Policy and Legal Advice Centre (PLAC III)

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

Technical assistance requested:	1 (one) Senior Non-Key Expert and 1 (one) Junior Non-Key Expert in the area of Negotiating Ch. 28, Consumer and health protection – draft Law on Medicines for Human Use
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:	The Ministry of European Integration of the Republic of Serbia
Target Beneficiaries:	Negotiating Group Ch. 28; Ministry of Health, Medicines and Medical Devices Agency of Serbia (MMDAS) and other relevant stakeholders
Budget Line/Expert Category:	One Senior and one Junior Non-Key Expert
Duration of the assignment:	50 working days (35 WD SNKE and 15 WD for JNKE), from March until September 2023

1. Relevant background information

Background information in relation to the PLAC III project:

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

In general, the Project aims to foster 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. Upon completion of the screening process in 2015, the Serbian public administration has entered into much more demanding and obliging exercises 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 and adequate institutional capacity of public administration with highly competent staff are of crucial importance. In the core period of the negotiations, the PLAC III project shall support domestic line institutions and the negotiating structures both in the performance of quality operational work in relation to the 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 in Chapter 28 protect consumers' economic interests and, in relation to product safety, dangerous imitations and liability for defective products, including high common standards for medicines for human and veterinary use.

The EU also ensures high common standards for upholding patients' rights in cross-border healthcare and tackling serious cross-border health threats including communicable diseases.

The EU legal framework for human medicines sets standards to ensure a high level of public health protection and the quality, safety and efficacy of authorised medicines. In addition, it promotes the functioning of the internal market, with measures to encourage innovation. It is based on the principle that a medicinal product requires marketing authorisation by competent authorities before being placed on the market.

The country progress report of the European Commission (EC) for Serbia for 2022 (Serbia 2022 Progress Report, SWD (2022) 338 final) states that Serbia is moderately prepared in consumer and health protection. Limited progress was made concerning the digitalisation of the health sector, as well as the increase in healthcare professionals. However, Serbian legislation on medicines for human use has yet to be aligned with the Union acquis (Serbia 2022 Progress Report, p. 97 and 100).

Indeed, as indicated in the Screening Report for Chapter 28 – Consumer and health protection, legal alignment remains to be completed in regards to medicinal products for human use, the rules on imports, good clinical practice and clinical trials. Furthermore, all Serbian marketing authorisation has to be in accordance with the rules and provisions of the EU legislation in this field.

The Ministry of Health (MoH) is in charge of the preparation of legislation surveillance of its implementation and inspection control, determination of fulfilment of the requirements for the manufacturing of medicines and medical devices, creation of galenic medicines, wholesale and retail of medicines, and medical devices.

The Medicines and Medical Devices Agency of Serbia (MMDAS) was established in 2004 by the Law on Medicines and Medical Devices (Official Gazette of the RS, No. 84/04 and 85/05 – another law) and it is a competent institution for the authorisation of medicines for human use. Activities carried out in the Agency cover, as well, the operations preceding the issuance of marketing authorisations and the activities carried out upon the placing on the market of medicinal products and medical devices.

Medicines for human use are regulated by the Law on Medicines and Medical Devices (Official Gazette of the RS No.30/10,107/12,105/17 and 113/17) and by-laws. The legislation in force is partially aligned with Directive 2001/83/EC on the Community code relating to medicinal products for human use; Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practices in respect of medicinal products for human use and investigational medicinal products for human use; Directive 2004/9/EC on the inspection and verification of good laboratory practice (GLP); Directive 2004/10/EC relating to the application of the principles of good laboratory practices and the verification of their applications for tests on chemical substances; Directive 2001/20/EC relating to the implementation of good clinical practice in the

conduct of clinical trials on medicinal products for human use; and Commission Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use. as well as the requirements for authorisation of the manufacturing or importation of such products.

However, Directives 2001/83/EC, 2003/94/EC and 2004/9/EC have been subject to a number of amendments at an EU level to date. Furthermore, Directive 2001/20/EC and Commission Directive 2005/28/EC have been repealed by Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use (Clinical Trials Regulation, CTR) and Commission Implementing Regulation (EU) 2017/556 on the detailed arrangements for the good clinical practice inspection procedures pursuant to Regulation (EU) No 536/2014, respectively.

As a result, the National Programme for the Adoption of the Acquis (NPAA) 2022-2025 envisaged the adoption of a new law to provide the basis for comprehensive harmonisation with the EU legal framework governing medicinal products for human use (NPAA, section 3.28.2. Public Health).

For this reason, the support of experts is needed in order to assist the MoH and MMDAS in conducting a legal gap assessment of the Serbian legislation against the relevant acquis and in preparation of the draft Law on Medicines for Human Use enabling full compliance with the Union acquis framework for authorising the marketing of medicinal products for human use, monitoring of authorised products and common rules for quality, safety and efficacy.

After the adoption of the new legal solution, the preparation of by-laws for full alignment, implementation and enforcement of the acquis will be carried out.

There are no ongoing or planned assistance projects regarding the activity covered by this ToR.

3. Description of the assignment:

3.1 Specific objectives

The specific objective of this assignment is to provide support to the MoH, MMDAS and the Negotiating Group for Ch. 28 (NG 28) in order to enhance the harmonisation of Serbian legislation with the EU legal framework governing medicinal products for human use through the development of a new Law on Medicines for Human Use in compliance with the Union acquis governing requirements and procedures for marketing authorisation, rules for monitoring authorised products, and quality, safety and efficacy of pharmaceuticals.

