



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. 27, Environment and Climate Change – medical and pharmaceutical waste management legislation
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. 27; Ministry of Environmental Protection
Budget Line/Expert Category:	One Senior and one Junior Non-Key Expert
Duration of the assignment:	45 working days (35 WD SNKE and 10 WD for JNKE), from March until November 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 27 – Environment and Climate Change

Waste management is one of the most challenging and complex parts of the Union acquis when it comes to harmonising national legislation with EU environmental law and policy requirements. The application of legal norms in the waste management sector requires significant investments. Also, adequate and efficient institutional establishment and capacities at a national and local level are critical for the implementation and enforcement of the Union acquis in the field of waste management.

The Government of Serbia submitted the negotiating position for Chapter 27 – environment and climate change (Negotiating Position) to the European Commission in January 2020. Serbia opened negotiations in Cluster 4 – Green Agenda and Sustainable Connectivity Green on 14 December 2021. Serbia annexed to the position detailed Directive Specific Implementation Plans (DSIPs) for the Waste Framework Directive, Directive on Packaging and Packaging Waste and Landfill Directive.

In the EU Common Position, the EU notes Serbia's good level of legislative alignment in the waste management sector. However, the EU invited Serbia to speed up the implementation of the acquis, in particular as regards waste prevention, waste reduction, waste separation, separate collection and waste recycling and extended producer responsibility. The EU invited Serbia to prepare and present waste management plans (WMP) that include information on all waste streams, including hazardous waste and to create an inventory of accumulated 'historical' hazardous waste, to improve hazardous waste characterisation, categorisation in industries, to secure and mark sites where hazardous waste is stored and to create a register of polluters.

The country progress report of the European Commission (EC) for Serbia for 2022 (Serbia 2022 Progress Report) SWD (2022) 338 final, states that Serbia has achieved some level of preparation in the field of environment and climate change. Overall, Serbia made limited progress during the reporting period including on last year's recommendations, in particular by continuing to increase environmental funding and investments, improving trans-boundary cooperation and developing its national energy.

Serbia should considerably step-up ambitions towards a green transition and focus on intensifying implementation and enforcement work, such as ensuring strict adherence to rules on environmental impact assessment, closing non-compliant landfills, increasing investing in waste reduction, separation, and recycling, enhancing the administrative and financial capacity of central and local authorities. A coordinated, institutional structure is required to deliver the size and quality of the investments that Serbia needs.

Regarding waste management, Serbia has a good level of alignment with the Union acquis; however, implementation remains at an early stage. In early 2022, Serbia adopted a national waste management program 2022-2031 and a waste action plan 2022-2024, which had been developed with EU and Swedish support.

Medical and pharmaceutical waste is governed by Waste Framework Directive 2008/98/EC (Waste Framework Directive) as last time amended by Directive (EU) 2018/851.

Medical and pharmaceutical waste that displays one or more of the hazardous properties listed in Annex III of the Waste Framework Directive is classified as hazardous waste. From waste generation to final disposal or recovery, the directive bans the mixing of hazardous medical and pharmaceutical waste with other categories of hazardous waste or with other waste, substances

or materials, including dilution of hazardous substances and imposes additional labelling, record-keeping, monitoring, and control obligations. Furthermore, Member States shall take measures so that the wastes arising from medical or veterinary establishments which are infectious are not accepted in a landfill in accordance with Landfill Directive 1999/31/EC.

In order to strengthen the re-use and the prevention, recycling and other recovery of waste, Member States may take legislative or non-legislative measures to ensure that any natural or legal person who professionally develops, manufactures, processes, treats, sells or imports products (producer of the product) has extended producer responsibility (EPR). Such measures may include an acceptance of returned products and of the waste that remains after those products have been used, as well as the subsequent management of the waste and financial responsibility for such activities. Where such measures include the establishment of extended EPR schemes, the general minimum requirements of the Waste Framework Directive laid down in Article 8a shall apply.

The general provisions related to medical waste are contained in the Law on Waste Management ("Official Gazette of the RS" Nos 36/2009, 88/2010, 14/2016 and 95/2018) which prescribes the definition of medical waste as a special waste stream, including pharmaceutical waste and stipulates obligations of producers of such waste and lays down the basic legal requirements regarding the management of medical waste.

The competences for medical waste management and pharmaceutical waste management are split between the Ministry of Environmental Protection and the Ministry of Health, respectively.

Provisions of the Law on Waste Management governing the management of medical and pharmaceutical waste are further implemented through:

- The Rulebook on Medical Waste Management ("Official Gazette of the Republic of Serbia", No. 48/19); and
- The Rulebook on the Manner and Procedures for Pharmaceutical Waste Management ("Official Gazette of the Republic of Serbia", No. 49/19).

The Serbian National Waste Management Strategy, which includes the National Waste Management Plan for 2020-2025 that was developed through the IPA project "EU Support for Waste Management Policy" envisages the adoption of regulatory measures to improve the current legal framework in the field of medical and pharmaceutical waste, including:

- Introducing a legal basis for the establishment of an EPR scheme for pharmaceutical waste in relevant legislation;
- Developing a methodology for establishing and managing the financial contributions that producers will pay to cover the costs of all aspects of pharmaceutical waste management;
- Setting EU-compliant technical requirements for medical waste treatment before disposal;
- Setting EU-compliant technical requirements for pharmaceutical waste treatment.

That being said, it must be assured that the national regulatory measures correctly transpose and comply with the WFD's provisions and waste management acquis applicable to medical and pharmaceutical waste.

