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 Human Organs
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 July 2019 – December 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 – Consumer and Health Protection - Blood, tissues, cells and organs

EU Country report for 2019 states that Republic of Serbia "… is moderately prepared in consumer and health protection. Some progress was made including the adoption of the Law on the transplantation of cells and tissues and the Law on human organ transplantation. However, the recommendations of the previous report have not been met. In the coming year, Serbia should in particular:

- strengthen the administrative capacity of relevant authorities for consumer protection, market surveillance and sanitary inspection
- strengthen the overall managerial capacity, human resources and financial sustainability of the public health insurance fund."

The Ministry of Health has conducted a number of 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 the Transplantation of Cells and Tissue, included harmonisation with 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.

Law on Human Organ Transplantation is harmonised with Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation and Commission Implementing Directive 2012/25/EU laying down information procedures for the exchange, between Member States, of human organs intended for transplantation. Further alignment is necessary to fully implement the requirements from the Law and the Directives. In this context the Ministry of Health has established a Working Group for the preparation of regulations in the field of transplantation of human organ. 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 Organs 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) Drafting four Rulebooks based on the Law on Human Organ Transplantation aligned with the two directives

b) Drafting a Report on recommendations highlighting the most important issues for an efficient implementation of the law on the transplantation of organs

c) 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) Drafting Table of Concordance of the level of compliance of draft Rulebooks with Union acquis: Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation and Commission Implementing Directive 2012/25/EU laying down information procedures for the exchange, between Member States, of human organs intended for transplantation

b) Perform a gap analysis of the existing legislation of the Republic of Serbia in the area of biomedicine within the scope of this assignment (the two directives)

c) Holding workshop presenting the results of the work

3.3 Outputs

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

a) A Report on recommendations drafted

b) 4 Rulebooks drafted

c) Workshop held

The Junior NKE is expected to deliver the following outputs:

a) ToCs drafted

b) A gap analysis prepared

c) 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 (WD) in total have been planned for Senior Non-Key expert and 15 working days (WD) 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 July 2019 – December 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 (20 working days):

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

4.2. General professional experience (25 points)

- At least 8 (eight) years of general postgraduate professional experience with harmonisation of legislation and/or policy making in the field of Ch 28, public health, gained in an EU member state, candidate or potential candidate country

4.3. Specific professional experience (50 points)

- Postgraduate professional experience in harmonisation of legislation related to Union acquis in the field of biomedicine, gained in an EU member state, candidate or potential candidate country
- Previous postgraduate professional experience in implementation of Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation and/or Commission Implementing Directive 2012/25/EU laying down information procedures for the exchange, between Member States, of human organs intended for transplantation, gained in an EU member state, candidate or potential candidate country, would be an advantage.

5. Expert Profile - Junior NKE (15 working days)

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

5.2 General professional experience (25 points)

- At least 5 (five) years of general postgraduate professional experience in the field of harmonisation of 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 and/or Tables of concordance gained in an EU member state, candidate or potential candidate country
- Knowledge of Serbian legal system 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 ehoward@dmiassociates.com no later than 12 July 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 Organs".**

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

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Please note that all the pre-selected experts for either of the positions are requested to sign a Statement of Availability (SoA) in which they acknowledge and confirm their availability to accomplish this assignment within the indicated period, at the indicated starting date (if any) and within the number of working days requested.

For more information, please contact Project Manager at DMI Associate Marion Bayard: mail to mbayard@dmiassociates.com or Elizabeth Howard ehoward@dmiassociates.com.