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Report No: PAD2705

INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT

PROJECT PAPER

ON A

PROPOSED ADDITIONAL LOAN AND RESTRUCTURING

IN THE AMOUNT OF EUR25.0 MILLION
(US$31.10 MILLION EQUIVALENT)

TO

THE REPUBLIC OF SERBIA

FOR AN

ADDITIONAL FINANCING FOR THE SECOND HEALTH PROJECT

FEBRUARY 27, 2018

Health, Nutrition & Population Global Practice
Europe And Central Asia Region

CURRENCY EQUIVALENTS

(Exchange Rate Effective January 2018)

Currency Unit =	New Serbian Dinar
95.3 RSD =	US$1
EURO 1 =	US$0.803

FISCAL YEAR
January 1 - December 31

Regional Vice President:	Cyril E Muller
Country Director:	Linda Van Gelder
Senior Global Practice Director:	Timothy Grant Evans
Practice Manager:	Enis Barış
Task Team Leader(s):	Ana Holt

ABBREVIATIONS AND ACRONYMS

ACHI	Australian Classification of Health Interventions
CT	Computerized Tomography Imaging
DALYs	Disability Adjusted Life Years
DRG	Diagnostic Related Group
GoS	Government of Serbia
GRS	Grievance Redress Service
HIF	Health Insurance Fund
HTA	Health Technology Assessment
IBRD	International Bank for Reconstruction and Development
ICD-10	International Statistical Classification of Diseases and Related Health Problems 10th Revision
INN	International Non-Proprietary Name
IRR	Internal Rate of Return
LINACs	Linear accelerators
MoF	Ministry of Finance
MoH	Ministry of Health
MRI	Magnetic Resonance Imaging
NCDs	Non-communicable diseases
PHC	Primary Health Center
PCU	Project Coordination Unit
PDO	Project Development Objective
POGM	Project Operation and Grants Manual
PPSD	Project Procurement Strategy for Development
RECO	The Republican Expert Committee on Oncology
SSHP	Second Serbia Health Project
US	Ultrasound
VOI	Vojvodina Oncology Institute

BASIC INFORMATION – PARENT (Second Serbia Health Project - P129539)

Country	Product Line	Team Leader(s)		
Serbia	IBRD/IDA	Ana Holt		
Project ID	**Financing Instrument**	**Resp CC**	**Req CC**	**Practice Area (Lead)**
P129539	Investment Project Financing	GHN03 (9318)	ECCWB (7001)	Health, Nutrition & Population

Implementing Agency: Ministry of Health

Is this a regionally tagged project?	
No	
[ ] Situations of Urgent Need or Capacity Constraints [ ] Financial Intermediaries [ ] Series of Projects	Bank/IFC Collaboration No

Approval Date	Closing Date	Original Environmental Assessment Category	Current EA Category
25-Feb-2014	30-Sep-2019	Partial Assessment (B)	Partial Assessment (B)

Development Objective(s)

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

Ratings (from Parent ISR)

	Implementation

	08-Oct-2015	04-Apr-2016	15-Sep-2016	06-Mar-2017	07-Sep-2017
Progress towards achievement of PDO	MS	MS	MU	MS	MS
Overall Implementation Progress (IP)	MS	MS	MU	MS	MS
Overall Safeguards Rating	S	S	S	S	S
Overall Risk	M	M	M	M	M

BASIC INFORMATION – ADDITIONAL FINANCING (Additional Financing for Second Serbia Health Project - P166025)

Project ID	Project Name	Additional Financing Type	Urgent Need or Capacity Constraints
P166025	Additional Financing for Second Serbia Health Project	Restructuring, Scale Up	No
Financing instrument	**Product line**	**Approval Date**	
Investment Project Financing	IBRD/IDA	20-Mar-2018	
Projected Date of Full Disbursement	**Bank/IFC Collaboration**		
31-Dec-2021	No		
Is this a regionally tagged project?			
No			

[ ] Situations of Urgent Need or Capacity Constraints

[ ] Financial Intermediaries

[ ] Series of Projects

PROJECT FINANCING DATA – PARENT (Second Serbia Health Project - P129539)

Disbursement Summary (from Parent ISR)

Source of Funds	Net Commitments	Total Disbursed	Remaining Balance	Disbursed
IBRD	40.00	8.77	29.71	23 %
IDA				%
Grants				%

PROJECT FINANCING DATA – ADDITIONAL FINANCING (Additional Financing for Second Serbia Health Project - P166025)

FINANCING DATA (US$, Millions)

SUMMARY

Total Project Cost	31.10
Total Financing	31.10
Financing Gap	0.00

DETAILS

International Bank for Reconstruction and Development (IBRD)	31.10

COMPLIANCE

Policy

Does the project depart from the CPF in content or in other significant respects?

[ ] Yes [✓] No

Does the project require any other Policy waiver(s)?

[ ] Yes [✓] No

INSTITUTIONAL DATA

Practice Area (Lead)

Health, Nutrition & Population

Contributing Practice Areas

Climate Change and Disaster Screening

This operation has been screened for short and long-term climate change and disaster risks

Gender Tag

Does the project plan to undertake any of the following?

a. Analysis to identify Project-relevant gaps between males and females, especially in light of country gaps identified through SCD and CPF

Yes

b. Specific action(s) to address the gender gaps identified in (a) and/or to improve women or men's empowerment

Yes

c. Include Indicators in results framework to monitor outcomes from actions identified in (b)

Yes

PROJECT TEAM

Bank Staff

Name	Role	Specialization	Unit
Ana Holt	Team Leader (ADM Responsible)		GHN03
Benedicta T. Oliveros	Procurement Specialist (ADM Responsible)		GGOPC
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Extended Team

Name	Title	Organization	Location
Goran Hellers	Hospital Master Plan Specialist		Stockholm
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Paolo Giribona	Medical Equipment Consultant		

SERBIA

ADDITIONAL FINANCING FOR SECOND SERBIA HEALTH PROJECT

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I. BACKGROUND AND RATIONALE FOR ADDITIONAL FINANCING

A. Introduction

1. **This Project Paper seeks the approval of the Executive Directors to provide a first additional financing from an International Bank for Reconstruction and Development (IBRD) Loan in the amount of EUR25 million (US$31.1 million equivalent) to the Republic of Serbia for the Second Serbia Health Project (P129539).** The original Loan in the amount of EUR 29.1 million (US$40 million equivalent), approved by the Board of Executive Directors on February 25, 2014, was declared effective on May 8, 2015 and has a Closing Date of September 30, 2019. The proposed Additional Financing (AF) would finance the implementation of scale-up activities that are in line with the parent project activities. These activities would support a comprehensive health reform program towards improving access to prevention and care for the most prevalent cancers, enhancing quality and efficiency, through rationalizing oversized health facilities. Provision of modern diagnostic equipment under the project will be fully aligned with the extended reform agenda, including optimization of the health network and the development of a long-term comprehensive national cancer strategy.

2. **The proposed AF will also include the restructuring of the parent project** to revise (a) the *Project components; (b) update the Project Results Framework; and (c) extend the Closing Date to December 31, 2021.*

3. **The Additional Financing is consistent with OP/BP 10.00, which states that Additional Financing is justified to compensate cost overruns and/or to support the scaling up activities.** The proposed Additional Financing and restructuring of the project would enable the Project to meet its development objectives and contribute to Serbia's health sector reform program. The AF extends coverage of diagnostic equipment to areas not previously covered and supports second-generation of health financing reforms.

4. **An exception was received from the Regional Vice President on January 19, 2018 to proceed with the preparation of the Additional Financing as the original project had not been consistently rated as Moderately Satisfactory in the preceding 12 months.** From September 2016 to March 2017, both DO and IP were rated as Moderately Unsatisfactory due to significant delays in the implementation of Component 1 (Strengthening health financing) and Component 2 (Efficient purchasing of pharmaceuticals and medical products) and the lack of essential staff at the Project Coordination Unit (PCU). During the implementation support visit of December 2017 significant improvements in the implementation of these Project components were observed as both technical coordinators for Components 1 and 2 were replaced with qualified staff. Implementation of activities under Component 3 (Strengthening Quality) are progressing satisfactorily. Project DO and IP have thus been rated as Moderately Satisfactory since March 2017.

5. Six linear accelerators (LINAC) and three CT-simulators have been procured for four health care institutions in Serbia (Belgrade, Kragujevac, Nis and Kladovo), including building and refurbishing of bunkers and the dismantling of old equipment on some locations under the parent project. In parallel, the Government of Serbia (GoS) has purchased four LINACs from the budget to achieve international standards in radiotherapy coverage. The project will further support improvements towards equitable access to cancer care and management through upgrading of the diagnostic and treatment platform across the country.

B. Original Objective, Design and Scope

6. The Project Development Objective (PDO) of the parent Second Serbia Health Project (P129539), which remains relevant, is *to contribute to improving the efficiency and quality of the public health system of the*

Republic of Serbia through the strengthening of: (i) health financing, purchasing, and maintenance systems; and (ii) quality improvement systems and management of selected priority non-communicable diseases. Project effectiveness was extended twice due to delays with meeting the conditions of effectiveness, which postponed Project implementation by one year.

7. The parent Project comprises four components:

Component 1: Improvement of Health Financing. Sub-component 1.1: Support Hospital Financing Reforms. Strengthen transparency of and incentives for efficiency of the Health Insurance Fund financing for public hospitals through (i) carrying out a phased implementation of a Diagnostic Related Group (DRG) payment system, including conducting a DRG costing exercise and building awareness and capacity of public hospitals' staff for the implementation of said payment system; (ii) carrying out a gradual shift of hospital acute care financing from inputs to DRGs; (iii) improving the information systems, through upgrades to central systems, and software installation or upgrades, as the case may be, at selected hospitals; (iv) supporting amendments to regulations and by-laws that give effect to the hospital financing reforms; and (v) providing technical advice on options to improve efficiency of financing for non-acute care in hospitals and governance arrangements to strengthen management in hospitals. Sub-component 1.2: Strengthen Primary Health Care Financing. Improve the efficiency and quality of preventive and certain other primary care services through (i) strengthening the incentives for performance in the Health Insurance Fund health provider payment mechanisms through refinement of performance criteria for variable payments made to health workers; (ii) designing and piloting implementation of Quality Improvement Sub-grants for improvement of quality of health care, including increased access to health care and preventive services by vulnerable groups (such as Roma, the elderly, and the disabled); (iii) strengthening implementation and monitoring capacity of primary health care financing reforms through development of transition plans for capitation financing to Primary Health Care Centers and development of managerial capacity and skills for Primary Health Care Centers; and (iv) develop proposals for amendments to regulations and by-laws that give effect to the primary care financing reform.

Component 2: Efficient Purchasing of Pharmaceuticals and Medical Products. Sub-component 2.1: Establish a Centralized Procurement System. Develop and implement a centralized system for the procurement of pharmaceuticals, medical supplies, diagnostic reagents and medical equipment through (i) carrying out a competitive tendering process for multi-source items and reference pricing for single source items (ii) developing specific framework agreements to be entered by the Health Insurance Fund and suppliers within the centralized procurement system; (iii) carrying out pilot testing of (1) e-Prescription system and modules for Primary Health Care Centers, hospitals, Health Insurance Fund, and pharmacies; (2) e-Procurement system to support centralized procurement; (3) development and training of a unified information technology system for monitoring in-market availability and dispensing of pharmaceuticals; and (iv) developing proposals for amendments to regulations and by-laws that give effect to health sector procurement reform. Sub-component 2.2: Strengthen Health Technology Assessment Capacity. Strengthen the Borrower's capacity to carry out improved Health Technology Assessment through (i) developing partnerships with relevant regional and international Health Technology Assessment organizations; (ii) strengthening the capacity of the relevant institutions of the Borrower, selected pursuant to the criteria set forth in the Project Operations and Grants Manual, to carry out improved Health Technology Assessment for pharmaceuticals and medical devices; (iii) developing proposals for strengthened institutional arrangements of the Borrower, including through amendments to regulations and by-laws for improved Health Technology Assessment; and (iv) supporting the establishment of a Health Technology Assessment unit within an entity of the Borrower to be selected by the Borrower and acceptable to the World Bank, based upon the institutional arrangements developed under the

preceding sub-section (iii). Sub-component 2.3: Improve the Medical Equipment Maintenance Systems. Support the improvement of the Ministry of Health maintenance system through (i) carrying out a preliminary assessment of the existing (1) system of distribution of medical equipment; (2) procedures for medical equipment maintenance and repairs management; (3) costs and allocation of maintenance funds; and (4) procurement of spare parts and equipment maintenance and repairs services; and (ii) on the basis of the outcome of the preliminary assessment in (i) above, supporting the establishment of a governmental agency for medical technology management; and (iii) selecting a qualified Independent Service Organization for the provision of highly qualified multi-vendor maintenance services on a pilot basis to selected hospitals.

Component 3: Strengthening Quality of Service Delivery. Sub-component 3.1: Strengthen Quality Improvement Systems. Support the Ministry of Health to (i) develop national clinical practice guidelines aligned with international standards; (ii) based on the national clinical practice guidelines referred in (i), develop clinical pathways covering priority disease areas and carry out a phased implementation of said clinical pathways in selected hospitals and Primary Health Care Centers; (iii) provide targeted support, with the support of National Agency for Accreditation of Health Care Institutions, to selected Primary Health Care Centers for the improvement of quality of provision of health care for priority services, through the provision of training and technical assistance; (iv) support the improvement of reporting and use of information on service quality and efficiency at the Ministry of Health, Health Insurance Fund, Institute of Public Health, Regional Institutes of Public Health, (v) implement a Health Management Information System, and strengthen the national eHealth Development Framework; and (vi) develop proposals for amendments to regulations and by-laws that give effect to the quality of service delivery reforms. Sub-component 3.2: Improve Cancer Management. Increase the coverage and quality of radiation therapy cancer treatment at specialized tertiary oncology centers, selected pursuant to criteria set forth in the Project Operation and Grants Manual (POGM), through (i) procurement and installation of a number of accelerators determined pursuant to criteria set forth in the POGM, and associated equipment and works; and (ii) supporting the improvement of monitoring of patient outcomes and the strengthening of the national cancer registry system, through training, information systems, and technical assistance.

Component 4: Monitoring, Evaluation, and Project Management. Carry out Project management, monitoring and evaluation activities, and audits, and financing of Operating Costs, studies, and Training.

C. Project Progress to Date

8. Despite delays in effectiveness and some issues that affected progress in the implementation of activities under Components 1 and 2 (see paragraph 4 above), progress has significantly improved once these issues were resolved. Over the past 11 months, steady improvement in implementation has been evident and tangible results were achieved in both health financing and pharmaceutical policies. **Progress towards achievement of the PDO** is being monitored and reported by the Project Coordination Unit (PCU) of the Ministry of Health (MoH) through its regular progress reporting. The parent Project is well under way and target values for PDO indicators are on track, and some of them exceeded the 2017 targets. Four out of 14 Intermediate Results Indicators have exceeded the planned targets for 2017; the remaining 10 indicators are on track, but with some delay due to past pace of implementation of related activities. Table 1 reflects progress to date:

Table 1. Progress Towards Achievement of PDO

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

PDO Indicator	Baseline	Current	End Target	Status
1. Percentage of total acute care hospitalization cases in public hospital reported accurately based on DRGs	0	70	95	On track.
2. Percent reduction in average unit price relative to baseline for the 50 most frequently dispensed multisource pharmaceuticals that are procured through centralized framework contracts	0	27	30	On track.
3. Number of patients who started radiotherapy treatment at public hospitals within 28 days from the day of medical prescription	3000	n/a	4200	Indicator is being revised.
4. Percentage of registered adult patients in Dom Zdravljas with recorded blood pressure value, Body Mass Index, smoking status and recommended tips for healthy behavior in the preceding 5 years in their medical records	35	32	50	Indicator is being revised.