Within the scope of the assignment, selected experts shall assist the beneficiaries in conducting the legal gap assessment of Serbian legislation, drafting the Tables of Concordance and drafting the Law on Medicines for Human Use transposing and/or providing a legal basis for full transposition of Directives 2001/83/EC (as last time amended by Directive (EU) 2022/642); 2003/94/EC (as last time amended by Directive (EU) 2022/642) and full alignment with Clinical Trials Regulation (CTR), Regulation (EC) No. 726/2004 (as last time amended by Regulation (EU) 2019/5), Regulation (EC) No 1394/2007 (as last time amended by Regulation (EU) 2019/1243) and Commission Regulation (EC) No 1234/2008 (as last time amended by Commission Delegated Regulation (EU) 756/2021).

The experts shall take into account the European Medicines Agency's Committee for Medicinal Products for Human Use's scientific guidelines interpreting the requirements for the demonstration of quality, safety and efficacy set out in the Community directives.

The new legal text shall provide a sufficient legal basis for the preparation and adoption of implementing by-laws to achieve full alignment with the acquis and enable its appropriate implementation and enforcement by MoH and MMDAS.

At the end of the activity, a workshop presenting the outputs of the assignment shall be held.

3.2 Requested services

The Senior NKE in the area of medicinal products for human use is expected to provide the following services:

1. Assist the MoH, MMDAS and NG 28 in:

    a. Preparing a Legal Gap Analysis of national legislation in the field of medicinal products in relation to the EU framework governing medicinal products for human use with recommendations on legal steps to close the gap; and
    b. Drafting of the Law on Medicines for Human Use harmonised with the Union acquis governing requirements and procedures for marketing authorisation of medicinal products for human use, rules for monitoring authorised products, and on quality, safety and efficacy;

2. Prepare and hold a workshop and present the outputs of the assignment.

The Junior NKE in the area of medicinal products for human use is expected to provide the following services:

1. Assist the SNKE in preparing the Legal Gap Analysis;
2. Drafting the ToCs of Serbian legislation in relation to the EU legal framework governing medicinal products for human use (precise scope to be defined at the assignment's kick-off meeting);
3. Prepare and hold a Workshop and present the outputs of the assignment

3.3 Outputs

The Senior NKE is expected to deliver the following outputs:

1. Legal Gap Analysis (LGA) with recommendations drafted;
2. The draft Law on Medicines for Human Use drafted;
3. Workshop held.

The Junior NKE is expected to deliver the following outputs:

1. LGA (in collaboration with the SNKE), drafted;
2. ToCs, drafted;
3. Workshop held.

3.4 Reporting

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

- A Final Mission Report, no later than 1 week after the completion of tasks under this assignment. This report will include a description of all activities and outputs provided by the NKEs in the context of this assignment;

- A brief Interim Report - only upon request of the PLAC III team: TL and/or KE2.

Submission of reports:

- A Final Mission Report prepared in the agreed quality shall be submitted to the Team Leader of the Project for review, comments and final approval;
- The reports shall be signed by the SNKE and the Team Leader, responsible for endorsing the reports;
- The reports and all prepared documents shall be submitted in a hard copy and electronic version to the Team Leader of the Project.

3.5 Specifics

The 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.

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

3.6 Expert input

3.6.1 Total working days

35 working days (WDs) in total have been planned for Senior Non-Key Expert and 15 working days (WDs) 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 during the period from March until September 2023. However, the starting date will be confirmed at a later stage.

3.6.3 Location/place of assignment

The SNKE and the JNKE must deliver 100% of the input in Serbia, unless otherwise agreed due to extraordinary circumstances (i.e., COVID-19). All home-based days are subject to prior approval by the EU Delegation Project Manager responsible for the PLAC III project.

3.6.4 Working language

English

4. Experts' profile – Senior NKE (35 working days):

4.1 Qualifications and skills (25 points)

- A level of education which corresponds to completed university studies of at least 3 years, attested by a diploma such as law, pharmacy or medicine;
- Computer literacy;

- Proficiency in report drafting;
- Excellent communication and analytical skills;
- Proficiency in the English language;
- Independence and freedom from conflicts of interest in the undertaken responsibilities.

4.2 General professional experience (25 points)

- At least 8 (eight) years of general postgraduate professional experience related to the public health sector.

4.3 Specific professional experience (50 points)

- At least 3 (three) preferably 5 (five) years of postgraduate professional experience in drafting and/or implementing legislation in relation to the Union *acquis* in the medicines for human use;
- Experience in the field of harmonization with the Union *acquis*, gained in an EU Member State, a candidate or a potential candidate country;
- Knowledge of the Serbian legal system will be an advantage.

5. Experts' 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 attested by a diploma such as law, pharmacy, medicine or similar, relevant to the assignment
- Computer literacy
- Proficiency in report drafting
- Excellent communication and analytical skills
- Proficiency in the English language
- Independence and freedom 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 related to the Union acquis gained in an EU Member State, candidate or potential candidate country.

5.3 Specific professional experience (50 points)

- Postgraduate professional experience in the harmonisation of the national legislation with the Union acquis
- Knowledge of the Serbian legal system will be an advantage.

6. Applications

Applications (EU format CV and application letter in English) need to be submitted by email to mbayard@dmiassociates.com and akhani@dmiassociates.com no later than 27 March 2023, 17:00 hrs, titled:

"Application for the position – Senior NKE or Junior NKE in the area of Ch. 28, Consumer and health protection – draft Law on Medicines for Human Use"

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

Pre-selected experts will be 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 and within the number of working days requested.

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 the Project Manager at DMI Associates Marion Bayard: mbayard@dmiassociates.com or Arianne Khani: akhani@dmiassociates.com.