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|  | Policy and Legal Advice Centre, Republic of Serbia |  |
| A project implemented by DMI Associates, Altair Asesores, Hulla&Co. Human Dynamics, INCOM and HD European Consulting Group |  | This project is funded  by the European Union |

**Terms of Reference (TOR) for a Short term assignment**

**Technical assistance requested: (One)** 1 expert on Public Health – Medicinal Products and Medical Devices

**The project**

**Title:** Policy and Legal Advice Centre (PLAC), Serbia

**Ref:** EuropeAid/131430/C/SER/RS

**Main beneficiary:** European Integration Office of the Republic of Serbia (SEIO)

**Financing institution:** European Union

**Budget Line / Expert Category:** Non Key Short-Term Senior Expert

**Team Leader:** Marija Pejčinović Burić

**Project background and description PLAC (scope of the work)**

The scope of this assignment is to assist the Project in its objective to improve the current system for legal approximation process and the level of harmonisation of the national legislation with the EU *acquis,* thus contributing to a fundamental element of the EU integration process. Further improvement of the European integration structures, including in key line ministries, strengthening verification of the compatibility of government policies and draft legislation with the *acquis* and EU integration requirements, improving legislation quality, and enhancing cooperation among line institutions are key priorities. The project will assess and enhance the concrete and systemic integration of the transposed *acquis* in the national legislative framework. To that regard, line institutions at Government central level and the Parliament will be involved through specific assistance. When a plan or a strategy for harmonisation is developed, the project will contribute implementing it. The sustainability of results, including ensuring the necessary capacities for implementation and follow-up, will be specifically in focus.

The PLAC project should achieve three results:

**RESULT 1** Strengthened structures related to harmonization and approximation of national legislation with EU legislation, including mechanisms for consultation of relevant external stakeholders

**RESULT 2** Compatibility of national legislation with EU legislation improved through preparation of relevant draft laws

**RESULT 3** Enhanced capacities of the relevant institutions (in particular SEIO, the Secretariat for Legislation, the General Secretariat and line ministries) for harmonization of Serbian legislation with the EU *acquis* and implementation of national legislation.

**Description of the assignment**

**Title:** Non-key Short-Term Senior Expert

**Brief description of the assignment:**

The Republic of Serbia started transposition of the relevant EU *acquis* in the field of medicines and medical devices by enacting a new Law on Medicines and Medical Devices in 2012. Hence, the Law is harmonized only with EU *acquis* enacted before 2010. In order to fully transpose the EU *acquis* the aforementioned law needs to be amended in order to fully comply with the EU legislation, with particular regard to legislation adopted since 2010.

Therefore, the expert shall provide a compatibility check and an analysis of the existing Serbian legislation with the EU *acquis*, in particular with the legislation entered on since 2010. Following the results of the compatibility check and the analysis, the expert shall draft amendments to the Law on Medicines and Medical Devices to fully harmonize it with the EU *acquis*. Also, the expert shall draft a Rulebook to implement the Law with regard to the directive 89/105/EEC and hold workshop on the implementation of the amended legislation and the Rulebook.

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

**Number of required experts: One** (1) Non Key Senior Expert on Public Health - Medicinal products and medical devices.

**Duration of the assignment:** 50 working days

**Period of the assignment:** January/2014 – March/2014

**Place of assignment:** Belgrade, Serbia.

**Working language:** English.

**Expert Activities:**

Description of the activities:

- Perform compatibility check of Serbian legislation and draft Table of Concordance (in accordance with the Act of Government n° 020-04-26/2006-01), with recommendations for full harmonization.

- Assess the current state of play of the implementation issues and draft recommendations on how to implement the suggested modified legislation.

- Draft amendments to the Law on Medicines and Medical Devices to make it fully EU harmonized.

- Draft fully EU harmonized draft Rulebook on method, procedures and requirements for destruction of medicinal products and medical devices, basic substances and other material used in production and wholesale and retail sale in special shops of medicinal products and medical, as well as production of galenic and main medicinal products

- Provide workshop on implementation of the new regulation

Outputs

* Table of Concordance drafted
* Amendments to the law drafted
* Rulebook drafted
* Recommendations on implementation of the amended legislation and the Rulebook drafted
* Workshop(s) held

**Expert Profile**

*Qualifications and skills (25 points)*

* A university degree (where a university degree has been awarded on completion of three years study in a university or equivalent institution) in Law or Pharmaceutics.
* Fluency in English, fluency in Serbian would be an asset.
* Computer literacy.
* Good communication and reporting skills.

*General professional experience (25 points)*

* Minimum 10 years of professional experience in institutional reform or policy making in an EU Member State or candidate/potential candidate country

*Specific professional experience (50 points)*

* Minimum 5 years and ideally more than 7 years of professional experience in the field of legal drafting and/or policy making.
* Minimum 5years of professional experience in the field of EU Medicinal products and medical deviceslegislation.
* Experience in the field of approximation/harmonization with the EU acquis in a Member State, Candidate or Potential Candidate country would be an asset.

Applications (EU format CV and application letter, both in English) need to be submitted by e-mail to [*mbayard@dmiassociates.com*](mailto:mbayard@dm%20iassociates.com) with a copy to [*nderxen@dmiassociates.com*](mailto:nderxen@dmiassociates.com) not later than 17:00 hrs, 12th December 2013, titled:

**Application for the position**

**Non-key Short-Term Senior Expert on in the field of Public Health – Medicinal Products and Medical Devices**

References must be available on request. Only candidates with a correct CV will receive a confirmation on receipt of their application. Only short-listed candidates will be contacted.

The Project is an equal opportunity employer that encourages applications from women and minorities.

All applications will be considered strictly confidential.

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

For more information, please contact Marion Bayard, project manager, DMI: [mbayard@dmiassociates.com](mailto:mbayard@dmiassociates.com) / +33 4 72 00 35 90