9. **Implementation Progress**. *Component 1:* Diagnostic-Related Groups (DRGs) and primary care related financing reforms have significantly moved forward, and despite a few challenges in their implementation, there is a strong political will and commitment in the MoH to advance this agenda. Fourteen selected pilot hospitals have started reporting as of June 2017, and will start full implementation of accounting based on DRGs as of January 2018. In parallel, introduction of new clinical pathways and adequate hospital informatization, which will allow for full implementation of DRG, are near finalization. Financing formula for primary care has been revised and criteria for performance evaluation adjusted to include quality indicators.

10. *Component 2:* Pharmaceutical policies interventions are focusing on capacity building for the Health Insurance Fund (HIF) for implementation of pharmacoeconomic analytics and Health Technology Assessment (HTA), and draft models for advertising centralized public procurement by INN for prescription drugs. Several workshops and round tables on antimicrobial resistance have been organized over the past six months for various target audiences (health workers, students, public health institutions, managers). These interventions have led to a decrease of antibiotics use up to 18 percent.

11. *Component 3*: Activities on strengthening quality of service delivery are progressing as planned, the main accomplishment being contract signing for the procurement of the new linear accelerators (LINACs), ancillary equipment and construction works. The bidding process was lengthy and complex in nature, and was particularly affected by the limited number of suppliers. The training on applying new radiotherapy technologies for medical staff, doctors, physicians and technicians from respective institutions was implemented in parallel with bidding tenders for the construction of bunkers and procurement of LINACs.

Furthermore, sufficient number of staff to operate LINACs has been achieved despite overall hiring freeze in the public sector, thanks to relentless efforts of the MoH.

12. After over two and a half years of implementation approximately 21 percent of the project funds have been disbursed. This level of disbursement will significantly increase given that a US$21 million contract was signed on the procurement and installation of six linear accelerators. Accordingly, disbursement is expected to reach EUR 22 million (approximately 70 percent of the total Loan) by the end of FY18.

13. Overall, the MoH ownership of the project development objectives has been evident over the past months. The coordination and the roles of key staff responsible for project implementation, including those in the PCU, have been defined in a satisfactory manner. This includes subordination and decentralized decision-making processes related to project activities.

D. Rationale for Additional Financing

14. The Borrower requested additional financing in the amount of EUR 25 million for the Second Serbia Health Project (SSHP). The proposed AF is requested to scale-up the activities of the parent project that are critical in expanding and ensuring project's impact to beneficiaries, including the Roma population. The activities to be financed by the AF are aligned with the PDO of the Second Serbia Health Project (SSHP) and aimed at fully achieving SSHP outcomes. The AF would further support the second-generation comprehensive reforms towards improving efficiency, enhancing quality, providing greater transparency, and rationalizing oversized health facilities using an integrative approach to addressing cancer management and covering radiotherapy services. Provision of modern diagnostic equipment under the Project would be fully aligned with the extended reform agenda, including optimization of health network and development of a long-term comprehensive national cancer strategy.

15. Results of the parent Project (such as centralized procurement of pharmaceuticals and initial results from the DRG reporting piloting) encouraged the MoH in pursuing a deeper reform. Building on the achievements of the parent Project, the AF would enable the Bank to seize an opportunity to support the MoH in scaling up activities through health care network optimization and comprehensive cancer management reform.

16. The AF will also include: (i) adding a new sub-component under component 1; (ii) revising the Results Framework; and (iii) extending the parent project Closing Date by 27 months until December 31, 2021. The following provides sectoral justification for the proposed AF and more specifically for Component 1 (Improvement of Health Financing) and Component 3 (Strengthening Quality of Service Delivery).

17. **Health Care Network.** Fragmentation and under-utilization of capacities in the country have been well identified and documented. The MoH is aiming to address this issue and has asked for Bank support in this exercise, including designing and implementing measures towards network optimization and functional and organizational integration of Primary Health Centers (PHC) and regional general hospitals into health centers, piloting of developing palliative care, opening day hospitals (i.e., small surgery under local anesthesia, chemotherapy, internist care, etc.) and other interventions towards increased and more efficient utilization of existing capacities.

18. PHC centers and hospital system, especially in large urban areas, are rather disconnected from each other. Doctors in specialized hospitals say that they do not have any meaningful contacts with the PHC doctor before or after treatment episode in a hospital facility. This causes longer stays in hospitals and duplication of diagnostic testing, inefficiency in the utilization of expensive hospital infrastructure and lower functional outcomes of treatment. Although PHC centers have staff on duty after normal business hours on week days and on Saturdays, very few patients use PHC services as they mostly use emergency (ER) services in hospitals

for simple health problems. The hospital managers are overwhelmed with diagnostic work that should be done at PHC centers. The picture seems different in the regions where communication and working relations between PHC and hospital care facilities are more effective.

19. There is evidence of duplication and inefficiency within the hospital system. Fragmentation of services does not support patient centered service delivery. In addition to economic inefficiency, this undermines service quality. For example, hospitals offering ER services, even in large catchment area, do not have a full range of required specialties, necessitating re-referrals and leading to delays in starting appropriate treatments. Hospitals that offer emergency services only a few days a week cause inefficiency in the utilization of emergency services infrastructure.

20. Hospital physical infrastructure and equipment are often outdated. Buildings are 50 to 60 years old and many are in need for refurbishment or upgrade. This situation does not provide efficient quality services even if these facilities receive continuous repairs and upgrades. There is an obvious need for substantial investments in hospital infrastructure. In a situation where the service delivery system is fragmented and duplicated and financial means are insufficient for all needed investments, it is difficult to envisage any efficient and meaningful improvements in hospital infrastructure without conducting a comprehensive service delivery system functional mapping and network optimization planning. The Project will finance the network optimization plan which would also serve as an instrument to attract other sources of funding from various international partners.

21. **Cancer management in Serbia.** Cancer statistics registration uses outdated paper forms and a multi-step data collection system. This process is not efficient and increases the chance for errors. Data collection does not include proper internationally comparable disease stage at the time of diagnosis nor does it enable measurement of five-year survival rates. It is therefore impossible to evaluate actual level of detection and treatment of malignant tumors in the country, and consequently it is difficult to measure effectiveness of any interventions. Relevant parliamentary legislative amendment has recently passed to modernize data handling. However, the necessary by-laws and regulations are yet to be prepared and enacted.

22. Cancer-related survival rates are low in Serbia when compared to Western European countries. According to Globocan 2012, the age standardized rate of cancer incidence is 269.7 per 100,000 population in Serbia, which is lower than Western European countries of 292.1. On the other hand, the age standardized cancer-specific mortality rate in Serbia is 147.8 per 100,000 population, which is substantially higher than 105.0 in Western European countries.

23. Proposed AF activities related to cancer management would be aimed at supporting a holistic approach in cancer management. Additional treatment and diagnostic equipment purchase would fill hardware gaps while technical assistance in cancer management strategy would improve policy addressing prevention, early detection and diagnostics. As a comprehensive intervention, this would serve as a base for the improvement of cancer management in Serbia which would further support improvement in health care quality.

II. DESCRIPTION OF ADDITIONAL FINANCING

24. The original PDO will remain unchanged and the AF activities are in line with the original development objective. There will be no new type of activities; project design and implementation arrangements will remain the same. The AF is in line with the current Country Partnership Framework (CPF) FY16-20 (Report No. 94687-YF), which pays special attention to improved efficiency, access and quality of cancer treatment, hospital and primary care, as well as efficient purchasing of pharmaceuticals (Table 2).

Table 2. CPF Health Indicators

Outcome	Indicator Name	Baseline	YR1/ FY16	YR2/ FY17	YR3/ FY18	YR4/ FY19	End Target/ FY20	Frequency	Data Source/Methodology	Responsibility for Data Collection
Improved oversight of admission and service use at the secondary (hospital level) health care	Percentage of total acute care hospitalization cases in public hospitals reported accurately based on DRGs	0	20	40	60	80	95	Annual	HIF/IPH	HIF data (calendar year)
Improved transparency and contain costs in procurement of pharmaceuticals	Percent reduction in average unit price relative to baseline for the 50 most frequently dispensed multi-source pharmaceuticals that are procured through centralized framework contracts.	0	20	25	30	30	30	Annual	HIF expenditure data	HIF
Improved access to timely cancer treatment	Number of patients who started radiotherapy treatment at public hospitals within 28 days from the day of medical prescription	3000	3000	3200	3500	4000	4200	Annual	Data from oncology units	IPH
Improved quality of care at the primary health care level	Percentage of registered adult patients in Dom Zdravljas with recorded blood pressure value, Body Mass Index, smoking status and recommended tips for healthy behavior in the preceding 5 years in their medical records	35	35	37	40	45	50	Annual	IPH report on quality indicators	MoH/IPH

25. **Results Framework**. The project Results Framework (RF) is revised to reflect the proposed AF investments and scale-up of some activities, in addition to the 27 months extension of the Closing Date to December 31, 2021 and improve the measurability of specific indicators (Section VIII). Specifically, the following changes are proposed:

New PDO level indicators:

- Percentage of registered insured persons covered by the targeted examination for early detection of a) breast (age 50-69 in the past two years), b) cervical (age 25-64 in the past three years) and c) colorectal (age 50-74 in the past two years) cancers: this indicator is added to improve the monitoring of prevention and early detection of the most common forms of cancer and to assess the impact of the National Cancer Strategy to be developed under the AF; age group are defined according to European guidelines.

Revised PDO level indicator:

- Percentage of patients starting radiotherapy treatment at public hospitals within 28 days between the date of issuance of treatment protocol and the first radiotherapy session for a) breast, b) cervical,

c) prostate, and d) lung cancers (disaggregated by gender): this indicator is revised to measure improvement in waiting time between treatment protocol issuance and first radiotherapy session for the most common forms of cancer;

- Percentage of registered adult patients in Dom Zdravljas (Primary Health Care Centers) with recorded blood pressure, BM, smoking status and recommended tips for healthy behavior in the preceding 12 months in their medical records: this indicator is revised to measure progress in healthy behavior in preceding 12 months instead of five years.

New Intermediate Results Indicators:

- Strengthen systems for Health Technology Assessment;
- Reduction in the total consumption of antibacterials for systemic use (J01) DDD/1000 person/per day: this indicator is added given the Project's contribution in addressing antimicrobial resistance;
- Annual training organized for health Roma mediators: this indicator is added to measure project's support to the Roma population;
- Percentage of patients satisfied with the quality of care in PHC facilities: this indicator is added to reflect citizen engagement efforts.

Revised Intermediate Results Indicators:

- From "Percentage of Dom Zdravljas, hospital outpatient departments and pharmacies implementing e-prescription system" to "Percentage of a) Dom Zdravljas and b) pharmacies implementing e-prescription system": this indicator is revised to reflect the fact that only Dom Zdravljas and pharmacies would be subject to an e-prescription system;
- From "Number of Dom Zdravljas that have completed staff training on priority clinical pathways" to "Number of health care institutions that have completed staff training on priority clinical pathways": this indicator is revised to expand coverage to all health care institutions instead of only primary health care institutions.

Dropped Intermediate Results Indicators:

- Percentage of health institutions implementing e-procurement system for pharmaceuticals: this indicator is dropped due to the MoH newly established Expert Working Group that is still deciding on the manner and pace of development and introduction of e-procurement, which also impact Public Procurement Agency;
- Percentage of pharmaceuticals newly approved for public financing in the preceding 12-month period recommended for inclusion on the basis of a Health Technology Assessment: this indicator is dropped as a new Intermediate Results Indicator has been introduced to better reflect project activities.

26. **Proposed components for the AF**. The following are the scale-up activities to be financed under the proposed AF.

COMPONENT 1: Improvement of Health Financing (Euro 3.0 million)

27. This component will comprise three sub-components.

28. *Sub-component 1.1: Support Hospital Financing Reforms (Euro 0.9 million).* Based on the preparatory work supported by the parent project (including training on proper DRG reporting for healthcare institutions and

HIF staff), a new DRG-based financing model for hospitals is being piloted in 14 hospitals since January 2018. Introduction of DRG-based financing is a long term and comprehensive reform that takes a number of years to be fully implemented. This reform requires close inter-governmental coordination mainly between MoH, Ministry of Public Administration and Local Self Government (MPALSG), and MoF. Accurate DRG reporting readiness is a key precondition for this reform to be successful. The parent project has been instrumental in strengthening and mainstreaming reporting capacity of the MoH. Three initial quality indicators for hospital treatment are being defined and alongside two key performance indicators will serve as a basis for hospital financing. The MoF already allocated funds in the 2018 Budget for the incentive payment.

29. Roll-out of the DRG-based payment to all hospitals in Serbia (total of 71) is planned for 2019. Specific activities envisaged under the AF would include: i) provision of technical support to integrate the hospital level clinical pathways into the E-health System for hospital information systems; ii) definition of admission criteria based on the European version of Appropriateness evaluation protocol and adaptation to national level; iii) introduction of initial hospital matrix for performance monitoring and incentive for hospital physicians and clinical teams, and iv) improvement of regulatory framework to recognize and define performance, expenditures and to account DRG into budgeting. The AF activities (i), (ii) and (iii) will further support the PDO related to health financing as they will help define quality standards for inpatient treatment to mitigate against DRG misinterpretation by health care providers. Activity (iv) of the AF will provide additional support to the MoH to establish the regulatory framework necessary for proper implementation of DRG-based financing.

30. *Sub-component 1.2: Strengthen Primary Health Care Financing (Euro 0.8 million).* The financing model for PHC has improved by the introduction of quality indicators in the formula that was developed with support from the parent project. The new payment system, where a portion of the salaries for PHC teams will be directly linked to performance on 10 quality indicators, will be introduced in 2020. The MoH and the Health Unions have come to an agreement that all further salary increases in the health sector would count towards the variable or performance-based portion of the salary. Further monitoring, evaluation and upgrade of the financing formula is of utmost importance for the success of this reform; and the regulatory framework need updating to recognize and allow for such changes. The AF would support the activities launched under the parent project by strengthening the managerial skills of heads of PHC facilities. This will further support the PDO related to health financing in primary health care as managerial skills will be a major factor for the sustainability of the project results. The AF will also provide technical support integrating the PHC level clinical pathways into the E-health System for PHC information systems.

31. *New proposed sub-component 1.3: Develop a Health Care Network Optimization Plan (Euro 1.3 million).* Due to fragmentation and documented under-utilization of capacities, there is a dire need for a Network Optimization Plan for public health institutions. At minimum, the Plan would define:

- optimal capacity for the network of health institutions to correspond to the needs of population;
- functional and organizational integration of primary care centers and regional hospitals;
- a human resources strategy redefining services and capacities based on needs for PHC and hospitals;
- volume and scope of services, which would provide efficiency, quality and safety of care; and
- the provision of appropriate regulatory framework to allow for such restructuring (drafting health care law and secondary legislation needed for the adoption of government decree which would implement health network optimization plan).

