



Additional Financing Appraisal Environmental and
Social Review Summary
Appraisal Stage
(AF ESRS Appraisal Stage)

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BASIC INFORMATION

A. Basic Project Data

Country	Region	Borrower(s)	Implementing Agency(ies)
Tunisia	MIDDLE EAST AND NORTH AFRICA	Republic of Tunisia	Ministry of Health
Project ID	Project Name		
P175785	Additional Financing for Tunisia COVID-19 Response Project		
Parent Project ID (if any)	Parent Project Name		
P173945	Tunisia COVID-19 Response project		
Practice Area (Lead)	Financing Instrument	Estimated Appraisal Date	Estimated Board Date
Health, Nutrition & Population	Investment Project Financing	2/2/2021	3/23/2021

Proposed Development Objective

To prevent, detect and respond to the threat posed by COVID-19 and strengthen national systems for public health preparedness.

Financing (in USD Million)	Amount
Current Financing	0.00
Proposed Additional Financing	0.00
Total Proposed Financing	0.00

B. Is the project being prepared in a Situation of Urgent Need of Assistance or Capacity Constraints, as per Bank IPF Policy, para. 12?

No

C. Summary Description of Proposed Project [including overview of Country, Sectoral & Institutional Contexts and Relationship to CPF]

On March 2, 2020, the Government of Tunisia (GOT) confirmed its first case of COVID-19 and took immediate steps to try and contain the spread of the virus, which was initially successful and led to a phased easing of restrictions.



Starting early August 2020, however, Tunisia has been facing a significant with cumulative confirmed cases doubling from 1,500 to over 3,000 over the same period. As of January 4, 2020 there are over 142,000 cumulative confirmed cases and over 4,800 confirmed deaths. 54 percent of confirmed cases were females, while about 60 percent of the deaths were males. Test positivity rate is at 20 percent, which is significantly above the WHO-recommended threshold of 5 percent, suggesting both low testing capacity as well as uncontrolled spread.

As a result, the GoT requested additional support in the amount of US\$100 million to contribute to the efforts to fight the pandemic already undertaken through the parent project “Tunisia COVID-19 Response Project” (P173945). The parent project in the amount of US\$20 million was approved on April 30, 2020 and was developed as part of the COVID-19 Strategic Preparedness and Response Plan (SPRP) using the Multiphase Programmatic Approach (MPA), which was approved by the Board on April 2, 2020 (PCBASICO219761). On October 13, 2020, the Board of Executive Directors approved an additional financing (PAD4185) to the Global COVID-19 MPA in the amount of US\$12 billion. The primary objectives of the proposed AF are to further strengthen preparedness and response activities under the parent project and to enable affordable and equitable access to COVID-19 vaccines and help ensure effective vaccine deployment in Tunisia through health system strengthening.

As mentioned above, the parent project in an amount of US\$20 million was approved on April 30, 2020. The PDO of the parent project is to improve COVID-19 detection and infection control in Tunisia through increasing the availability of COVID-19 equipment and supplies. It includes two components: (i) Emergency COVID-19 Response (US\$19.85 million); and (ii) Implementation Management and Monitoring and Evaluation (US\$0.1 million). The parent project aims to support the Ministry of Health (MOH) in its efforts to immediately respond to the COVID-19 emergency and fill its gaps in terms of medical equipment and supplies, personal protective equipment (PPE), and infection control products.

The proposed AF will meet the government’s preliminary estimated financing needs of US\$100 million to support financing the Tunisia COVID-19 vaccination strategy. Specifically it would provide additional resources for expanding the scope of the existing two components as well as add two new components to the parent project. The project’s current two components, (i) Emergency COVID-19 Response, and (ii) Implementation Management and Monitoring and Evaluation will be maintained and scaled up and two new components (iii) Supporting Health Systems Strengthening, and (iv) Contingency Emergency Response Component (CERC) will be added in line with the Global MPA.