As a result, expert support is needed to assist the Ministry of Environmental Protection (MoEP) and Negotiating Group in Chapter 27 in developing a legal and institutional gap analysis of national provisions governing medical and pharmaceutical waste management against the requirements of the WFD and other relevant waste management acquis and to draft legislative

acts that improve the current legal framework in the field of medical and pharmaceutical waste and fully comply with the Union acquis requirements applicable to this specific waste stream.

At present, there are no ongoing 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 assist the MoEP and Negotiating Group in Chapter 27 (NG 27) to conduct a legal and institutional gap analysis of national provisions governing medical and pharmaceutical waste management against the requirements of the WFD and waste management acquis and to draft amendments to the by-laws currently in force with guidelines on the implementation of new provisions that fully comply with the Union acquis requirements applicable to this specific waste stream.

The newly aligned regulatory framework shall cover in particular:

- Setting technical requirements for medical waste treatment before disposal in compliance with the best available techniques (BAT) and BAT reference document (BREF) for waste treatment and with relevant requirements of the Union waste management acquis;
- Introducing a legal basis for the establishment of an EPR scheme for pharmaceutical waste in the relevant legislation in compliance with WFD, Articles 8 and 8a;
- Setting technical requirements for pharmaceutical waste treatment in compliance with best available techniques (BAT) and BAT reference document (BREF) for waste treatment and with relevant requirements of the Union waste management acquis and
- Developing a methodology for establishing and managing the financial contributions that producers will pay to cover the costs of all aspects of pharmaceutical waste management in compliance with WFD, Articles 8, 8a and 14;

Within the scope of the assignment, a selected expert shall develop a report on the Republic of Serbia's medical and pharmaceutical waste stream flows and treatment capacities, legal and institutional framework and status of implementation and an analysis of the state of play on reporting and quality of data at a national level for medical and pharmaceutical waste streams and propose measures for improvements.

The experts shall take into account outputs of the previous PLAC assignments, data and information available in waste management strategies, plans, programmes adopted by Serbian authorities, the EU Common Position in Chapter 27 and the Serbian negotiating position in Ch. 27 including the Action Plan for the Development of Administrative Capacities (APDAC) and directive specific implementation plans (DSIPs) annexed to the negotiating position relevant to the assignment.

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

3.2 Requested services

The Senior NKE in the area of waste management is expected to provide the following services:

1. Perform a legal and institutional gap analysis of the Serbian legal framework against the requirements of the Union acquis applicable to the medical and pharmaceutical waste management, explaining best practices in selected Member States on implementation of EPR schemes and economic instruments, identifying the key issues in the national legislation and proposing solutions for closing the gaps identified;
2. On the basis of the findings of the gap analysis, assist the MoEP in:
 - a. Drafting amendments to the Rulebook on medical waste management (“Official Gazette of the Republic of Serbia“, No. 48/19) setting technical requirements for the treatment of medical waste before disposal in compliance with BAT and BREF for waste treatment and with the requirements of the Union acquis applicable to medical waste management;
 - b. Drafting amendments to the Rulebook on the manner and procedures for pharmaceutical waste management (“Official Gazette of the Republic of Serbia“, No. 49/19) setting:
 - Technical requirements for the treatment of pharmaceutical waste before waste management operations in compliance with BAT and BREF for waste treatment and with the requirements of the Union acquis applicable to pharmaceutical waste;
 - Criteria and conditions for the operation of an EPR scheme for pharmaceutical waste and establishing and/or managing the financial contributions that producers will pay to cover the costs of all aspects of pharmaceutical waste management in compliance with WFD, Articles 8, 8a and 14;
 - c. Drafting of guidelines on the implementation of amendments to the rulebooks;
3. Prepare and hold a Workshop and present the outputs of the assignment.

The Junior NKE in the area of waste management legislation is expected to provide the following services:

1. Analyse the state of play on the reporting and quality of data at a national level for medical and pharmaceutical waste streams and propose measures for improving reporting and data quality to comply with the relevant acquis;
2. Prepare and hold a WS and present the outputs of the assignment.

3.3 Outputs

The SNKE is expected to deliver the following outputs:

1. A legal and institutional gap analysis report with best practices on EPR and economic instruments in selected Member States explained, and proposals of solutions for closing the gaps identified, drafted
2. Amendments to the Rulebook on Medical Waste Management (“Official Gazette of the Republic of Serbia“, No. 48/19), drafted;
3. Amendments to the Rulebook on the Manner and Procedures for Pharmaceutical Waste Management (“Official Gazette of the Republic of Serbia“, No. 49/19), drafted;
4. Guidelines on the implementation of amendments to the rulebooks, drafted;

5. Workshop held.

The Junior NKE is expected to deliver the following outputs:

1. An analysis of the state of play on reporting and quality of data for medical and pharmaceutical waste streams with a proposal of measures for improving reporting and data quality to comply with the relevant acquis, drafted;
2. 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 the Senior Non-Key Expert and 10 working days (WDs) for the 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 through several missions during the period from March until November 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, economy, natural, environmental, or technical sciences 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 undertaken responsibilities.

4.2 General professional experience (15 points)

- At least 8 (eight) years of general postgraduate professional experience related to the Union acquis gained in an EU member state, candidate or potential candidate country.

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 and/or strategies and policies in the waste management sector, gained in an EU member state, candidate or potential candidate country.
- Knowledge of the Serbian legal system will be an advantage.

5. Experts' Profile – Junior NKE (10 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, economics, natural or technical science 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 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 waste management sector i.e. in developing waste management plans, waste characterisation and/or morphology
- Postgraduate professional experience in performing reviews of institutional and/or legal framework related to the environmental sector will be an advantage
- 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 e-mail 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. 27, Environment and Climate Change, Waste Management – medical and pharmaceutical waste management legislation”

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.