32. The proposed AF will provide technical support to (i) develop a health care network optimization plan for public health institutions; (ii) develop palliative care, outpatient care at hospitals and other interventions that may be necessary towards efficient utilization of existing capacities; and, (iii) carry out advocacy activities. All

activities under this sub-component will support the achievement of the PDO as network optimization will significantly contribute to both efficient health financing and quality of health care.

33. **Subcomponents 1.1. and 1.2. will be affected by the overall reform of public sector salaries system that will come into force in full by January 1, 2020.** The new system of public sector salaries will come into force on January 1, 2019 with provisions related to performance based portion of salary becoming effective on January 1, 2020. This means that the full implementation of DRG and PHC related salary incentive scheme would be possible after January 1, 2020. The Law on public sector employees envisages that all public-sector employees (including in public health care) will be remapped to a new salary matrix in 2018. During 2019, criteria for performance based part of the salary will be developed in readiness to implement the new system in full on January 1, 2020. Specific legal and regulatory actions are under discussions with the MoH, MoF and the Ministry of Public Administration and Local Self Government. Scale-up activities will be defined once actions are agreed between the Bank and Government.

COMPONENT 2: Name of the component is changed from *Efficient Purchasing of Pharmaceuticals and Medical Products* to *Improve Access to Quality Health Care* (Euro 1.5 million)

34. *Sub-component 2.1: Improve Access to Medicines (Euro 0.2 million).* Activities under the original sub-component regarding the establishment of a centralized procurement system for pharmaceuticals are expected to be completed as planned by the end of the original Loan (September 30, 2019) and will therefore not require further support from the AF. However, under the AF, this sub-component would provide technical support to improve the E-health System to support the rational use of antibiotics. These activities would support the PDO related to improvement of efficiency and quality of purchasing of pharmaceuticals and capitalize on the successful implementation of the centralized procurement system for pharmaceuticals.

35. *Sub-component 2.2: Strengthening Health Technology Assessment Capacity (Euro 0.7 million).* Pharmaceutical policies interventions focusing on building the capacity of the HIF Pharmaceutical Department – training for the implementation of pharmacoeconomic analysis and health technology assessment (HTA) is already provided under the original project. The aim is to build capacity to execute proper cost-benefit analysis prior to the introduction of new drugs and/or medical equipment into the system. Institutionalizing HTA (transitioning from ad hoc analysis to a formal process under which decision-making is based on the HTA) is a complex process. Technical assistance and training will be provided to: (i) perform HTA and EBM Situation Analysis; (ii) build and document an international HTA experience; (iii) acquire knowledge and develop expertise for local HTA implementation; (iv) define institutionalization and institutional arrangements for HTA; (v) establish an appropriate HTA process and identify priority areas; (vi) translate research results into recommendations for decision making; (vii) build experience in strategic planning. Planned activities under this sub-component would strengthen capacity for HTA and build upon capacity building activities envisaged by the parent project.

36. *Sub-component 2.3: Improve Medical Equipment Maintenance Systems (Euro 0.6 million).* One of the main goals of the parent project is to develop a strategic and cost-effective approach to maintenance of medical equipment. The total replacement value of the equipment installed in Serbian health care 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 care system.

37. A preliminary assessment of the current distribution of medical equipment, procedures for maintenance and repairs management, costs and allocation of funds for maintenance, and procurement of spare parts and services will be completed under the ongoing project. The proposed AF would support the MoH to: (i) establish an entity for medical technology management; (ii) establish a maintenance system for high cost equipment, including linear accelerators, CTs, MRIs.

38. This component would finance goods, technical assistance, and training.

COMPONENT 3: Strengthen Quality of Service Delivery (Euro 19.0 million)

39. *Sub-component 3.1: Strengthen Quality Improvement Systems. Clinical Pathways (Euro 0.8 million Euro).* It is expected that the 32 clinical pathways currently being piloted in selected health care institutions will be officially adopted and implemented under the parent project. An additional 16 clinical pathways for PHC centers will also be developed and implemented under the parent project. The proposed AF will i) support the integration of primary and secondary health care clinical pathways and improve health care quality and management of waiting times for patients with malignant diseases; ii) update existing, and develop new clinical practice guidelines; iii) carry out training on integrated pathways for healthcare professionals; iv) develop a national registry for monitoring and evaluation non-communicable disease; and v) create a disease management program database for most frequent non-communicable disease. All AF activities under this sub-component will contribute to the PDO primarily through the improvements of health care quality.

40. This sub-component would finance technical assistance, training, and operating costs.

41. *Sub-component 3.2: Improve Cancer Management (Euro 18.2 million).* Proposed activities under the AF are as follows:

42. The Serbian Comprehensive Cancer Management Strategy (Euro 0.5 million) covers prevention, diagnostics and treatment. Although efforts have been made in the past by the MoH with support from the World Bank and the European Commission to address screening and early detection of leading malignant diseases (cervical, colon and breast cancer), no significant progress has been achieved to date. Diagnosed cancer cases are predominantly stages III or IV. A comprehensive approach to cancer control is needed to improve and align cancer prevention and enhance efficiency so as to (a) establish and strengthen early disease detection system; (b) promote use of digital technologies in cancer registration and patient treatment data collection, transfer, treatment decisions, and analytics against an internationally recognized format; (c) institutionalize more vigorous health promotion activities; and (d) put in place appropriate infrastructure and advanced treatment modalities for tertiary level cancer treatment to enhance the effectiveness and efficiency of human and financial resources.

43. Improvement of National Coverage of Radiotherapy Services (Euro 5.5 million). Six linear accelerators (LINAC), varying in technical specifications and requirements, and three CT-simulators have been procured for the four oncology institutions in Serbia (Belgrade, Kragujevac, Nis and Kladovo) under the parent project and full installation should be completed by March 2018. In parallel, the Government of Serbia has purchased four LINACs from the budget aiming to achieve international standards for radiotherapy coverage.

44. About 11,000 people in the northern province of Vojvodina (VOI) are affected by cancer annually, 4,000 of whom need radiation or combined chemotherapy and radiotherapy. On a monthly level, more than 200 patients for whom the oncological committee has indicated radiation therapy are registered in the list of appointments. In September 2017, the waiting list for radiation therapy at the VOI included 368 patients.

Approximately 60 percent of patients from the waiting list are breast cancer patients followed by gynecological and colorectal cancers. To date, VOI has not benefitted from the procurement of equipment for radiotherapy. To achieve full territorial radiotherapy coverage and provide equity, access and standardized quality of cancer treatment across the country, the proposed AF would finance two new LINACS, one CT-simulator and rehabilitation of the two bunkers for VOI. The VOI's Radiotherapy Clinic has qualified staff and is fully equipped for new accelerators. Due to Government's prerogative to secure equity in access and quality of cancer treatment throughout the country, this activity would be subject to retroactive financing in the amount of up to Euro 5.0 million.

45. Interconnectivity of radiotherapy services (Euro 0.5 million). In addition to two new LINACS, the Project would support the establishment of networking capacity among radiotherapy centers. This would facilitate more efficient utilization of equipment and improve quality of service delivery.

46. *Climate Change and Disaster Risk*. Given that this sub-component will support the rehabilitation of two bunkers for the LINACs, climate change and geophysical hazards (such as flood as in 2014) could impact the structural integrity, materials, siting, longevity and overall effectiveness of the investments. However, this risk to project activities is considered low. Nevertheless, the planned works for the two bunkers will incorporate climate and natural disasters resilience considerations (e.g., resilience to floods, extreme temperature increases, etc.).

47. Improvement of Timely Diagnostics in Oncology (Euro 12.2 million). While the original project has supported Serbia in meeting international standards in treatment, the need for diagnostic equipment remains high. Late diagnosis is common and not only adversely affects treatment outcome but also increases the overall cost of health care due to costlier treatment required for advanced stages. Below, data from the Institute for Oncology and Radiology of Serbia shows disease stages in patients with malignant tumors at the time of diagnosis:

Malignant disease stage	(%)
In situ	0.8
Localized disease	41.8
Regional metastases	35.5
Distant metastases	16.7
Undefined	5.2

48. According to current international guidelines in advanced oncology management, digital diagnostic imaging plays a fundamental role in the early detection and quantification of tumors, allowing a precise definition of the most effective treatment strategy to be followed for each specific patient. Ultrasound (US), MRI, and CT are the diagnostic technologies with the highest impact in cancer diagnosis, specifically:

- US can be adequate and definitive for many gynecological and urological tumors;
- CT with contrast should be performed for known or suspected body regions, unless a contraindication or other need is identified;
- CT and MRI of the affected area(s) drives much of initial, re-staging and surveillance.
- MRI is usually considered when CT imaging is inconclusive or when required for specific tumor characteristics.

49. The latest data from the Institute of Public Health show that Serbia is among the countries with the lowest number of CT scanners and MRIs in Europe. Considering the current limited availability of advanced diagnostic

imaging units (CT and MRI) in the country, and the presence of remarkable waiting lists for accessing these examinations, investment in this area is essential to complete the cancer management network.

50. A precise identification of the quantity of units and of the installation sites will be an important task of the network optimization plan, to be done during a first phase of the project implementation. However, considering the current availability of diagnostic machines in public hospitals, the procurement of at least 10 MRI units and 6-8 CT units can be foreseen. Through the optimization of the procurement procedures, the allocated financing for this component could also be sufficient to procure additional US units. This would allow the optimal management of a large component of tumors and complement the screening programs for the early detection of breast cancer.

51. As the precise mapping of MRI, CT, and US units to be procured will take several months, the definition of the technical specifications will be carried out in parallel allowing for a more precise tailoring of the performances of the machines to be procured to the actual requirements of the beneficiary health facilities.

52. The proposed AF would finance procurement of CT scanners and MRIs, but the precise number and distribution of new diagnostic equipment will be subject to a comprehensive needs analysis. Preliminary cost assessment, including a provisory number of ultrasound units (for complementing breast cancer early detection, besides mammography), and extended warranty for 3 years has been shown in the table below:

Table 3. Extended warranty of equipment

Device	unit cost	Q.ty	total cost	extended warranty (1 + 2 years)	Total
MRI	800.000	10	8.000.000	1.120.000	9.120.000
CT	350.000	6	2.100.000	294.000	2.394.000
Ultrasound	40.000	20	800.000	112.000	912.000
				TOTAL (USD):	**12.426.000**

53. Given the critical importance of a proper policy framework to maximize the benefits of new equipment procured through the AF, the following conditions of disbursement against the procurement of diagnostic equipment will be in place. Disbursement will be made if the stated actions are completed in a manner satisfactory to the Bank: (i) adoption of a Revision of the National cancer management program "Serbia against cancer" published in the Official Gazette of the Republic of Serbia number 20/2009; (ii) adoption of a Government Decree on National program for the health care network optimization plan; and (iii) adoption of a Rule book on internal organization of the Ministry of Health that will create a unit in charge for administrative and technical medical equipment maintenance system.

54. This sub-component would finance works, goods, technical assistance, and training.

COMPONENT 4: Monitoring, Evaluation and Project Management (1.5 million Euro)

55. The proposed AF will cover the additional 27 months extension period of day-to-day management, monitoring and evaluation, audits of the project. This component will also provide training for Roma health mediators to support the Roma population. It will finance operating costs, studies, and training. Table 4 below shows current and AF costs by component and sub-component.

Table 4. Cost by Component and Sub-component for the Parent Project and the AF

Original components/ Sub-components	*New proposed components/ subcomponents*	*Current Loan (EUR million)*	*AF (EUR million)*	*Total cost by component/ sub-component (EUR million)*
1. Improvement of Health Financing		6.03	3.00	9.03
Sub-component 1.1. Support Hospital Financing Reforms		3.34	0.90	4.24
Sub-component 1.2. Strengthen Primary Health Care Financing		2.69	0.80	3.49
	New sub-component 1.3. Develop a Health Care Network Optimization Plan (Masterplan)		1.30	1.30
2. Efficient Purchasing of Pharmaceuticals and Medical Products	**Improve Access to Quality Health Care**	4.79	1.50	6.29
Sub-component 2.1. Establish a Centralized Procurement System	Improve Access to Medicines	1.67	0.2	1.87
Sub-component 2.2. Strengthening Health Technology Assessment	Strengthening Health Technology Assessment Capacity	1.67	0.70	2.37
Sub-component 2.3. Improve Medical Equipment Maintenance Systems		1.45	0.60	2.05
3. Strengthening Quality of Service Delivery		15.98	19.00	34.98
Sub-component 3.1. Strengthen Quality Improvement Systems		2.54	0.80	3.34
Sub-component 3.2. Improve Cancer Management		13.44	18.20	31.64
4. Monitoring, Evaluation, and Project Management		2.18	1.50	3.68
Front-End Fees		0.07	0.06	0.07
Total		29.05	25.00	54.05

III. KEY RISKS

56. The overall Project risk is rated Moderate. This rating considers risks to achieving the development results based on analysis of each of the risk categories. The risk assessment for the parent project will remain relevant to cover implementation risks and mitigation measures under the AF. Due to the range and complexity of reforms pursued, the main sources of risk refer to the potential changes in the political and governance environment and the fiduciary areas. Potential changes in ministerial leadership, which is currently supportive of the reform, could slow down the pace of its implementation. This will be mitigated by closely working with relevant technical level staff. Procurement of high cost LINACs poses a substantial fiduciary risk due to the complexity and high value of this type of procurement. This would be mitigated by amendment to the existing contract, which would simplify the procurement and accelerate its pace. Also, current PCU fiduciary capacity has been assessed as adequate. No additional risks are expected from the proposed AF. The Bank task team will continue to monitor potential risks. The risk ratings summary is provided in Table 5.

Table 5. Risk Rating Summary

Risk Category	Rating
Political and Governance	Substantial
Macroeconomic	Moderate
Sector Strategies and Policies	Moderate
Technical Design of Project or Program	Moderate
Institutional Capacity for Implementation and Sustainability	Moderate
Fiduciary	Substantial
Environment and Social	Moderate
Stakeholders	Moderate
Other	--
Overall	Moderate

IV. APPRAISAL SUMMARY

A. Economic and Financial Analysis

57. **The economic analysis of the AF for the SSHP project** (Annex 2) has been conducted to answer the following questions: (i) what is the likely development impact from the AF for project, and (ii) is the financing from the public sector able to sustain the achievements from the proposed investment?

58. **The development impact of the project.** The costs and benefits of the additional financing for the project were estimated over the 2017–2030 period. The Project is expected to save about 25,000 Disability Adjusted Life Years (DALYs) over the projection period. The main direct benefit of the project derives from the economic value of averted DALYs and cost savings generated by primary care, improved cancer care, and hospital financing reforms. Investment in improved cancer care will require additional maintenance and recurrent costs, but the expected benefits in terms of improved health outcomes based on DALYs averted exceed the costs. Moreover, additional investment in improved hospital care and financing, including integration of clinical pathways into hospital information systems and applying admission criteria based on the European version of Appropriateness evaluation protocol, will help contain expenditure growth by saving over $100 million over the 2017–2030

period.

59. **The most conservative scenario,** which assumes a moderate inflation rate and low effectiveness of the interventions relative to international experience, results in a net present value of nearly US$58.6 million and a 40.6 percent Internal Rate of Return (IRR). These analyses were quite sensitive to the value of a DALY and to higher estimates on the effectiveness of the interventions. Increasing the value of a DALY from 1 to 3 times GDP per capita significantly increases the estimated IRR from 40.6 to 184.4 percent. If higher estimates on effectiveness of the interventions are applied the rise in the estimated IRR is very high. In contrast, the IRR was not very sensitive to the deflator (inflation) rate or to the discount rate for DALYs averted. Alternative scenarios and their effect on the Project's economic performance with AF are presented in Annex 2: Economic and Fiscal Analysis.

