input in Belgrade, Serbia.

4. Expert Profile - Senior NKE:

4.1. Qualifications and skills (25 points)

- A level of education, which corresponds to completed university studies of at least 3 years in the relevant field attested by a diploma such as Law, Medicine or similar, relevant to the assignment;
- Proficiency in English language
- Computer literacy
- Be proficient in report drafting
- Excellent communication and analytical skills
- Be independent and free from conflicts of interest in the responsibilities they take on
- Knowledge of Serbian language will be an advantage

4.2. General professional experience (25 points)

- At least 8 (eight) years of general postgraduate professional experience with harmonisation of national legislation with Union acquis and/or policy making in the field of Biomedicine, gained in an EU member state, candidate or potential candidate country

4.3. Specific professional experience (50 points)

- Postgraduate professional experience in drafting of legislation in relation to Union acquis in the field of biomedicine, gained in an EU member state, candidate or potential candidate country
- Previous professional experience in implementation of either of the listed Directives gained in an EU member state, candidate or potential candidate country, will be an advantage.

5. Expert Profile - Junior NKE

5.1 Qualifications and skills (25 points)

- A level of education, which corresponds to completed university studies of at least 3 years in the relevant field attested by a diploma such as Medicine, Law or similar, relevant to the assignment
- Proficiency in English language;
- Computer literacy;
- Be proficient in report drafting;
- Excellent communication and analytical skills;
- Be independent and free from conflicts of interest in the responsibilities they take on
- Knowledge of Serbian language will be an advantage

5.2 General professional experience (25 points)

- At least 5 (five) years of general postgraduate professional experience with harmonisation of national legislation with Union acquis, gained in an EU member state, candidate or potential candidate country

5.3 Specific professional experience (50 points)

- Postgraduate professional experience in drafting of legislation gained in an EU member state, candidate or potential candidate country
- Knowledge of Serbian public health system related to biomedicine will be an advantage

6. Applications

Applications (EU format CV and application letter, both in English) need to be submitted by e-mail to mbayard@dmiassociates.com and nderxen@dmiassociates.com no later than 11 June 2019, 17:00 hrs, titled: **"Application for the position – Senior or Junior NKE in the** area **Ch. 28 - Consumer and Health protection, Biomedicine, Transplantation of Cells and Tissues.**

References must be available on request. Only short-listed candidates will be contacted.

The Project is an equal opportunity employer. All applications will be considered strictly confidential.

Advertised posts are not available to civil servants or other officials of the public administration in the beneficiary country, Serbia.

For more information, please contact Project Manager at DMI Associates Marion Bayard: mbayard@dmiassociates.com or Nina Derxen: nderxen@dmiassociates.com.