D. Environmental and Social Overview

D.1. Detailed project location(s) and salient physical characteristics relevant to the E&S assessment [geographic, environmental, social]

As mentioned above, this is an Additional Financing to the existing Tunisia COVID-19 Response Project (P173945) which aimed at acquiring medical diagnostic, testing supplies and personnel protective equipment. The Additional Financing will finance the procurement of COVID-19 vaccines and activities designed to strengthen vaccination planning and management, storage and distribution, including cold chain management. Additionally, the project will finance activities supporting program delivery including communication activities, strengthening last-mile delivery, and information systems. Finally, the project will include a Contingency Emergency Response Component (CERC), which content has not been defined yet. While none of these activities have been identified to date, it was agreed



that up to 20% of the Additional Financing can be retroactively financed, as long as the activities meet the requirements of the ESF and its associated environmental and social standards. The Additional Financing will not finance the production of vaccines.

Tunisia will have several options for vaccine purchase and financing mechanisms, which are expected to include: (i) direct purchases by countries from vaccine manufacturers, either individually or jointly with other countries; (ii) purchase of excess stocks from other countries that reserve excess doses; and/or (iii) advance purchase mechanisms such as participating in COVAX. As defined in the Global COVID-19 MPA AF Board Paper, given the unprecedented pace of vaccine development, the Bank will accept as the threshold for eligibility of IBRD/IDA resources for vaccine purchase either: (i) approval by Stringent Regulatory Authorities (SRAs) in three regions; or (ii) WHO prequalification and approval by 1 SRA. Current COVAX AMC guidance indicates that eligible countries including Tunisia will be able to receive enough free doses to vaccinate 16 percent of their population, even though free doses are not guaranteed. If Tunisia receives these free doses, then the proposed Bank financing for vaccines will cover vaccine dose purchases for up to 34 percent of the population.

The Ministry of Health (MoH) has finalized its national COVID-19 vaccination strategy, with first vaccine administration activities being expected to start in April 2021. The MoH will make the vaccination free of cost to citizens and residents of Tunisia. The vaccine(s) will be administered on a voluntary basis. The strategy envisions reaching 50 percent population coverage by end-2021. However, the vaccination program will remain constrained by their real-time availability and the supply of vaccines available in the course of 2021 is expected to be limited. To address issues associated with transparency, prioritization, changing vaccine supply levels and their various scenarios, the strategy includes a phased approach to vaccine deployment, including the definition of priority groups.

The strategy has the triple objectives to (i) diminish the impact of the pandemic in terms of mortality and severe morbidity; (ii) maintain the capacity of the health care system and protect health care staff and (iii) reduce the psychological, economical and societal impacts associated with the pandemic. In alignment with the WHO SAGE COVID-19 Vaccine Prioritization Framework, the strategy is based on the principles of (i) equitable access to free, effective, safe and scientifically validated quality vaccines in a timely manner and (ii) personal decision-making based on transparent and understandable data. The vaccination strategy aims to determine priority groups for vaccination, based on public health and the gradual arrival of vaccine doses. The strategy will remain dynamic in view of new information on the vaccine that could have an impact on the operational plan. The WB health and E&S specialists have reviewed the strategy and have assessed it to be fair, inclusive and non-discriminatory.

The vaccine will be rolled out incrementally, starting with high-risk health workers and those above age 75, followed by other health workers, those between 60-75 years of age, essential workers in public and private sectors, as well as those with comorbidities, before expanding to the population between 16-60 years old. While the exact definition of essential workers is in the process of finalization, this group is expected to include teachers, those in nursing homes and social care settings, as well as those in essential private sector jobs such as groceries or security services. Comorbidities are included as heart conditions, chronic kidney disease, obesity, hypertension, diabetes and cancers.

The strategy plans to have at least one vaccination site for each of the 6 regions open all week and one vaccination site for each of the 264 delegations open during the weekend. The vaccination sites could be in basic health centers or schools, but the specific sites have not been identified yet. For certain groups (e.g. long-term care residents, health professionals, soldiers, prisoners, etc.), vaccination will take place either at their housing site or workplace



(retirement homes, prisons, hospitals). Mobile teams will be organized to reach specific populations, such as people with reduced mobility or residents of remote areas, etc. Each of the sites will have at least one vaccination team, consisting of 12 vaccinators, physician and other personal to ensure subscription, security, cleaning and other tasks.