60. **Rationale for public sector provision/financing.** The AF for the Project provides additional support to capacity building of public sector institutions, and strengthening of public health financing systems. It also supports priority activities that are pure "public goods" and are core responsibilities of Government – including strengthening of health information, monitoring, and regulation. All entities involved in the Project activities are public sector organizations (including public health centers that are only nominally autonomous). This proposed Project does not involve the introduction of new programs that could be alternatively performed by the private sector, but instead strengthens existing Government programs and ongoing reforms to alleviate binding constraints to performance.

B. Technical

61. The AF is designed to meet Serbia's needs in the health sector by strengthening the efficiency and quality of public health system. As with the parent project, AF investments in performance-adjusted capitation reforms will be from tried and tested standards in primary care and DRGs for acute hospital care. The specifications for purchased medical equipment will continue to be based on modern, established and well-proven technology, and reflect experience gained during the implementation of the parent project.

62. The technical approaches included in the parent project were based on the experience of high-performing OECD or upper-middle income countries considering Serbia's aspiration to higher income status. The technical approaches proposed in each component were based on well documented international experience. These include the proposed shift toward performance-adjusted capitation reforms in primary care and DRGs for acute hospital care; adaptation of best international practices to improve central procurement and frame contracts for pharmaceuticals; HTA; strengthening quality through clinical pathways, accreditation, and systems for quality monitoring and management; and best international practices for improving cancer treatment and patient care. The project also focuses on priority areas where Serbia lags behind other countries, including the need to significantly improve screening and treatment for NCDs at primary care level. Multiple interventions and components of the project focus on this objective and will be mutually reinforcing (e.g., strengthened financial incentives through primary care payment system; scaling up clinical pathways; reducing costs for priority NCD medications with high public health impact; and enhanced monitoring of screening coverage, treatment quality, and patient outcomes).

C. Financial Management and Procurement.

63. The AF will have the same Project Coordination Unit (PCU) in charge of fiduciary aspects and will rely on the same arrangements and requirements as the parent project in terms of planning and budgeting, accounting, financial reporting, internal controls, flow of funds and external audit. The legal covenants include quarterly financial reports to be prepared and delivered to the Bank within 45 days after the end of the reporting quarter

and annual financial statements to be audited and delivered six months after the end of the audited period.

64. Procurement under this AF will be subject to the New Procurement Framework. All procurement will be conducted through the procedures as specified in the World Bank's Procurement Regulations for IPF Borrowers - Procurement in Investment Project Financing Goods, Works, Non-Consulting and Consulting Services, July 2016 (Procurement Regulations). The project will also be subject to the World Bank's Anti-Corruption Guidelines, dated July 1, 2016.

65. A Project Procurement Strategy for Development (PPSD) was prepared during appraisal, and includes a Procurement Plan covering the first 12 months of project implementation. A revised Project operation and Grants Manual (POGM) will be adopted by the MoH as a condition of effectiveness.

D. Social (including Safeguards)

66. **Citizen Engagement (CE).** The project aims to build on the existing efforts of the MoH to strengthen understanding and fulfillment of patient rights, which are defined by law and regulated. Three laws regulate the rights of citizens to health care in Serbia: Patient Rights Law, Health Insurance Law, and Health Care Law. In accordance with Articles 38, 39 and 42 of the Patient Rights Law, local governments ensure the protection of patients' rights by appointing patients' rights advisors and setting up a Health Council. The patients' rights advisor performs acts on the submitted complaints and provides information and advice with regards to patients' rights. The Health Council comprises representatives of the local government, patient civic associations, local health care institutions and the competent branch of the National Health Insurance Fund. Article 221 of the Health Insurance Law ensures the protection of the rights of insured persons. This is further regulated by the Regulation on the Method and the Procedure for Protection of the Rights of the Persons Insured by the National Health Insurance Fund and is implemented by the health insurance organization with which the person is insured. The name of the insured persons' advocate, their working hours and contact phone number are to be displayed in a prominent place in every health care institution. The insured persons' advocates submit their reports in accordance with this Regulation. The Health Care Law regulates the rights of citizens not insured.

67. To support citizen engagement, an intermediate indicator is added to measure the percentage of patients satisfied with the quality of care in PHC facilities. The IPH is conducting an annual survey which tracks patient satisfaction in PHC facilities. The Project will work with the MoH and the IPH to further strengthen the process of collecting this data and further support citizen engagement.

E. Environment (including Safeguards)

68. The Environmental category of the project will remain B. The environmental safeguards and civil engineering procedures of the parent project will continue to be followed under the AF. The Borrower updated the Environmental Management Framework (EMF) prepared for the parent project to include activities that will be financed under AF, and publicly re-disclosed it in January 2018. Draft EMF was published on January 24 on the MoH web site and in the newspaper "Politika" on January 25, 2018. It was discussed at the stakeholders' meeting on January 30, 2018 when the public consultation was concluded. The Final EMF was disclosed at the MoH website on January 31, 2018 and in the World Bank's Image Bank website on February 1, 2018.

69. Implementation of the project-funded activities is not expected to have any significant negative impact on the environment. Most of the activities will be environmentally-neutral. However, Project Component 3.2 will include civil works and installation of linear accelerators for radiation treatment as well as decommissioning of the old radiation equipment. The environmental risk associated to this activity includes noise, dust, vibrations and management of construction waste during civil works. All the above can be successfully managed by

application of good engineering/construction practice. Specific care will be taken in the management of construction sites (as hospitals will continue to operate during execution of the civil works) and general health and safety issues. Decommissioning and transport of old radiation equipment will be made in full compliance with the national laws and undertaken by fully licensed contractors. Final disposal of the equipment will be made in Vinca Institute for Nuclear Science, which is a licensed and authorized national institution for management and storage of radiation equipment and fuel.

70. Operational Policy on Physical Cultural Resources (OP/BP 4.11) is precautionary triggered. After selection of facilities for installation of medical equipment for radiation treatment it will be determined whether any of the buildings chosen for rehabilitation are designated cultural property. As provided for in the EMF, in these cases the site-specific EMPs will include clauses related to heritage protection and conservation.

F. Other Safeguard Policies (if applicable)

71. Not applicable.

V. WORLD BANK GRIEVANCE REDRESS

72. Communities and individuals who believe that they are adversely affected by a World Bank (WB) supported project may submit complaints to existing project-level grievance redress mechanisms or the WB's Grievance Redress Service (GRS). The GRS ensures that complaints received are promptly reviewed in order to address project-related concerns. Project affected communities and individuals may submit their complaint to the WB's independent Inspection Panel which determines whether harm occurred, or could occur, as a result of WB non-compliance with its policies and procedures. Complaints may be submitted at any time after concerns have been brought directly to the World Bank's attention, and Bank Management has been given an opportunity to respond. For information on how to submit complaints to the World Bank's corporate Grievance Redress Service (GRS), please visit *http://www.worldbank.org/en/projects-operations/products-and-services/grievance-redress-service*. For information on how to submit complaints to the World Bank Inspection Panel, please visit *www.inspectionpanel.org*

VI. SUMMARY TABLE OF CHANGES

	Changed	Not Changed
Change in Results Framework	✓	
Change in Components and Cost	✓	
Change in Loan Closing Date(s)	✓	
Change in Safeguard Policies Triggered	✓	
Change in Implementing Agency		✓
Change in Project's Development Objectives		✓
Cancellations Proposed		✓

Reallocation between Disbursement Categories		✓
Change in Disbursements Arrangements		✓
Change of EA category		✓
Change in Legal Covenants		✓
Change in Institutional Arrangements		✓
Change in Financial Management		✓
Change in Procurement		✓
Change in Implementation Schedule		✓
Other Change(s)		✓

VII. DETAILED CHANGE(S)

RESULTS FRAMEWORK

Project Development Objective Indicators

Percentage of total acute care hospitalization cases in public hospitals reported accurately based on DRGs
Unit of Measure: Percentage
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	0.00	70.00	95.00	Revised
Date	16-Oct-2013	10-Jan-2018	31-Dec-2021	

Percent reduction in average unit price relative to baseline for the 50 most frequently dispensed multi-source pharmaceuticals that are procured through centralized framework contracts
Unit of Measure: Percentage
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	0.00	27.00	27.00	Revised
Date	16-Oct-2013	10-Jan-2018	31-Dec-2021	

Percentage of patients starting radiotherapy treatment at public hospitals within 28 days between the date of issuance of treatment protocol and the first radiotherapy session for a) breast, b) cervic
Unit of Measure: Text

Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	No monitoring system in place to report on the indicator	No monitoring system in place	Monitoring system in place to measure the indicator, baseline and target values defined	Revised
Date	16-Oct-2013	10-Jan-2018	31-Dec-2021	

Percentage of registered adult patients in Dom Zdravljas with recorded blood pressure value, BMI, smoking status and recommended tips for healthy behavior in the preceding 12 months in their med recor
Unit of Measure: Percentage
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	35.00	32.00	45.00	Revised
Date	16-Oct-2013	10-Jan-2018	31-Dec-2021	

Percentage of registered insured persons covered by the targeted examination for early detection of a) breast (age 50-69 in the past two years), b) cervical (age 25-64 in the past three years) and c)
Unit of Measure: Text
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	a) 6%; b) 27%; c) 10%	a) 6%; b) 27%; c) 10%	a) 25%; b) 35%; c) 35%	New
Date	30-Nov-2017	10-Jan-2018	31-Dec-2021	

Intermediate Indicators

Percentage of pilot Dom Zdravljas who meet grant agreement performance criteria in the preceding one year
Unit of Measure: Percentage
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	0.00	0.00	30.00	Revised
Date	16-Oct-2013	10-Jan-2018	31-Dec-2021	

DRGs payment system developed and financing for a portion of acute hospital care based on DRGs initiated
Unit of Measure: Yes/No
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	No	No	Yes	Revised
Date	16-Oct-2013	10-Jan-2018	31-Dec-2021	

Number of pharmaceuticals and health products that are procured through centralized framework contracts
Unit of Measure: Number
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	0.00	1,421.00	700.00	Revised
Date	16-Oct-2013	10-Jan-2018	31-Dec-2021	

Percentage of a) Dom Zdravljas and b) pharmacies implementing e-prescription system
Unit of Measure: Text
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	DZs - 0 Pharm - 0	DZs - 10% Pharm - 27%	DZs - 90% Pharm - 90%	Revised
Date	16-Oct-2013	10-Jan-2018	31-Dec-2021	

Percentage of health institutions implementing e-procurement system for pharmaceuticals
Unit of Measure: Percentage
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	0.00	0.00	85.00	Marked for Deletion
Date	16-Oct-2013	14-Feb-2017	30-Sep-2019	

Strengthen systems for medical equipment maintenance
Unit of Measure: Text
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	No national systems or policies in place, Medical equipment database in the IPH	A medical equipment registry set up within IHIS	Budget allocated to expand maintenance system. National system(s) in use	Revised
Date	16-Jan-2014	10-Jan-2018	31-Dec-2021	

Percentage of pharmaceuticals newly approved for public financing in the preceding 12-month period recommended for inclusion on the basis of a Health Technology Assessment
Unit of Measure: Percentage
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	0.00	0.00	50.00	Marked for Deletion
Date	16-Oct-2013	14-Feb-2017	30-Sep-2019	

Number of clinical pathways developed
Unit of Measure: Number
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	14.00	32.00	48.00	Revised
Date	16-Oct-2013	10-Jan-2018	31-Dec-2021	

Number of health care institutions that have completed staff training on priority clinical pathways
Unit of Measure: Number
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	50.00	50.00	160.00	Revised
Date	16-Oct-2013	10-Jan-2018	31-Dec-2021	

Percentage of adult diabetic patients in Dom Zdravljas with at least one determined value of glycosylated hemoglobin (HbA1c) in the last year
Unit of Measure: Percentage
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	45.00	42.00	50.00	Revised
Date	16-Oct-2013	10-Jan-2018	31-Dec-2021	

Ranking of health institutions according to quality criteria in place based on quality indicators in health care
Unit of Measure: Text
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	Existing quality indicators	Existing quality indicators	Ranking of health institutions according to	Revised

			quality criteria based on data from previous year/Yes	
Date	16-Jan-2014	10-Jan-2018	31-Dec-2021	

Percentage of registered adult patients in DZs with hypertension under treatment whom in the last recorded blood pressure (measured in the preceding one year) is ≤ 140/90 mm Hg
Unit of Measure: Percentage
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	45.00	51.00	70.00	Revised
Date	16-Jan-2014	10-Jan-2018	31-Dec-2021	

Number of health workers receiving training
Unit of Measure: Number
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	500.00	5,459.00	13,000.00	Revised
Date	16-Jan-2014	10-Jan-2018	31-Dec-2021	

Number of new linear accelerators installed at national level
Unit of Measure: Number
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	0.00	1.00	8.00	Revised
Date	16-Oct-2013	10-Jan-2018	31-Dec-2021	

Strengthen systems for Health Technology Assessment
Unit of Measure: Text
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	Limited institutional efficiency related to the decision making process in the area of drug reimbursement	Weak, ineffective institutional capacities related to the decision making process in the area of drug reimbursement	The linkage between national clinical practice guidelines and basic benefit package well established and functional. The new, robust and transparent,	New

			system of evidence based supported decision making process fully established and functional	
Date	30-Nov-2017	10-Jan-2018	31-Dec-2021	

Reduction in the total consumption of antibiotics for systemic use (J01) DDD/1000 person/per day
Unit of Measure: Percentage
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	0.00	18.00	22.00	New
Date	30-Nov-2017	10-Jan-2018	31-Dec-2021	

Annual training organized for health Roma mediators
Unit of Measure: Number
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	0.00	0.00	4.00	New
Date	30-Nov-2017	10-Jan-2018	31-Dec-2021	

Percentage of patients satisfied with the quality of care in PHC facilities
Unit of Measure: Percentage
Indicator Type: Custom

	Baseline	Actual (Current)	End Target	Action
Value	78.00	78.00	80.00	New
Date	30-Nov-2017	10-Jan-2018	31-Dec-2021	

COMPONENTS

Current Component Name	Current Cost (US$, millions)	Action	Proposed Component Name	Proposed Cost (US$, millions)
Strengthening Health Financing	7.60	Revised	Improvement of Health Financing	11.20
Efficient Purchasing of Pharmaceuticals and Medical Products	7.00	Revised	Improve Access to Quality Health Care	8.90

Strengthening Quality of Service Delivery	22.40	Revised	Strengthening Quality of Service Delivery	46.00
Monitoring and Evaluation and Project Management	3.00	Revised	Monitoring and Evaluation and Project Management	4.90
TOTAL	**40.00**			**71.00**

LOAN CLOSING DATE(S)

Ln/Cr/Tf	Status	Original Closing	Current Closing(s)	Proposed Closing	Proposed Deadline for Withdrawal Applications
IBRD-83380	Effective	30-Sep-2019	30-Sep-2019	31-Dec-2021	30-Apr-2022

Expected Disbursements (in US$, millions)

Fiscal Year	2014	2015	2016	2017	2018	2019	2020	2021	2022
Annual	0.16	1.89	3.12	4.25	5.42	4.89	4.59	4.36	2.42
Cumulative	0.16	2.05	5.17	9.42	14.84	19.73	24.32	28.68	31.10

