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

Technical assistance requested:	1 (one) Senior Non-Key Expert in the area of Ch. 28 – Consumer and Health protection, Health Technology Assessment (HTA)
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 Non-Key Expert
Duration of the assignment:	10 working days; the assignment period September- December 2019

1. Relevant background information

Background information in relation to PLAC III project:

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

EU rules protect consumers' economic interests and in relation to product safety, dangerous imitations and liability for defective products. The EU also ensures high common standards for tobacco control, blood, tissues, cells and organs, patients' rights in cross-border healthcare, and serious cross-border health threats including communicable diseases, as well as medicines for human and veterinary use.

EC Country Progress report for 2019 states that the Republic of Serbia (RS) is moderately prepared in consumer and health protection. Some progress was made but the recommendations of the previous report have not been met. In the coming year, Serbia should in particular to strengthen the overall managerial capacity, human resources and financial sustainability of the public health insurance fund. There were no developments on medicines for human and veterinary use, or on maximum sale price criteria for medicines. Serbian legislation on pricing of medicinal products has yet to be aligned to the EU acquis

With an awareness that the transparent and transferable information on the short- and long-term effectiveness of health technologies is essential in decision making procedures for a better outcome for patients and society in the coming years, the Republic of Serbia (RS) should in particular work on strengthening the overall sustainability of the public health system. The Strategy on Public Health in Republic of Serbia ("Official Gazette RS" No 61/18) has as general goal to support the development of affordable, high-quality and efficient health care and specific aim to improve the assessment of health technologies by introduction economic analysis, which will improve the decision-making process on medicines, medical devices and procedures.

The decision-making process regarding placing a medicine on the reimbursable drug list is entrusted exclusively to National Health Insurance Fund (NHIF) which is also responsible for the technical part of the analyses, that is, assessments and evaluations, i.e. proposing criteria for the final decision (mainly through commission work, managed-entry agreements and negotiating processes). However, the fact remains that EU accession in the field of medicines and other technologies implies acceptance of Council Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (the Transparency Directive 89/105/EEC) and the principles of evidence-abased decision-making, so HTA returns to the focus of interest of health policy makers.

Institute of Public Health of Serbia "Dr Milan Jovanović Batut" represents institution responsible for HTA at national level according to Law on Healthcare (Official Gazette RS No: 25/2019).

The Law on Medical Devices is adopted by National Parliament in November 2017 and it has been in force since 2 December 2018. This law is fully harmonised with EU legislation and it received positive opinion of the European Commission. The Serbian Government planned to adopt new Law on Medicinal Products by the end of 2019.

At the same time, the demands facing decision makers when introducing drugs in the reimbursable medicines list in terms of determining the cost-effectiveness compared to outcomes of treatment and the need to negotiate lower prices of medicines, clearly indicate that there is a real need for the improvement of knowledge and capacity in this field and inclusion of the acquired experience in strategic planning through building international experience and acquiring knowledge for professional expertise.

In order to support and facilitate the acquisition and exchange of knowledge at the local level, the Ministry of Health (MoH) of the Republic of Serbia also supports a multidimensional approach sharing the experience with other countries.

Expert assistance related to Health Technology Assessment (HTA) through the PLAC project is needed and would be useful and helpful to Serbia in HTA improvements aiming to become equal in collaboration with other EU countries as regulated in Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (Directive 24/2011/EU).

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

During the negotiating process, Serbia has to harmonise its legal system with that of EU across all sectors. The specific objective of this assignment is to provide assistance to the Ministry of Health by giving a proposal for amendments to the existing regulations and a proposal for drafting new regulations on HTA performance in line with the Union acquis in this field.

3.2 Requested services

The Senior NKE is expected to provide the following services:

a) To analyse the existing umbrella Laws and bylaws regulating area of health technology assessment (HTA) and perform a gap analysis

b) Make suggestions for necessary improvements in order to strengthen HTA system (procedure, tools, capacity building) in order to establish a transparent procedure, evidence-based reports and efficient collaboration in EU HTA networks with other countries

c) Propose amendments of the existing regulation and proposals of new regulations, for its alignment with the EU acquis

3.3 Outputs

The Senior NKE is expected to deliver the following outputs:

- **A report containing:**
  - findings of the analysis of the existing umbrella Laws and by-laws on HTA in comparison to Union acquis (Directive 89/105/EEC, Directive 2011/24/EU)
  - findings of the compliance assessment of the existing legislation in relation to Union acquis and effects of proposals of amendments to the HTA regulation and recommendations how to achieve a full compliance
  - findings and proposals of improvements that can be made in order to have transparent procedures in the decision making in the area of funding new health technologies with evidence-based assessments
  - proposal for additional resources that can be introduced into HTA system and identify necessary activities that should be undertaken in order to get an improved HTA system;

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 the SNKE in the context of this assignment.
- A brief interim report - only upon a request of the PLAC III team: TL and/or KE 2

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

The SNKE shall work under the guidance and follow the instructions of the Team Leader. SNKE 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 planned mission.

3.6 Expert input

3.6.1 Total working days

10 working days (WD) in total have been planned for Senior 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 September 2019 – December 2019. The exact starting date will be agreed at later stage.

3.6.3 Location/Place of assignment

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

4. Expert's Profile - Senior NKE (10 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, Economy, Medicine, Pharmacy 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 in the field of harmonisation of national legislation with Union *acquis* gained in an EU member state, candidate or potential candidate country.

4.3 Specific professional experience (50 points)

- Postgraduate professional experience with Health Technology Assessment (HTA) gained in an EU member state, candidate or potential candidate country.
- Knowledge of Serbian legal system will be an advantage

5. 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 19 August 2019, 17:00 hrs, titled:

"Application for the position – Senior NKE in the area Health Technology Assessment (HTA)"

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.

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 Associates Marion Bayard: mail to mbayard@dmiassociates.com or Elizabeth Howard ehoward@dmiassociates.com