TERMS of REFERENCE

Development of Health Technology Management (HTM) policy at national level

RS-AFSSHP-8830YF-CS-IC-21-2.3.4

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), Loan No. 8338-YF 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 subcomponents:

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.

Key Issues

A critical concern for the project is protecting the substantial investments that have already been made, including different kinds of health technology. A strategic approach to maintenance of medical equipment, aimed at developing a cost-effective system, represents one of the priorities for the delivery of good quality health services in Serbia. The total replacement value of the health technology installed in Serbian health facilities is estimated at about US$800-900 million. An internationally accepted figure for the annual cost of a good maintenance program is 6-8 percent of the equipment capital value, which would correspond to an expenditure of US$56-63 million per year - much higher than the budget currently allocated for maintenance. This explains in part the large number of unrepaired devices in hospitals. Hospitals also encounter difficulties procuring spare parts for high-tech equipment, contributing to equipment "downtimes" of several months. Despite fiscal constraints, the problem cannot be ignored, as it reduces patient access to lifesaving technology and contributes to a progressive depletion of the medical technology assets in the national health system.

Due to the lack of national guidelines or strategy there are no uniform approaches and almost no awareness about maintenance within healthcare facilities staff and the development of maintenance structures and staffing is left to the health facilities.

The health technology includes a variety of equipment types: laboratory diagnostic equipment, imaging equipment, equipment and tools used in the operating theatre amongst many others.

The project already identified a need to improve the overall health technology management capacity, including a focus on the medical equipment maintenance capacity which led in 2019 to the creation of the Medical Equipment Maintenance Unit (MEMU) (officially *Group for Human Resources, Equipment and Investment in Health Institutions*) within the MoH.

Nevertheless, the creation of this unit requires, at the same time, a national health technology management policy that should address the existing gaps in the area of health technology management:

- the lack of a clear vision on the extent of activities the MEMU should reach,
- the lack of a structure at national level to manage the existing health technology,
- the lack of specialized professionals to work in the field (biomedical engineers),
- the lack of training programs to develop the required biomedical engineering capacity,
- the lack of incentives for professionals to get involved in the support area of the health sector
- the lack of standardized equipment definitions.

At the same time, the national health technology management policy should propose a) the methods by which such a system could be introduced at government level as well as the c) the human, financial and physical resources needed to deliver this approach at different levels of the system.

Therefore, the need to develop a health technology (health or medical equipment) management policy and a roadmap to later on define an action plan including the development of guidelines based on international standards or norms such as the life cycle approach to equipment management; to create budget lines for equipment maintenance and repair at national level and at hospital levels and to coordinate the activities of different partners involved in the support of health technology at national level requires the development a Health Technology Management National Policy.

Objectives of the Consultancy

The overall objective of consultancy is:

- To complete a wide-ranging situational analysis to support the policy development in this field.
- To propose a Health Technology Management Policy at national level
- To provide a road map for the implementation of the policy development at central level for a horizon of 1-3 years.

Scope of Services

Inception report

Short inception report (max 10 pages) detailing the consultancy approach including desk-based work such as comparison of international norms, development of a work plan, timeline and completion of initial stakeholder mapping within **4 days** of contract signature.

Situational analysis of current approach to health technology management

The analysis should examine the current approach to the practice of health technology management and the utilization of the BMET cadre from the central to county level within the health system, and consider what plans are being made going forward. It should cover the following elements (not an exhaustive list):

- Overall approach and expectations of MoH in the field of biomedical engineering.
- The need for/availability of /plans for production of key policy documents and guidelines and documents.
- Role and function of the health technology management units within the structure of MoH.
- Key responsibilities the health technology management units within the structure of MoH has and / or should have in order to implement HTM Policy.
- Main obstacles to further success in the implementation of a national approach to the management of health technology.
- HR issues – succession planning, on-going training needs, long term plans for the cadre.
- Financing issues.

A key aspect of the situational analysis will be to establish the extent of current and future Bank's support.

The situation analysis should be completed in **5 working days** after the approval of the Inception Report.

Health Technology Management (HTM) Policy

The Policy is expected to include:

- Equipment Planning guidelines or minimum requirements
- Equipment Procurement procedures and guidelines
- Equipment Maintenance management procedures
- Replacement and Decommissioning procedures
- Responsibilities on registration of medical devices
- Responsibilities on the registration of medical equipment maintenance suppliers.

All the documents should take into account national policies (HR policy, Healthcare Facilities Policies, etc.), international good practices in the field, WHO documents.

The HTM Policy document should be completed in **10 working days** after the approval of the Inception Report.

Road Map

A road map should be prepared to support the development of an enhanced national approach to health technology management based on the situational analysis and the SWOT (Strengths, Weaknesses, Opportunities and Threats) identified in the situation analysis. The road map should provide an outline of the key steps and the main documents which will be needed in order to implement national policy framework

- identify milestones as well as the time it will take the implementation of each stage of the process.
- consider digital solutions to some of the issues identified
- be expressed as a series of short-, medium- and long-term actions, with costs if possible
- consider overarching issues such as HR (training and education), financial issues (budget lines for spare parts etc), links with other aspects of the equipment lifecycle (eg procurement) and safe and effective use of equipment by the end user.

The road map will be an important document to aid the government and partners in the planning of activities, make investment decisions and track and monitor the progress of the implementation by creating ownership and effective handover to the Ministry of Health.

The road map should be completed in **5 days** after the approval of the Inception Report.

The Final report is should summarize the main points proposed for the health technology management as well the key milestones in the road map.

The final report should be completed in **1 days** after the approval of the Road Map

Duration of the Consultancy and Contracting Modality

Duration of the Assignment: one month

Expected Outputs and Deliverables

1. Inception Report
2. Situation Analysis
3. HTM Policy
4. Road Map
5. Final Report

No	Phase	Activities and Deliverables	(Maximum) Time Allocation
1	Inception Report (mission to country)	Conduct stakeholder interviews, Desk review	4 days
3	Preparation of Situational Analysis (home office)	Produce situational analysis	5 days
4	Preparation of HTM Policy (home office)	Develop HTM Policy	10 days
5	Preparation of Road map (home office)	Prepare road map	5 days
6	Final Report (home office)	Produce final report	1 day
			25 days

Qualifications of Consultant

Qualifications of expert

- Education/training: Masters level qualification in biomedical engineering or similar field

- General professional experience: at least 8 years of professional experience working in the sector of biomedical engineering
- Specific professional experience: Experience of more than 10 years in assignments advising public institutions (Ministries of Health or major health facilities) with significant time allocated to the production of policy documents, strategic frameworks, development of policy documents for the sector of medical equipment management and maintenance.
- Leadership/management experience: at least 3 years management experience
- Multilateral Funding Projects experience: at least 3 years
- Language: Fluent written and spoken English
- Knowledge of Serbian Language would be considered an advantage
- Regional experience in the implementation of similar projects in Balkan countries would be considered an advantage

Soft skills

- Team skills
- Initiative
- Communication skills
- Sociocultural competence
- Efficient, partner- and client-focused working methods
- Interdisciplinary thinking