SYSTEMATIC OPERATIONS RISK-RATING TOOL (SORT)

Risk Category	Latest ISR Rating	Current Rating
Political and Governance	Moderate	Substantial
Macroeconomic	Moderate	Moderate
Sector Strategies and Policies	Moderate	Moderate
Technical Design of Project or Program	Moderate	Moderate
Institutional Capacity for Implementation and Sustainability	Substantial	Moderate
Fiduciary	Moderate	Substantial
Environment and Social	Moderate	Moderate
Stakeholders	Moderate	Moderate
Other	Moderate	Moderate
Overall	Moderate	Moderate

COMPLIANCE

Change in Safeguard Policies Triggered

Yes

Safeguard Policies Triggered	Current	Proposed
Environmental Assessment OP/BP 4.01	Yes	Yes
Natural Habitats OP/BP 4.04	No	No
Forests OP/BP 4.36	No	No
Pest Management OP 4.09	No	No
Physical Cultural Resources OP/BP 4.11	No	Yes
Indigenous Peoples OP/BP 4.10	No	No
Involuntary Resettlement OP/BP 4.12	No	No
Safety of Dams OP/BP 4.37	No	No
Projects on International Waterways OP/BP 7.50	No	No
Projects in Disputed Areas OP/BP 7.60	No	No

LEGAL COVENANTS – Additional Financing for Second Serbia Health Project (P166025)

Sections and Description
No information available

VIII. RESULTS FRAMEWORK AND MONITORING

Results Framework
COUNTRY : Serbia
Additional Financing for Second Serbia Health Project (P166025)

Project Development Objectives

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

Project Development Objective Indicators

Action	Indicator Name	Core	Unit of Measure	Baseline	End Target	Frequency	Data Source / Methodology	Responsibility for Data Collection
Revised	Name: Percentage of total acute care hospitalization cases in public hospitals reported accurately based on DRGs		Percentage	0.00	95.00	Annual	HIF/IPH	HIF (data calendar year)
Description: Numerator: Number of acute care hospitalization cases in public hospitals reported accurately based on nomenclature of services performed in secondary and tertiary health care Australian Classification of Health Interventions (ACHI) and International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10). Reporting for DRG requires reporting according to the ICD 10 which is than used as a basis for the coding of procedures based on ACHI which is than classified into relevant DRG by the software for grouping. Therefore, accurate reporting on ACHI and ICD-10 is								

a precondition for proper DRG application.

Denominator: Total number of acute care hospitalization cases in public hospitals

Revised	**Name:** Percent reduction in average unit price relative to baseline for the 50 most frequently dispensed multi-source pharmaceuticals that are procured through centralized framework contracts		Percentage	0.00	27.00	Annual	HIF Expenditure data	HIF
Description: Unit price t – unit pricet+1 /Unit price t Baseline is 2013 HIF Price List. Out of 166 drugs (as international nonproprietary names) chosen for pilot 2014 tender, 50 drugs will be defined and the percent reduction in their unit price will be measured during project.								
Revised	**Name:** Percentage of patients starting radiotherapy treatment at public hospitals within 28 days between the date of issuance of		Text	No monitoring system in place to report on the indicator	Monitoring system in place to measure the indicator, baseline and target values	IPH	Data from oncology units	Annual

	treatment protocol and the first radiotherapy session for a) breast, b) cervic				defined			
Description: Percentage of patients starting radiotherapy treatment at public hospitals within 28 days between the date of issuance of treatment protocol and the first radiotherapy session for a) breast, b) cervical, c) prostate, and d) lung cancers (disaggregated by gender). Percentage of patients at public hospitals diagnosed with selected cancers in Serbia who receive radiotherapy as part of their standard treatment regimen within 28 days between the date of issuance of treatment protocol and the first radiotherapy session.								
Revised	**Name:** Percentage of registered adult patients in Dom Zdravljas with recorded blood pressure value, BMI, smoking status and recommended tips for healthy behavior in the preceding 12 months in their med recor		Percentage	35.00	45.00	Annual	IPH report on quality indicators	MoH/IPH
Description: Numerator: Number of registered adult (18 years and over) patients in DZs with recorded Blood Pressure value, Body Mass Index, smoking status and recommended tips for healthy behavior in the preceding 12 months [all must be recorded to be included in the numerator] Denominator: Number of registered adult (18 years and over) patients in DZs.								

New	**Name:** Percentage of registered insured persons covered by the targeted examination for early detection of a) breast (age 50-69 in the past two years), b) cervical (age 25-64 in the past three years) and c)		Text	a) 6%; b) 27%; c) 10%	a) 25%; b) 35%; c) 35%	Annually	IPH	IPH/MoH
Description: Percentage of registered insured persons covered by the targeted examination for early detection of a) breast (age 50-69 in the past two years), b) cervical (age 25-64 in the past three years) and c) colorectal (age 50-74 in the past two years) cancers. According to European guidelines								

Intermediate Results Indicators

Action	Indicator Name	Core	Unit of Measure	Baseline	End Target	Frequency	Data Source / Methodology	Responsibility for Data Collection
Revised	**Name:** Percentage of pilot Dom Zdravljas who meet grant agreement performance criteria		Percentage	0.00	30.00	Annually	HIF Records/IPH data on quality indicators	HF/PCU

	in the preceding one year							
Description: Numerator: Number of pilot DZs who satisfied (verified) quality performance thresholds specified in grant agreements in the preceding one year. Denominator: Total number of DZs who signed quality improvement grant agreements in the preceding one year.								
Revised	**Name:** DRGs payment system developed and financing for a portion of acute hospital care based on DRGs initiated		Yes/No	No	Yes	N/A	HIF data and informant interview	PIU/HIF
Description: Yes/ No								
Revised	**Name:** Number of pharmaceuticals and health products that are procured through centralized framework contracts		Number	0.00	700.00	Annually	HIF data	HIF
Description: Number of pharmaceuticals and health products that are procured through centralized framework contracts. The values for 2016 and 2017 also include brand-named drugs for the reason that the central public procurement for public pharmacies is announced per brand-name (one INN can be found under various BRAND names in the market, manufactured by various manufacturers). Considering that potential changes in the central public procurement procedure are expected, the planned values for the following years are based on the total number of INNs available in our market, and currently this number stands at approximately 700.								
Revised	**Name:** Percentage of a) Dom Zdravljas and b) pharmacies implementing e-		Text	DZs - 0 Pharm - 0	DZs - 90% Pharm - 90%	Annually	HIF data from cental e-prescription component	HIF

	prescription system							
Description: Percentage Numerator: Number of Dom Zdravljas, hospital outpatient departments and pharmacies implementing e-prescription system inthe preceding one year Denominator: Number of Dom Zdravljas, hospital outpatient departments and pharmacies planned to implement thee-prescription system in the preceding one year Implementation of e-prescription defined as having operational online system for tracking prescription or dispensing of drugs.								
Revised	**Name:** Strengthen systems for medical equipment maintenance		Text	No national systems or policies in place, Medical equipment database in the IPH	Budget allocated to expand maintenance system. National system(s) in use	Annually	Operational data from MoH/IPH	MoH/IPH
Description: The following yearly benchmarks should be satisfied: (i) Assessment of medical equipment status completed; key performance indicators (KPIs) identified; (ii) Multi-vendor maintenance contract piloted; (iii) Governmental unit established for oversight of medical equipment maintenance system, and Master Plan for medical equipment management issud by MOH								
Revised	**Name:** Number of clinical pathways developed		Number	14.00	48.00	Annually	MoH/IPH	MoH/IPH
Description: Cumulative number of clinical pathways developed for use in primary care and hospitals.								
Revised	**Name:** Number of health care institutions that have completed staff training on priority clinical pathways		Number	50.00	160.00	Annually	MoH/IPH	MoH

Description: Number of health care institutions that have completed staff training on priority clinical pathways. Priority clinical pathways will cover prioritized diseases and risk factors including: cardiovascular disease; hypertension; smoking cessation; diabetes mellitus, and cancer screening at primary care level. In accordance with the Health Institutions Network, Serbia has a total of 355 public health care institutions, and the target is over 50% trained.								
Revised	**Name:** Percentage of adult diabetic patients in Dom Zdravljas with at least one determined value of glycosylated hemoglobin (HbA1c) in the last year		Percentage	45.00	50.00	Annually	IPH report on quality indicators	MoH/IPH
Description: Numerator: Number of registered adult (18 years and over) patients in DZs with a registered diagnosis of diabetes mellitus (type I or type II) with at least one determined value of glycosylated hemoglobin (HbA1c) in the last year Denominator: Number of registeredadult (18 years and over) patients in DZs with a registered diagnosis of diabetes mellitus (type I or type II).								
Revised	**Name:** Ranking of health institutions according to quality criteria in place based on quality indicators in health care		Text	Existing quality indicators	Ranking of health institutions according to quality criteria based on data from previous year/Yes	Annually	MoH/IPH	MoH
Description: Yes/No The following benchmarks will be used to monitor implementation: (i) improvement on quality indicators adopted; (ii) guidelines for quality indicators								

developed; (iii) Web database developed; (iv) quality indicators data collected annually; (v) ranking of health institutions according to quality criteria performed								
Revised	**Name:** Percentage of registered adult patients in DZs with hypertension under treatment whom in the last recorded blood pressure (measured in the preceding one year) is ≤ 140/90 mm Hg		Percentage	45.00	70.00	Annually	IPH report on quality indicators	MoH/IPH
Description: Percentage Numerator: Number of registered adult patients in DZs with hypertension under treatment whom in the last year recorded blood pressure (measured in the previous year) is < or equal to 140/90 mm Hg Denominator: Number of registered adult (18 years old and over) patients in DZs with hypertension under treatment								
Revised	**Name:** Number of health workers receiving training		Number	500.00	13,000.00	Annually	MoH	MoH
Description: This indicator measures the cumulative number of health personnel receiving training through a Bank-financed project.								
Revised	**Name:** Number of new linear accelerators installed at national level		Number	0.00	8.00	Annually	MoH	MoH
Description: Cumulative number of new linear accelerators successfully installed and operational across key institutes in Serbia								
New	**Name:** Strengthen systems for Health		Text	Limited institution	The linkage	Annually	MoH/IPH	MoH/IPH

	Technology Assessment			al efficiency related to the decision making process in the area of drug reimburse ment	between national clinical practice guidelines and basic benefit package well establishe d and functional. The new, robust and transparen t, system of evidence based supported decision making process fully establishe d and functional			
Description: Strengthen systems for Health Technology Assessment (HTA)								
New	**Name:** Reduction in the total		Percentage	0.00	22.00	Annually	HIF	HIF/PIU

	consumption of antibiotics for systemic use (J01) DDD/1000 person/per day							
Description: In accordance with the Law on Medicines and Medical Devices, the Medicines and Medical Devices Agency of Serbia collects and processes data on the trade and consumption of medicines in one calendar year, on the basis of data collected for wholesalers and marketing authorization holder. These are official data verified by the WHO. The value taken as a baseline value in 2015, when activities regarding the control of antimicrobial resistance were initiated. The total consumption of antibacterial medicines for systemic use (J01) expressed as DDD/1,000 inhabitants/per day was amounting to 36.6 in 2015.								
New	**Name:** Annual training organized for health Roma mediators		Number	0.00	4.00	Annually	IPH	IPH/PIU
Description: Roma health mediators are women of ethnic Roma origin (fluent in Romani language) who have at a minimum a primary school diploma and are hired by primary health care centers. Their primary task is to work in home nursing and care services to strengthen the linkage between the Roma community and health care facilities; to educate the Roma population in the area of health care to improve health status and accessibility of the health system to these vulnerable groups. There are currently 85 mediators working in 60 municipalities (out of 167) in Serbia. This indicator aim at supporting Roma population by having mediators being trained for outreach								
New	**Name:** Percentage of patients satisfied with the quality of care in PHC facilities		Percentage	78.00	80.00	Annually	MoH	MoH
Description: This indicator reflects the citizens engagement efforts								

Target Values

Project Development Objective Indicators

Action	Indicator Name	Baseline	YR1	YR2	YR3	YR4	YR5	YR6	YR7	YR8	YR9	End Target
Revised	Percentage of total acute care hospitalization cases in public hospitals reported accurately based on DRGs	0.00	0.00	0.00	50.00	70.00	75.00	80.00	95.00	95.00	95.00	95.00
Revised	Percent reduction in average unit price relative to baseline for the 50 most frequently dispensed multi-source pharmaceuticals that are procured through centralized framework contracts	0.00	0.00	0.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00
Revised	Percentage of patients starting radiotherapy	No monitoring							Monitoring system in	Monitoring system in	Monitoring system	Monitoring system

	treatment at public hospitals within 28 days between the date of issuance of treatment protocol and the first radiotherapy session for a) breast, b) cervic	system in place to report on the indicator							place to measure the indicator	place to measure the indicator, baseline and target values defined	in place to measure the indicator, baseline and target values defined	in place to measure the indicator, baseline and target values defined
Revised	Percentage of registered adult patients in Dom Zdravljas with recorded blood pressure value, BMI, smoking status and recommended tips for healthy behavior in the preceding 12 months in their med recor	35.00	35.00	35.00	35.00	32.00	33.00	36.00	40.00	45.00	45.00	45.00
New	Percentage of registered insured persons covered by the targeted examination for early detection of a)	a) 6%; b) 27%; c) 10%				a) 6%;b) 27%;c) 10%	a) 10%;b) 27%;c) 15%	a) 15%;b) 28%; c) 25%	a) 20%;b) 30%;c) 30%	a) 25%;b) 35%;c) 35%	a) 25%; b) 35%; c) 35%	a) 25%; b) 35%; c) 35%

	breast (age 50-69 in the past two years), b) cervical (age 25-64 in the past three years) and c)											

