Republic of Serbia Ministry of Health

TERMS of REFERENCE National consultant for HTA item 2.2.3 from AF-SSHP PP

Background

Background The Republic of Serbia has received a loan from the International Bank for Reconstruction and Development (IBRD) in the amount of EUR 29.1 million equivalent toward the cost of the Second Serbia Health Project (SSHP) and EUR 25 million equivalent toward the cost of the Additional Financing for the Second Serbia Health Project (AF-SSHP), Loan No.: 8830-YF.

The Project Development Objective (PDO) is to contribute to improving the efficiency and quality of the public health system through the strengthening of: (i) health financing, purchasing, and maintenance systems; (ii) quality improvement systems and management of selected priority non-communicable diseases.

The project includes four components with sub-components:

- 1: Improvement of Health Financing
 - 1.1 Support Hospital Financing Reforms
 - 1.2 Strengthen Primary Health Care Financing
- 2: Improve Access to Quality Health Care
 - 2.1. Improve Access to Medicines
 - 2.2. Strengthen Health Technology Assessment Capacity
 - 2.3. Improve Medical Equipment Maintenance Systems
- 3: Strengthening Quality of Service Delivery
 - 3.1. Strengthen Quality Improvement Systems
 - 3.2. Improve Cancer Management
- 4: Monitoring, Evaluation, and Project Management this component will support project management, monitoring and evaluation, as well as audits of the project's financial statements. It will also finance the project's operating costs, including translation, interpretation, equipment, supervision costs and PCU staffing costs.

Within the Component 2, Subcomponent 2.2. Strengthen Health Technology Assessment (HTA) Capacity, one of the main Project goals is a strategic approach to carry out improved HTA through: (i) developing partnerships with relevant regional and international HTA organizations; (ii) strengthening the capacity of the relevant institutions to carry out improved HTA for pharmaceuticals and medical devices; (iii) developing proposals for strengthened institutional arrangements including through amendments to regulations and by-laws for improved HTA; and (iv) supporting the establishment of a HTA unit within an entity selected by the MOH based upon the institutional arrangements to be developed.

To address a broad basic benefit package defined by rights to health care (granted by Health Care Law) and the growing burden of non-communicable diseases within a constrained fiscal space, the

Republic of Serbia already started interventions to improve the healthcare financing system to increase quality and efficiency at both primary care and hospital levels.

Main tasks and responsibilities

Support the activities related to strengthening of the Health Technology Assessment within the Ministry of Health.

Scope of Work

- Cooperation and teamwork with the International Consultant for HTA to assist, contribute and takeover deliverables of the international experts related to:
 - the institutional set-up and arrangements for decision making process that follows principles of HTA based on the governance structure and identify relevant business processes;
 - draft policy instruments to support the institutionalization of HTA;
 - assessment of the human resources needs of the Ministry of Health (MoH), Health Insurance Fund (HIF), Institute of Public Health of Serbia (IPHS) and other stakeholders regarding HTA capacities;
 - draft the terms of reference for missing HR capacities of the institutions for HTA;
 - draft a three-year capacity building plan for HTA;
 - conduct a training regarding needs assessment, regulatory science, health technology assessment, methodology of clinical trials and outcomes assessment for defined stakeholders;
 - develop and document the standard operating procedures and a manual of procedures on the HTA implementation;
 - identify and propose study tours on HTA to countries with developed HTA;
 - prepare the material to be presented to key stakeholders and potential users who are interested in HTA issues, for the purpose of support and consensus building.

It is essential that all steps during the whole process are discussed and agreed with MoH and PCU staff.

Requirements

- University degree in medical or health sciences (medicine or pharmacy);
- Minimum of 5 years of relevant professional experience;
- Excellent knowledge of Serbian legislation requirements pertaining to the Health Technology Assessment;
- Experience in IFI financed projects would be an asset;
- Experience of regulatory science, health technology assessment, methodology of clinical trials and outcomes assessment:
- Computer literate;
- Good command of English and Serbian, including oral and written reporting abilities.

Reporting requirements

The Consultant is obliged to report to the PCU Coordinator and Ministry of Health officials as required. Minimum reports to be prepared:

- Reports related to the tasks described in the Scope of Work including (i) time-frame for it, and (ii) Clear outputs/outcomes / results of said activities, all agreed with the MOH/PCU
- Monthly Reports the Consultant shall prepare the monthly reports describing tasks performed. This report will form a basis for payment and should be submitted at the end of each month.
- Ad hoc reports as requested by the Component 2 Coordinator, PCU Coordinator and/or MoH.

All reports should be submitted in English and/or Serbian language, as needed.

Duration of the assignment

The Consultant shall be engaged for up to 72 days in the period of one year. Duration of the assignment may be subject to extension depending on project needs.