An application called "EVAX" will be launched to organize anti-Covid-19 vaccination operations. This application, which is being developed by a team from the Ministry of Health in collaboration with the Ministry of Information and Communication Technologies and a team from the Independent Higher Body for Elections (Instance superieure independante pour les Elections - ISIE), will allow anyone wishing to be vaccinated against the coronavirus to register remotely and provide the necessary information regarding their family and health situation. A specialized team will be tasked through this application with examining all citizens' requests for the vaccine and a selection will be made according to priority categories. Once the vaccines are available, emails will be sent to those registered on this application to inform them of the date and time of vaccination and the appropriate vaccination centers. This application includes a section dedicated to monitoring the state of health of vaccinated people and will allow them to report any adverse effects of the vaccine, emphasizing that this mechanism was developed only as a precaution. In addition to EVAX, the MoH will put in place a toll-free number specific to the COVID-19 vaccination campaign. The toll-free number will allow concerned citizens to request information, submit complaints or register to be administered the vaccine.

At this stage the procedures to obtain consent are under discussion. The MoH is of the view that the act of self-registering to the EVAX platform and showing up to the vaccination appointment are sufficient in demonstrating consent to be vaccinated. However, it may include an additional window with a simple form for consent within the EVAX platform. The consent protocol for patients using the toll-free number to register for the vaccine has not been decided yet.

Finally, the COVID-19 vaccine products are temperature-sensitive and their cold chain storage and handling requirements are expected to vary in temperature from refrigerated (2°C to 8°C) to frozen (-15°C to -25°C) to ultra-cold (-60°C to -80°C). The cold chain will begin at the COVID-19 vaccine manufacturing plant, includes delivery to and storage at the COVID-19 vaccination provider site, and will end with the administration of COVID-19 vaccine to a person. The cold chain in Tunisia is managed by the Ministry of Health and consists in a central storage area, 24 regional storage centers (one in each governorate) and 184 storage areas at the district level. Some cold chain management weaknesses and disparities have been identified in different regions, with weaknesses in some geographic areas, such as Ariana, Sidi Bouzid, Jendouba, Ben Arous and Tataouine pertaining to low cold chain capacity especially to continuous temperature monitoring systems, and formalization of storage/transport policies and practices. However, the required temperature will depend on which COVID-19 vaccine will ultimately be acquired by the GoT. Plans are currently being finalized with regards to expanding and upgrading national cold chain storage and distribution capacity, including for vaccines requiring ultra cold chain.

The project is expected to support, wherever necessary, the capacity of cold chain facilities. This may include the acquisition of refrigeration equipment as freezers for vaccine storage at -80 C and fridges for vaccines storage at +2 +8 C as well as voltage regulators. It is also expected to finance some minor civil works for the establishment of a cold storage facility at regular and ultra cold chain storage sites in the suburb area of Tunis that are already being used actually by the Ministry of Health (MoH) to store equipment and vaccines. The rehabilitation consist in upgrading two storage sites through minor works to install the new refrigeration equipment (freezers, fridges..). In the case of the third site, the works include the installation of prefabricated negative and positive temperature cold rooms.



The project will cover all Tunisian territory. The climate in Tunisia varies from Mediterranean to Saharan with an annual average temperature from the North to the South between 18 to 20 C with peaks in summer reaching 45 C in some southern regions.

D. 2. Borrower's Institutional Capacity

The implementing agency is the Ministry of Health (MoH) through maintaining and strengthening the project implementation unit (unite de gestion par objectif or UGPO in French) of the Parent Project. Lessons-learned from the implementation arrangements of the Parent Project in terms of environmental and social risk management, including stakeholder engagement, highlighted the necessity to reinforce these arrangements by a combination of designating additional focal points and recruiting outsourced expertise to ensure adequate attention is provided to this aspect. The UGPO will remain in charge of fiduciary, environmental and social aspects. The UGPO will have an environmental and social focal point as well as a focal point for the implementation of stakeholder engagement activities.