Intermediate Results Indicators

Action	Indicator Name	Baseline	YR1	YR2	YR3	YR4	YR5	YR6	YR7	YR8	YR9	End Target
Revised	Percentage of pilot Dom Zdravljas who meet grant agreement performance criteria in the preceding one year	0.00	0.00	0.00	0.00	0.00	5.00	15.00	25.00	30.00	30.00	30.00
Revised	DRGs payment system developed and financing for a portion of acute hospital care based on DRGs initiated	No	N	N	N	N	N	N	Y	Y	Y	Y
Revised	Number of pharmaceuticals and health products that are procured through centralized framework	0.00	0.00	0.00	1,200.00	1,421.00	700.00	700.00	700.00	700.00	700.00	700.00

	contracts											
Revised	Percentage of a) Dom Zdravljas and b) pharmacies implementing e-prescription system	DZs - 0 Pharm - 0	DZs - 0% Pharm - 0%	DZs - 0% Pharm - 0%	DZs - 0% Pharm - 0%	DZs - 10% Pharm - 27%	DZs - 70% Pharm - 70%	DZs - 80% Pharm - 80%	DZs - 85% Pharm - 85%	DZs - 90% Pharm - 90%	DZs - 90% Pharm - 90%	DZs - 90% Pharm - 90%
Revised	Strengthen systems for medical equipment maintenance	No national systems or policies in place, Medical equipment database in the IPH	No national systems or policies in place. Medical equipment database in the IPH	No national systems or policies in place. Medical equipment database in the IPH	Assessment of laboratory equipment, MRI and CT status completed	A medical equipment registry set up within IHIS	Medical equipment database in the relevant institution. Multi-vendor maintenance contract piloted.	Multi-vendor maintenance contract evaluated. Entity established for oversight of medical equipment maintenance	Applicable regulatory document related to medical equipment maintenance system drafted	Budget allocated to expand maintenance system. National system(s) in use.	Budget allocated to expand maintenance system. National system(s) in use.	Budget allocated to expand maintenance system. National system(s) in use
Revised	Number of clinical pathways developed	14.00	14.00	14.00	18.00	32.00	34.00	36.00	40.00	48.00	48.00	48.00
Revised	Number of health care institutions that have completed staff	50.00	50.00	50.00	60.00	64.00	70.00	100.00	120.00	160.00	160.00	160.00

	training on priority clinical pathways											
Revised	Percentage of adult diabetic patients in Dom Zdravljas with at least one determined value of glycosylated hemoglobin (HbA1c) in the last year	45.00	45.00	45.00	42.00	42.00	43.00	44.00	45.00	50.00	50.00	50.00
Revised	Ranking of health institutions according to quality criteria in place based on quality indicators in health care	Existing quality indicators	Existing quality indicators/No	Existing quality indicators/No	Existing quality indicators/No	Existing quality indicators/No	Improved quality indicators/No	Guidelines for quality indicators and Web database developed/No	Quality indicators data collection/No	Ranking of Health Institutions according to Quality criteria, based on data from previous year/Yes	Ranking of Health Institutions according to Quality criteria, based on data from previous year/Yes	Ranking of health institutions according to quality criteria based on data from previous year/Yes
Revised	Percentage of registered adult patients in DZs with hypertension under treatment whom in the last recorded	45.00	45.00	45.00	45.00	51.00	55.00	60.00	65.00	70.00	70.00	70.00

	blood pressure (measured in the preceding one year) is ≤ 140/90 mm Hg											
Revised	Number of health workers receiving training	500.00	500.00	500.00	1,000.00	5,459.00	8,000.00	10,000.00	11,000.00	13,000.00	13,000.00	13,000.00
Revised	Number of new linear accelerators installed at national level	0.00	0.00	0.00	0.00	1.00	6.00	6.00	8.00	8.00	8.00	8.00
New	Strengthen systems for Health Technology Assessment	Limited institutional efficiency related to the decision making process in the area of drug reimbursement					Situation analysis completed. Roadmap document with detailed plan of activities for HTA system establishment drafted and adopted by the Ministry	Stakeholders groups as defined in the Roadmap and trained according to their roles. Implementation of activities in accordance with	HTA staff trained for the implementation of cost effectiveness analysis	The linkage between national clinical practice guidelines and basic benefit package well established and functional. The new, robust and	The linkage between national clinical practice guidelines and basic benefit package well established and functional. The new, robust and	The linkage between national clinical practice guidelines and basic benefit package well established and functional. The new, robust and

							of Health	implementation schedule defined in the Roadmap		transparent, system of evidence based supported decision making process fully established and functional	transparent, system of evidence based supported decision making process fully established and functional	transparent, system of evidence based supported decision making process fully established and functional
New	Reduction in the total consumption of antibiotics for systemic use (J01) DDD/1000 person/per day	0.00				18.00	19.00	20.00	21.00	22.00	22.00	22.00
New	Annual training organized for health Roma mediators	0.00				0.00	1.00	2.00	3.00	4.00	4.00	4.00
New	Percentage of patients satisfied with the quality of care in PHC facilities	78.00	0.00	0.00	0.00	78.00	78.50	79.00	79.50	80.00	80.00	80.00

Annex 1. Roma Health Mediators Program

1. The "Health Mediators Program", financed from permanent budget line of Ministry of Health, aims to improve health of the Roma population, especially women and children, to improve access to health care and to reduce inequalities. Main activities of the program are aimed towards increasing number of insured persons, vaccinated children, systemic check-ups; increasing number of people using services of counselling centres and preventive health centres; increasing number of Roma people registered with chosen primary care physicians and with adopted healthy lifestyles; increased knowledge of disease prevention; increased knowledge on family planning, nutrition and food storage, personal and general hygiene, increased knowledge on importance of waste disposal, and improved knowledge on abuse/neglect of women and children, on human trafficking, rights regarding health care and health insurance.

2. Total of 75 health mediators have been hired to work in 60 municipalities in Serbia.

3. From 2009-2011, under the DILS project (Delivery of Improved Local Services), supported by the World Bank Loan, 15 Roma mediators were financed to perform field work (education and supply of computers), in addition to 60 mediators financed by the OSCE. Besides that, education of all 75 Roma mediators was conducted under the project, in parallel to education of health care professionals in 42 primary health centres included in project and primary health centres willing to achieve additional knowledge towards improving everyday work with this vulnerable population.

4. From 2011-2014. DILS project provided additional financial support to 42 primary health care centers included in project for conducting project on local level, in cooperation with respective local self-governments. During the project life additional 28 PHC were included in this program and granted additional funds.

5. The Ministry of Health was actively involved in IPA Project “Democratization-Inclusion of Roma People”, with the following activities: forming of mobile teams for the inclusion of Roma people, which have been formed in 20 local self-governments in Serbia; inclusion of health mediators in health system, through education and obtaining health knowledge; through changes of by-laws and improvement of software to follow up on vulnerable groups.

6. In the Instrument for Pre-Accession of the European Union’s IPA 2012, a project envisaged strengthening the role of Roma health mediators, their further training with an idea to expand their engagement in this kind of commitment. Furthermore, the initiative envisaged that Roma Mediators become officially recognized and participate in the establishment of nomenclature of occupations, which would lead to staffing for Roma health mediators. This would allow their admission to permanent employment in public health institutions.

7. The Ministry of Health has issued a public call in September 2017 for submitting a proposal for the project: “Improving access to health care for the Roma population “in order to improve health of Roma, on which the interested associations could compete. The project has included Improving access to health care for the Roma population, prevention and education of health mediators. It is financed from the budget of Ministry of Health.

8. In September 2017, the Ministry of Health announced a public call for hiring for the purpose of expanding the verification of the activities for the project: “Improving access to health care for the Roma population “- for the obligation to set up for 10 new mediators.

9. From the beginning of the program until now, the following has been achieved:

- 37,502 first visits to families have been made by mediators;
- 140.408 citizens were registered with the health system for the first time: 46,453 women, 43,201 men and 50,754 children;
- Total of 221,166 visits were performed for members of Roma families who needed help in obtaining personal documents, achieving health insurance, including in the health system (examination of women by gynecologist, choice of doctors, vaccination of children and choice of pediatrician), enrollment of children to school, provision of various types of help (material assistance, assistance from the Red Cross, child allowance, scholarships, etc.);
- 170,278 visits were performed to Roma families and/or family members for the purpose of implementing health education through the planned conversation;
- 55,200 pieces of healthcare related materials (flyers, brochures, calendars of vaccinations and apparent means, handkerchiefs, condoms, toothpastes and brushes, etc.) were distributed;
- 31,808 adults underwent educational work through small group work, were given lectures and provided with posters, including: lectures for 6,265, workshops for 25,313, posters for 230;
- 460,125 visits were made to Roma families and family members to provide health education through a planned interview, lecture, and workshops;
- 16,330 citizens were provided with personal documents and health certificates;
- 28,003 selected a doctor;
- 30,018 children were vaccinated;
- 2,719 adults were vaccinated (Te-Al);
- 4,500 pregnant women controlled their health through and after maternity;
- General check-up was performed for 12,617 women;
- 11,177 women selected their gynecologist;
- 1,144 mammograms were made; and
- General check-up was conducted for enrollment in school and 7,710 children were enrolled.

Annex 2. Economic and Fiscal Analysis

1. The economic and fiscal analyses carried out during the preparation of the Project covered: (i) the estimation of the Project's development impact; (ii) the rationale for public involvement; (iii) the World Bank's contribution to the Project; and (iv) the fiscal impact and sustainability of the Project.

Estimation of Project's development impact

2. Health expenditure in Serbia is larger than in other comparable countries (see figure below). At the same time, Serbia has similar health outcomes or even less progress if compare them in terms of DALYs per 100,000. This indicates, that the country is facing a challenge of increasing efficiency in health spending and has the potential for improving health outcomes for Serbia's population. Therefore, the PDO of the proposed operation within AF aims to improve both the efficiency and the quality of the Serbian health system.

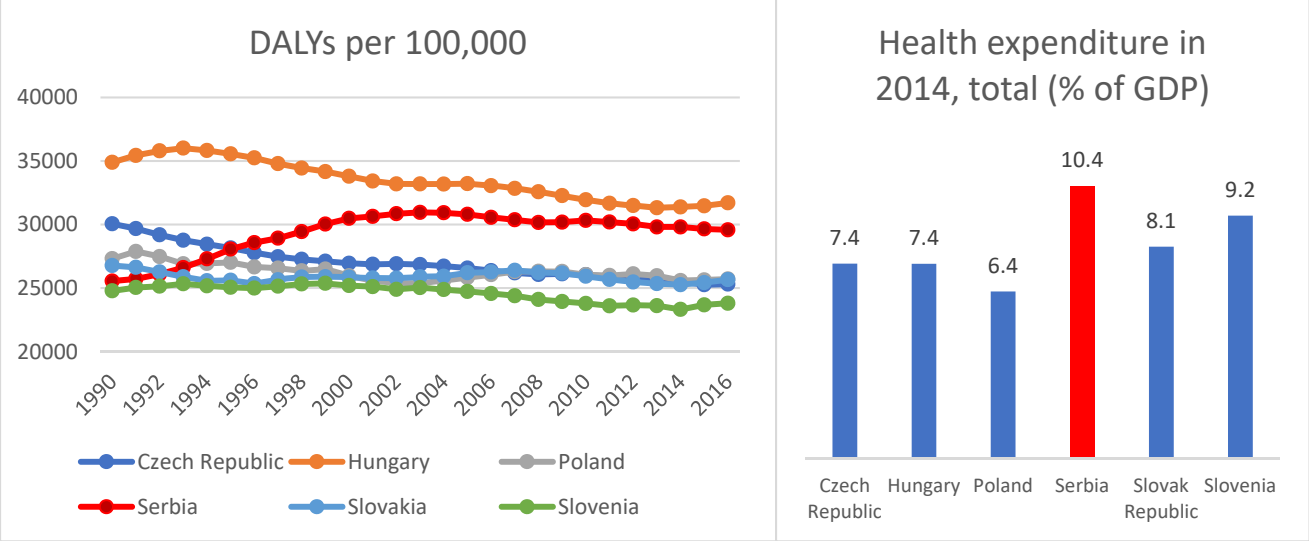

Figure 1 Comparison of health outcomes and health expenditures for Serbia and neighboring countries

3. The AF for the Project will expand support the following interventions aimed directly at producing efficiency savings: (i) hospital financing reforms, such as the introduction of integrated clinical pathways and the European protocol for the appropriateness of admissions in hospital care, and development of the Masterplan to support optimization of hospitals network; (ii) digital system for the centralized procurement of pharmaceuticals and other medical goods; and ii) strengthening of a Health Technology Assessment (HTA) unit. The AF for the project will also support interventions aimed primarily at improving quality of care, including: (i) refining the financing formula for primary health care; (ii) the establishment of a medical equipment maintenance system; (iii) investments to strengthen quality of care, such as the adoption of clinical practice guidelines and pathway, integration of care, refinement of the existing clinical practice guidelines, development of Disease Management Program for the most frequent NCDs, etc.; and (iv) investments to further improve cancer care (diagnostics and treatment).

4. The distinction between investments directed to increase efficiency and quality of care is to a certain degree subjective as discussed in the Project Appraisal Document (PAD) for the SSHP, however, as efficiency savings will free up resources that could remain in the health sector and enhance quality of care. Following the approach used in the PAD for SSHP, the estimate of the overall development impact of the Project is likely to be conservative.

5. Since this analysis covers the AF for the project, it focuses on the evaluation of the potential additional benefits for the achievement of the PDO. Table 1 summarizes the economic rationale for the accounted benefits, provides summary of the recent literature analysis, and explains the causal chain for those interventions included in the analysis linking them to the PDO.

6. The assumptions used in the cost-benefits analysis are listed below:

Basic discount rate. Financial costs (Project investments and recurrent costs) and financial savings are discounted at 6.2 percent, to account for future inflation that is the average inflation estimated for the last 10 years (2007-2016) period. A higher discount rate of 10 percent is also applied to verify the sensitivity of the results to this assumption.

Discount rate of the monetary value of future health benefits. The monetary value of the annual DALYs saved is discounted at 3 percent per guidelines from WHO and the Disease Control Priorities Project[1]. The higher rate of 5 and 7 percent is used for the sensitivity analysis.

Period of time considered. The cost-benefits of each intervention are calculated over the 2017-2030 period.

Population covered. In general, is assumed that most interventions will be implemented nationwide. Exception is the direct investment to cover the cost of LINACs in VOI. Therefore, the interventions will affect health results for the entire population, about 7.06 million people in 2016, or the efficiency level of all facilities. The incremental costs for the maintenance and actual radiotherapy treatment related to the acquisition of the LINACs in VOI were calculated according to the population of VOI and expected cancer incidence indicators for the region.

7. *Hospital financing reforms: introduction of integrated clinical pathways and European protocol for appropriateness of hospitalizations.* The development impact of hospital care optimization is estimated on the base of the expected improvement of overall efficiency (both allocative and technical efficiency) of public spending for acute hospital care, as the proposed intervention is expected to contain the future growth of public expenditures for acute hospital care. The specific assumptions adopted in the economic analysis of this intervention are similar to those used in the initial PAD:

- Future public expenditure for hospital care is modeled using a linear trend model based on the past evolution of total impatient expenditure.
- The adoption of hospital care interventions is expected to contain future expenditure growth by 0.5 percent (baseline effectiveness scenario) starting from year 2019.
- Recurrent costs are estimated to equal the average yearly investments for this sub-component.
- Benefits and costs are estimated over the 2017-2030 period.
- The additional benefits deriving from the enhanced transparency in the allocation of resources to hospitals and the potential benefits deriving from the improved health management

[1] See: http://www.dcp2.org/

information system are not expressively considered in the cost-benefits analysis. Therefore, the results are likely to be conservative.

8. *PHC financing reforms, quality improvement systems (refined clinical practice guidelines, integration of care, Disease Management Program etc.), and improved cancer care*. The benefits deriving from these interventions are estimated using the impact on population health status measured in term of averted Disability Adjusted Life Years (DALYs), which represent the sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability, and have a built-in age-weighting. The specific assumptions adopted in the economic analysis of these interventions are:

- The conditions that will be affected by improved PHC care, including the quality improvement systems and disease management plans for NCDs, which represent about 86 percent of the overall DALYs of the country estimated in 2016[2].
- The conditions that will be affected by improved cancer care, including early diagnostics and better access to radiation therapy, considering that cancers represent about 18 percent of the overall DALYs of the country estimated in 2016.
- The reductions in DALYs from the interventions of the Project (capital investments for better facilities and increased access to services, improved of performance-based contracting at PHC level, strengthening of a HTA unit and implementation of integrated clinical pathways) were estimated taking conservative values. Specifically, the reduction of DALYs from improved diagnostics of cancers and extended cancer radiation treatment is estimated to be at 1.5 percent leading to the expected cumulative decrease of DALY lost due to cancers by 4.7 percent in 2030; and the reduction of DALYs from the implementation of quality improvement systems for NCD care is estimated to be between 0.05 percent starting from 2019.
- The baseline DALYs were calculated for the various conditions from the Global Burden of Disease study estimates for Serbia[3]. The forward Projections of DALYs from NCDs and cancers for 2017 to 2030 is based on the historical trend.
- Valuation of DALYs used a very simple rule. Each DALY saved is valued at per capita income (using a starting value of about US$5,427 for 2018 and the average GDP growth rate of 3.36 percent, which represents the average for 2000-2016 array). An upper, but still conservative, estimate values each year of life as three times per capita income, as per the Disease Control Priorities Project and Copenhagen Consensus guidelines[4]. Studies of valuation of life in the United States utilize much higher values of year of life that would produce more extreme results.
- Discount Rates for DALYs: The monetary value of future stream of health benefits (i.e. annual DALYs saved) is discounted at 3 percent (with an upper sensitivity analyses of 5 and 7 percent), per guidelines from WHO and the Disease Control Priorities Project referenced above.

[2] Global Burden of Disease Study 2016. Global Burden of Disease Study 2016 (GBD 2016) Results. Seattle, United States: Institute for Health Metrics and Evaluation (IHME), 2016. Available from from https://http://vizhub.healthdata.org/gbd-compare/
[3] *ibid*
[4] D. Jamison, P. Jha, and D. Bloom, “Copenhagen Consensus 2008 Challenge Paper: Diseases,” 2008; http://www.givewell.org/files/DWDA%202009/Stop%20TB/Copenhagen%20Consensus%20Paper-Diseases.pdf

Table 1. Causal framework linking additional Project activities within the AF to the PDOs

Component/ sub-component	AF amount, Euro	Activities	Benefits accounted in the Economic analysis section for AF	Evidence (additional to PAD for the parent project)
Sub-component 1.1: Support Hospital Financing Reforms	0.9 million	i) Integration of clinical pathways developed under the project into hospital information systems; ii) Further definition of admission criteria based on the European version of Appropriateness evaluation protocol and adaptation to national level; iii) Introduction of initial hospital matrix for performance monitoring and incentive for hospital physicians and clinical teams, and iv) Improvement of regulatory framework.	Reduction of duplicative diagnostics, therapy and errors in prescriptions Reduction in unnecessary hospitalizations (0.5% annual savings of the hospital care budget)	Li, W. (2014)[5] Implementation of Integrated clinical pathway management for medical quality improvement in China's hospital helped reduce the length of stay and medical errors Application of the European version of Appropriateness evaluation protocol in the Dutch hospital showed that over 20% of the hospital stay was inappropriate[6], and implementation of the Protocol with direct feedback to surgeons about their own percentages of inappropriate stays and daily evaluation of appropriateness by the surgeons during their rounds reduced percentage of inappropriate stays from 14.3% to 7.9% in Spanish hospitals[7].
Sub-component 1.2: Strengthen Primary Health Care Financing	0.8 million	Further monitoring, evaluation and upgrade of the financing formula for PHC is of utmost importance for the success of this reform and needs to go together with addressing regulatory framework to recognize	Improved outcomes of NCD prevention and treatment-accounted at Project appraisal stage (slight incremental increase,	

[5] Li W., Liu K., Yang H., Yu C. Integrated clinical pathway management for medical quality improvement – based on a semiotically inspired systems architecture. European Journal of Information Systems, July 2014, Volume 23, Issue 4, pp 400–417 *https://link.springer.com/article/10.1057/ejis.2013.9*
6 Panis L., Verheggen F., Pop P.; To stay or not to stay. The assessment of appropriate hospital stay, a Dutch report, International Journal for Quality in Health Care, Volume 14, Issue 1, 1 February 2002, Pages 55–67, *https://doi.org/10.1093/intqhc/14.1.55 https://academic.oup.com/intqhc/article/14/1/55/2743494*
7 Antón, P., Peiró, S., Aranaz, J. M., Calpena, R., Compañ, A., Leutscher, E., & Ruíz, V. (2007). Effectiveness of a physician-oriented feedback intervention on inappropriate hospital stays. Journal of Epidemiology and Community Health, 61(2), 128–134. *http://doi.org/10.1136/jech.2005.040428 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2465655/*

Component/ sub-component	AF amount, Euro	Activities	Benefits accounted in the Economic analysis section for AF	Evidence (additional to PAD for the parent project)
		and allow for such changes.	at 0.05% of DALY annually)	
New proposed sub-component 1.3: Develop a Health Care Network Optimization Plan	1.3 million	Within the umbrella of the National Health Care Development Plan 2020-2025, the proposed AF will support the development of a health care network master plan.	Not accounted	
Sub-component 2.1: Establish a Centralized Procurement System	0.2 million	Support the establishment of e-health, and the continuation of activities on the rationale use of antibiotics in line with the National Program for the Control of Antibiotic-Resistant Bacteria and its Action Plan.	Not accounted	
Sub-component 2.2: Strengthening Health Technology Assessment Capacity	0.7 million	Technical assistance and further support to HTA unit	Accounted at Project appraisal stage	
Sub-component 2.3: Improve Medical Equipment Maintenance Systems	0.6 million	Support the MoH in establishing an entity for medical technology management, selection of an Independent Service Organization, to provide highly qualified multi-vendor maintenance services in one or more pilot hospitals; and a possible extension of the service to other health care facilities.	Not accounted	

Component/ sub-component	AF amount, Euro	Activities	Benefits accounted in the Economic analysis section for AF	Evidence (additional to PAD for the parent project)
Sub-component 3.1: Strengthen Quality Improvement Systems. Clinical Pathways	0.8 million	Support to integrate primary and secondary health care clinical pathways (for cancer and cardiovascular diseases at a minimum) to improve management of chronic diseases, which represent the major burden on health. It will also help improve health care quality and enable better management of waiting times for patients with malignant diseases. The AF will also support the update of existing clinical practice guidelines and develop new ones. Given the complexity of using integrated pathways, health care managers and professionals will also receive extensive training. The next step, to be financed under the AF, would be the development of Disease Management Program for the most frequent NCDs.	Better outcomes for NCD treatment (0.05% reduction in DALYs from NCDs)	McDonald et al. (2007)[8]: shared care strategies that encompass multidisciplinary groups for care coordination, disease management programs and case management have been shown to improve care outcomes in specific population groups, such as patients with psychiatric illnesses, stroke victims and patients with diabetes, with improvements being noted in mortality rates and hospital readmissions, among other outcomes. Other studies[9],[10] refer to improved care outcomes, appropriate health services utilization and technical efficiency Introduction of performance indicators to measure effectiveness of clinical pathways in Italy[11] helped achieve reductions in health care macro-variation phenomena (length of stay, patient pathways, etc.) and in performance micro-variation (variations in diagnostic and therapeutic prescriptions, protocol implementation, etc.) were shown in sites where pathways were implemented successfully. A

[8] McDonald KM, Sundaram V, Bravata DM et al. Closing the quality gap: a critical analysis of quality improvement strategies. *Volume 7 – Care coordination*. Rockville, MD: Agency for Healthcare Research and Quality, 2007
9 Curry N, Ham C. Clinical and service integration: the route to improved outcomes. London: The King's Fund, 2010
10 Ovretveit J. Does clinical coordination improve quality and save money? London: Health Foundation, 2011.
11Panella M., Marchisio S., Di Stanislao F.Reducing clinical variations with clinical pathways: do pathways work? International Journal for Quality in Health Care, Volume 15, Issue 6, 1 December 2003, Pages 509–521, *https://doi.org/10.1093/intqhc/mzg057 https://academic.oup.com/intqhc/article/15/6/509/1823636*

Component/ sub-component	AF amount, Euro	Activities	Benefits accounted in the Economic analysis section for AF	Evidence (additional to PAD for the parent project)
				significant improvement in outcome for patients who were treated according to the clinical pathway for heart failure was also demonstrated.
Sub-component 3.2: Improve Cancer Management	18.2 million	- development of the Serbian Comprehensive Cancer Management Strategy (Euro 0.5 million) to cover prevention, diagnostics and treatment. - Improvement of National Coverage of Radiotherapy Services (Euro 5.0 million) - two new LINACS and rehabilitation of the two bunkers for VOI - Improvement of Diagnostics Quality in Oncology (Euro 12.7 million) – procurement of CT scanners and MRIs for improved and early diagnostics in oncology, Positron Emission Tomography Center (PET Center) – Cyclotron for production of radiopharmaceuticals necessary for diagnostics and research	About 11,000 people in the northern province of Vojvodina (VOI) are affected by cancer annually, 4,000 of whom need radiation or combined chemotherapy and radiotherapy. Savings could be achieved through reduced funds for high-cost oncology drugs As per international standards, one PET Center should exist per 1,000,000 population, and Serbia fails to meet this standard. Current costs for diagnostics per one patient as paid by the Health Insurance fund are 295 Euro (for Clinical Center in Belgrade) and 379	Improved diagnostics of cancer and care for those who are susceptible to radiation therapy in terms of the reduction of DALYs from improved cancer care radiation treatment is estimated to be at 1.5 percent annually compared with no action, which is in line with the evidence cited in WHO Guide to cancer early diagnosis (2017)[12], which attributes significant impact on improving outcomes to reducing delays in cancer care at all stages. Radiotherapy is a key component of both radical (curative) and palliative treatment for cancer. Radiotherapy forms part of the management of 40 percent of patients cured of their disease[13]. In the US, mortality rates for the most common cancers—breast, prostate, lung, and colorectal—have declined significantly over the past decade, each dropping 2% annually[14] Based on data obtained in the published model[15], the

[12] http://apps.who.int/iris/bitstream/10665/254500/1/9789241511940-eng.pdf?ua=1
[13] Ahmad SS, Duke S, Jena R, et al; Advances in radiotherapy. BMJ. 2012 Dec 4345:e7765. doi: 10.1136/bmj.e7765.
14 Howlader N, Noone AM, Krapcho M, et al: SEER Cancer Statistics Review (CSR) 1975-2013. *http://seer.cancer.gov/csr/1975_2013*
15 Zubizarreta IE, Van Dyk J, Lievens Y. Analysis of Global Radiotherapy Needs and Costs by Geographic Region and Income Level. Clinical Oncology

Component/ sub-component	AF amount, Euro	Activities	Benefits accounted in the Economic analysis section for AF	Evidence (additional to PAD for the parent project)
			Euro (for Institute for Oncology VOI). Supporting a new PET Center to produce essential radiopharmaceuticals would bring the costs down to 85 Euro (for Clinical Center) and 142 Euro (for Institute for Oncology VOI)	cost per capita related to radiotherapy in the 49 European countries, amounted to US$7.36 on average, and more specifically to US$11.86 in HICs, US$2.02 in U-MICs and US$1.25in L-MICs. Yap et al. (2017)[16]: The estimated optimal radiotherapy utilization rate for all LMICs was 50%. There were about 4.0 million cancer patients in LMICs who required radiotherapy in 2012. This number is projected to increase by 78% by 2035. The 5-year population local control and survival benefits for all LMICs, if radiotherapy was delivered according to guidelines, were estimated to be 9.6% and 4.4%, respectively, compared with no radiotherapy use.
COMPONENT 4: Monitoring, Evaluation and Project Management	1.5 million	27 months extension period of day-to-day management, monitoring and evaluation, audits of the project	Not accounted	

Volume 29, Issue 2, February 2017, Pages 84-92
16 Yap ML, Hanna TP, Shafiq J., Ferlay J., Bray F, Delaney GP, Barton M. The Benefits of Providing External Beam Radiotherapy in Low- and Middle-income Countries. Clinical Oncology, Volume 29, Issue 2, February 2017, Pages 72-83

9. The overall results of the economic analysis for all interventions are presented in Table 1. With the AF, the project is expected to help avert additional 24,946 DALYs and achieve efficiency improvements from hospital optimization of over $100 million in nominal terms. The sum of costs and benefits (i.e. the NPV of the intervention) is largely positive and the estimated IRR range between 40.6 and 184.4 percent, depending of the assumptions on the effectiveness of the intervention and on the inflation used, which clearly show a demonstrate the positive development impact of the project. The use of more conservative scenarios for the sensitivity testing of the outcomes gives stable positive numbers for NPVs (lowest at $31.7 million) and IRRs from 29.5 in scenario 2 to 40.1 percent in scenario 1, as presented in Table 2 and 3 below. Application of all unfavorable conditions together will not reduce the IRR lower than 23 percent.

Table 2. NPV and IRR of improved and more efficient primary and hospital care, including improved cancer care (US$ '000s)

Variable	Total costs	Total benefits	Net benefits (1 DALY=1 times GDP per capita)	(Net benefits with high value: 1 DALY=3 times GDP per capita)
Baseline scenario: *Using average GDP growth of 3.36 percent, inflation rate of 6.2 percent and DALY discount rate of 3%*				
Values (in 000s)	118,034	230,025	111,991	407,930
NPV at 6.2% (in 000s)			58,624	239,930
IRR (2017-2030)			40.6%	184.4%
IRR (2017-2026)			37.0%	184.4%
IRR (2017-2023)			24.7%	183.1%

Table 3. Results of sensitivity analysis for NPVs and IRRs of interventions within AF program (US$ '000s)

Variable	Total costs	Total benefits	Net benefits (1 DALY=1 times GDP per capita)	(Net benefits with high value: 1 DALY=3 times GDP per capita)
scenario 1	*Using deflator rate of 10%, and DALY discount rate of 5%*			
Values (in 000s)	102,005	203,440	101,435	363,286
NPV at 10% (in 000s)			36,312	162,375
IRR (2017-2030)			40.1%	181.4%
scenario 2	*Using DALY discount rate of 7%*			
Values (in 000s)	118,034	181,117	63,083	296,300
NPV at 6.2% (in 000s)			31,716	178,477
IRR (2017-2030)			29.5%	167.7%
scenario 3	*Using GDP growth rate of 2%*			
Values (in 000s)	118,034	205,686	87,653	352,358
NPV at 6.2% (in 000s)			44,926	208,633
IRR (2017-2030)			34.6%	171.1%

The rationale for public involvement

10. To implement the provisions of 2006 Constitution, the Government needs to ensure the universal right to protection of physical and mental health. Implementation of the interventions under the AF will help the Serbian Health Insurance Fund (HIF) more efficiently procure and provide essential health care for population through public providers. It will also help improve health outcomes, focusing on NCD care management, and particularly cancer care, which in turn may help country achieve higher economic and social development goals.

Fiscal Impact and Sustainability

11. Public health expenditure in Serbia reached about USD 1,894 million in 2016[17]. This represents a 63 percent increase compared to 2003. The general government expenditure on health (GGHE) as percent of THE has decreased from 70.3 in 2003 to 58 percent in 2016. Total expenditure on health (THE) as percent of GDP was 10 percent in 2006-2010, but has decreased to 9 percent in 2016.

12. Public health expenditure after 2016 has been estimated using the following assumptions: (i) GDP is expected to grow at the average rate of 3.36 percent during the 2018-2030 period; and (ii) the level of THE as a share of GDP will remain constant at 9 percent, while GGHE will be on 60.6 percent on average, which is the average share for 2007-2016 period.

Table 3. Public health expenditure in Serbia, 2016-2030 in 000s USD

Year	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Total public health care budget in Serbia	1 894 105	2,155,073	2,227,559	2,302,484	2,379,929	2,459,979	2,542,721	2,628,246	2,716,648	2,808,023	2,902,472	3,000,097	3,101,007	3,205,310	3,313,121
Total AF investment			5,300	13,000	8,000	2,000	1,000								
AF investment into equipment			5,000	12,700											
Maintenance of LINACs, CTs and MRIs (*)				250	885	885	885	885	885	885	885	885	885	885	885
Cost of cancer diagnostics (all)			999	1,007	1,014	1,022	1,030	1,037	1,045	1,053	1,060	1,068	1,076	1,084	1,091
Cost of radiotherapy (VOI)			7,725	7,785	7,844	7,904	7,963	8,023	8,082	8,142	8,201	8,261	8,320	8,380	8,439
Costs of the project related to the GGHE	-	-	0.6%	1.0%	0.7%	0.5%	0.4%	0.4%	0.4%	0.4%	0.3%	0.3%	0.3%	0.3%	0.3%

Estimates after 2016, *maintenance at 5% of investment cost starting next year after procurement

[17] National Health Accounts, 2016

13. The estimated disbursements of the proposed Project will represent a very small share of public health expenditure, reaching at most around 0.56 percent of GGHE level in 2019, if all capital investment in equipment will be concentrated in that year. Additionally, the estimated cost of equipment maintenance and incremental additional costs of diagnostics and radiotherapy treatment in VOI has been accounted for[18] to estimate the sustainability of the additional pressures on the health care budget. At the same time, some interventions, such as the introduction of digitalized care pathways, verification of appropriateness of hospitalizations in acute hospitals and integrated care approach are expected to create significant cost saving that will compensate for the additional recurrent costs produced by the other interventions. Therefore, the overall fiscal impact of the AF for the Project is expected to be positive in the medium to long term.

[18] The average costs of diagnostics and treatment was obtained from the HIF for 2017 (e.g. prices in USD for CT was 21.27, MRI 24.52, whole body PET-CT 178.07), and an estimate on radiotherapy services provided in 2016 was USD 3,258.56.

Annex 3. Project Procurement Strategy for Development

1. Project Overview

Country:	Serbia
Full Project Name:	Additional Financing for Second Serbia Health Project
Total Finance ($):	EUR 25M (US$31.10 M equivalent)
Project Number:	P166025

1. **Project Description and Development Objectives:**

a) The Project Development Objective (PDO) of the parent Second Serbia Health Project (P129539), which remains relevant, is *to contribute to improving the efficiency and quality of the public health system of the Republic of Serbia through the strengthening of: (i) health financing, purchasing, and maintenance systems; and (ii) quality improvement systems and management of selected priority non-communicable diseases.* Project effectiveness was extended twice due to delays in meeting the conditions of effectiveness, which postponed Project implementation by one year.

b) The parent Project comprises four components: (a) Component 1: Improvement of Health Financing; (b) Component 2: Efficient Purchasing of Pharmaceuticals and Medical Products; (c) Component 3: Strengthening Quality of Service Delivery; and (d) Monitoring, Evaluation, and Project Management.

c) The original PDO will remain unchanged and the AF activities are in line with the original development objective. The AF is in line with the current Country Partnership Framework (CPF), which pays special attention to improved efficiency, access and quality of cancer treatment, hospital and primary care, as well as efficient purchasing of pharmaceuticals.

2. Strategic Assessment of Country, Borrower and Marketplace

a. Operational Context

d) The Borrower requested additional financing in the amount of EUR 25 million for the Second Serbia Health Project (SSHP). The proposed AF is requested to scale-up the activities of the parent project that are critical in expanding and ensuring project's impact to beneficiaries, including the Roma population. The activities to be financed by the AF are aligned with the PDO of the Second Serbia Health Project (SSHP) and aimed at fully achieving SSHP outcomes. The AF would further support the second-generation comprehensive reforms towards improving efficiency, enhancing quality, providing greater transparency, and rationalizing oversized health facilities using an integrative approach to addressing cancer management and covering radiotherapy services. Provision of modern diagnostic equipment under the Project would be fully aligned with the extended reform agenda, including optimization of health network and development of a long-term comprehensive national cancer strategy.

e) Results of the parent Project (such as centralized procurement of pharmaceuticals and initial results from the DRG reporting piloting) encouraged the MoH in pursuing a deeper reform. Building on the achievements of the parent Project, the AF would enable the Bank to seize an opportunity to support

the MoH in scaling up activities through health care network optimization and comprehensive cancer management reform.

f) The AF will also include: (i) adding a new sub-component under component 1; (ii) revising the Results Framework; and (iii) extending the parent project Closing Date by 24 months until September 30, 2021.

3. Client Capability and PIU Assessment

g) The project under the Additional Financing (AF) will continue to be implemented by the Project Coordination Unit (PCU) which is fully staffed except for the Deputy Director who will be hired under the AF. The PCU has the experience and technical capability to implement the activities. Where there is lack of expertise, consultants are positioned to be hired under open competition (international or national) as provided in the procurement plan to increase capacity of the PCU.

b. Market analysis

There are two big activities in the procurement plan: one for procurement of linear accelerators (LINACS) with a cost estimate of EUR 4,900,000 and the other for procurement of CT scanners, ultrasounds and MRIs with a cost estimate of EUR 12,240,000.

Segmentation of the market and identification of key-players:

Linear accelerators

Linear accelerators market holds few players operating in the segment for years with expertise and experience. During the last years, companies with a long tradition of high-quality products in this field (GE Healthcare, Siemens) abandoned the market. Currently, in the area of traditional radiotherapy (medium and high-energy accelerators, with emission of X-ray and electron beams) only two major players, Varian Medical Systems (USA) and Elekta Group (Sweden), share the total of EU and North America market. More recently, an emerging company (Neusoft Corp, China) acquired significant shares of the Asian market for low-energy radiotherapy (linear accelerators up to 6 MeV). Some other players are also present on the market of radiotherapy, offering systems for non-conventional treatments (e.g.: robotic radiosurgery, Cyberknife, Gamma Knife), but these systems are out of the scope of the project because of their extreme high cost, high technical complexity, and low number of treatments.

CT scanners

The global CT scanners market is growing at a significant rate, wherein product innovation is at the forefront of strategies for the vendors striving to gain ground over their competitors. Moreoever, the number of manufacturers is still growing, and new competitive companies entered the international market during the last few years. Philips Healthcare, GE Healthcare, Medtronic, Accuray, Samsung Electronics, Shenzhen Anke High-Tech, Carestream Health, Hitachi, Koning, Neusoft, Planmed, Shimadzu, Toshiba, and Siemens are some of the key companies currently occupying prominent positions in the global CT scanners market. The increasing number of manufacturers and the recent entry into the market of very competitive Asian companies resulted in the high level of competition among them and a significant reduction of prices for this diagnostic technology during the last few years.

MRI scanners

The global market for Magnetic Resonance Imaging is steadily growing, with applications in multiple clinical areas, including early detection and quantification of cancers, neurologic, and cardiovascular disorders. Key companies operating in the global MRI market include Siemens Medical, Philips Healthcare, GE Healthcare, Hitachi Ltd., Toshiba Corp., Neusoft, and Esaote SpA.

Ultrasound imaging

The global ultrasound imaging market is still growing with applications in multiple clinical areas, including the early detection of cancer pathologies. The global ultrasound imaging market is forecast to grow at a rate of 4.9% from 2018 to 2022. The major drivers for the growth of this market are the rising demand for minimal invasive and non-invasive diagnostic procedures, technology advancement, and an increasing number of patients. At least 10 major players are sharing this market and, besides the consolidated manufacturers (Philips, Siemens, GE, Toshiba, Esaote, Medison, etc.), a number of new Asian manufacturers from China and Korea (Mindray, Chison, Sonoscape, etc.) are acquiring important market shares with products of high quality offered at very competitive prices.

Procurement approach:

The parent project procured LINACS under competitive bidding and the contract was awarded to a Joint Venture led by Varian. The additional LINAC to be financed under AF will be procured through a Direct Selection from Varian based on the same unit price as in the contract signed in the parent project.

As mentioned above there are only two manufacturers of the equipment and recent experiences under parent project was that even though some 20 bidding packages were bought by prospective bidders only one bid was received. It was a JV in which the manufacturer Varian participated as a JV member. Another manufacturer, Elekta, through its representatives provided some comments to the specifications but in the end didn't submit a bid. Hence, the whole procurement process ended up with single bid from reputable manufacturer who also offered competitive price (within budget estimate). The entire procurement process from issuance of bidding documents (January 31, 2017) to contract signature (August 8, 2017) took a little over 6 months. In light of urgent need of the Client to have the additional equipment installed in hospitals for cancer patients, Direct Selection is the justified approach which will save significant time, as there is no obvious benefit in repeating a competitive process. Moreover, this is consistent with the provisions of Direct Selection, paras. 6.8 to 5.10 of the Regulations.

Procurement of CT scanners, ultrasounds and MRIs will be procured through a Request for Bids (open approach) as a large number of international manufacturers are available for all market segments, assuring a high level of competition and the participation of multiple bidders.

All remaining activities are small value consulting services and non-consulting services all subject to post review.

3. Procurement Risk Analysis

The overall coordination, management, implementation and oversight of procurement will be carried out by PCU which is implementing the parent project. Procurement risk rating is **Substantial** as procurement of medical equipment is always a challenge due to complaints which could potentially delay procurement. Since the total cost of medical equipment is EUR 17,140,000 out of the EUR 25M or 68.56% of total additional financing, any delay on their procurement can adversely affect the project. PCU staff have been

trained under the Regulations but are not yet familiar with their application. It will be appropriate that another training is conducted to address the procedures for the specified activities in the procurement plan. In addition to training, the procurement implementation support will include: (a) timely advice on various procurement related issues, (b) guidance on the Bank's Procurement Regulations; and (c) monitoring of progress against the procurement plan.

The prior review thresholds for Substantially risk projects as provided in the Procurement in IPF and Other Operational Procurement Matters, November 3, 2017 will apply:

- Works (including turnkey, supply & installation of plant and equipment, and PPP): US$10 million
- Goods, information technology, and non-consulting services, US$ 2 million
- Consulting services: firms, US$ 1 million,
- Consulting services: individuals, US$300,000

For the most part, the risks for selection of consulting services are low, since there is a robust market for the services required and they are not high value contracts. In addition, the PCU has already procured several consulting services in the parent project.

Summary of Risks Analysis

Risk Description	A Likelihood Rating	B Impact Rating	Overall Risk Score (A*B)	Description of proposed mitigation through the procurement process	Risk Owner	Procurement Process Likelihood Stage
Limited exposure of PCU in undertaking procurement under the Procurement Regulations for Borrowers	3	5	15	Refresher training of PCU staff on the procedures under the Procurement Regulations	PCU, MoH	Duration of procurement process
Preparation of Technical Specifications (and bidding documents) for the medical	3	3	9	PCU has technical experts to prepare the TS and procurement expert to put	PCU, MoH	Pre-bidding

Risk Description	A Likelihood Rating	B Impact Rating	Overall Risk Score (A*B)	Description of proposed mitigation through the procurement process	Risk Owner	Procurement Process Likelihood Stage
equipment to be procured				together the RfB		
Delay in evaluation of bids for high-value contracts	3	5	15	Close monitoring and follow-up of Bank team	PCU, MoH	Evaluation and Contract Award
Handling of Complaints	5	5	25	PCU to promptly address the complaint in consultation with the Bank.	PCU, MoH. Bank	Bidding Process, Notification of Contract Award

4. Procurement Objectives

The procurement objective is to carry out and complete the procedures for all contracts in a timely, efficient, transparent manner with an emphasis on fit-for-purpose, quality and value for money.

5. Recommended Procurement Arrangements for the Project

The details on each activity, their estimated cost and proposed procurement method are provided in the attached initial procurement plan. Below is the summary of high-value procurement activities.

Description	Type	Cost Estimate (EUR) '000	Selection Method
Procurement of CT scanners, Ultrasounds and MRIs	Goods	12,100	RFB (international)

Description	Type	Cost Estimate (EUR) '000	Selection Method
Supply and installation of two LINACS & one CT, and rehabilitation of the two bunkers	Goods	4,900	Direct Selection (DS)
Consultants services (Firm)	CS	850	QCBS
Independent Service Organization, to provide highly qualified multi-vendor maintenance services in one or more pilot hospitals	NCS	425	RFB
Selection of individual consultants	**CS**	**1,550**	**DS (multiple packages)***
Other consulting services	**CS**	**5,175**	**Multiple packages**
Subtotal	**Goods & NCS**	**17,425**	
Subtotal	**CS**	**7,575**	
TOTAL		25,000	

***** These individual consultants have been selected on competitive basis and are going to continue under the AF through Direct Selection and subject to post review.

Preferred arrangement for low value, low risk activities are: Request for Quotations (RFQ) for goods and Open Competition and/or Direct Selection for Consulting Services.

A. Procurement of works. *Currently not envisaged*.

B. Procurement of Goods and Non-consulting Services. Goods may be procured using procedures and methods (Request for Proposals, Request for Bids, Request for Quotations and Direct Selection) in accordance with Section VI. Approved Selection Methods: Goods, Works and Non-consulting Services of the Regulations.

C. Procurement of consulting services. Selection of consulting firms will be done using the World Bank standard procurement documents, such as Request for Proposal. Selection methods are: Quality-

and Cost-Based Selection, Least Cost Selection, Fixed Budget Selection, or Quality Based Selection following provisions of Regulations for Borrowers, Section VII. Approved Selection Methods: Consulting Services. For contracts below USD 300,000 equivalent, the Selection Based on Consultants' Qualification (CQS) method may be used. The short list can entirely comprise national consultants if the contracts with the firms are below USD 300,000 equivalent. Individual consultants are selected from those that expressed interest in response to a REOI. For direct selection of individual consultants, due justifications under the circumstances specified in para. 7.39 of Section VII of the Regulations apply.

D. General Procurement Notice (GPN). It will be prepared and submitted to the World Bank after negotiations. The World Bank will arrange for its publication in United Nations Development Business online and on the World Bank's external website. The GPN will contain information concerning the Borrower, amount, and purpose of the loan; scope of procurement reflecting the procurement plan; the name, telephone (or fax) number, and address(es) of the borrower's agencies responsible for procurement; and the address of a widely used electronic portal with free national and international access or website where the subsequent Specific Procurement Notices will be posted. Moreover, it will provide information on the scope of major procurements for the project, and soliciting expressions of interest from prospective bidders and/or consultants for this project.

E. Procurement Plan. The Client prepared an initial procurement plan for the AF which was agreed on February 7, 2018. The procurement plan will be updated in agreement with the WB project team at least annually or as required to reflect the actual project implementation needs and improvements in the PCU's institutional capacity.

F. Procurement supervision. Routine procurement reviews and supervision will be conducted by the APS (Accredited Procurement Specialist). In addition, one supervision visit is expected to take place per year when ex post reviews will be conducted. Procurement documents will be kept readily available for the WB's ex post review during supervision missions or at any other point in time. A post review report will be prepared annually and shared with the PCU**.**

Summary of PPSD

Procurement under the project will be subject to the New Procurement Framework. All procurement will be conducted through the procedures as specified in the World Bank's Procurement Regulations for IPF Borrowers - Procurement in Investment Project Financing Goods, Works, Non-Consulting and Consulting Services, July 2016 (Procurement Regulations). The project will also be subject to the World Bank's Anti-Corruption Guidelines, dated July 1, 2016.