The Directorate of Basic Healthcare (Direction des soins de santé de base-DSSB) in charge of the National Vaccination Program (PNV) will have technical responsibility for ensuring day-to-day implementation of activities pertaining to the purchase, deployment and administration of the vaccine. The DSSB will also work through the UGPO for procurement, financial management, and environmental and social aspects. The DSSB will also be responsible for the monitoring and evaluation of the project.

The strategic oversight and overall project coordination will be ensured by the existing Steering Committee for COVID-19 Vaccination Campaign. The Steering Committee was created on December 25, 2020, with a ministerial *arrêtée*, which stipulates its roles and responsibilities. The Steering Committee is headed by the Director of Institute of Pasteur and composed of representatives from Ministry of Health directorates, as well as from other ministries, such as defense, transport, social affairs and interior.

In terms of capacity strengthening, the MoH plans on recruiting around 10 individual experts (virologist, immunologist, logistics) including environmental and social specialists hired to support both UGPO and DSSB. Additionally, the MoH will recruit a consulting firm, as well as digital media, public relations and marketing companies to implement the communication and engagement campaign around the COVID-19 vaccination program. They will be key actors in the implementation of the stand-alone Stakeholder Engagement Plan (SEP) designed for the additional financing.

Since the establishment of the National Vaccination Program in 1979, the Ministry of Health, through the DSSB, has acquired a long-term experience in the introduction of new vaccines, administering vaccines through fixed and mobile sites, and conducting vaccination communication campaigns. According to data from the Ministry of Health, the vaccination rates for standard vaccines average around 90% of the national population. It has the capacity to train their staff in the proper procedures and protocols for storing, deploying and administering the various COVID-19 vaccine products it will procure through the project.

Moreover, the MoH also has experience in managing medical waste through the former World Bank-financed "Managing Healthcare Waste and Polychlorobiphenyls" Project (P100478). The MoH worked in close cooperation with the implementing agency, the National Waste Management Agency (ANGeD), to ensure that the necessary precautions were taken based upon a manual (Manual of procedures for the management of health waste activities,



February 2012) which was prepared for the management of Hazardous wastes from health care activities. Through the former World Bank-financed “Managing Healthcare Waste and Polychlorobiphenyls” Project (P100478), MoH has also acquired a good capacity to manage and implement ESMPs for many kind of of small civil works as construction/rehabilitation of medical waste management premises.

II. SUMMARY OF ENVIRONMENTAL AND SOCIAL (ES) RISKS AND IMPACTS

A. Environmental and Social Risk Classification (ESRC)

Substantial

Environmental Risk Rating

Substantial

The key environmental risks associated with the additional financing will be mainly associated to the use and management of waste generated by the vaccine administration activities, supplies, infection control products, and personal protective equipment (PPE). Risks also relate to the inadequate implementation of the various management plans, including the Infection Control and Waste Management Plan (ICWMP) that will be included in the updated ESMF, and Occupational Health and Safety (OHS) for health personnel (vaccine centers) and other workers who will be handling the storage and transportation of vaccines.

Although the AF mainly supports the procurement of COVID-19 vaccines, it will also finance minor rehabilitation works and logistical support for the deployment and administration of the vaccines, all of which entail environmental risks. Foremost among them are the management of infectious medical waste, and the Occupational Health and Safety (OHS) risks to health personnel on the front line during vaccination, and to other medical and cleaning staff during the handling of infectious medical wastes generated during the vaccination process. Healthcare-associated infections due to an inadequate adherence to OHS standards as recommended by WHO and the US Center for Disease Control (CDC) could lead to illness and death among health and laboratory workers.

As the COVID-19 vaccine products are temperature-sensitive, other risks of this AF are linked to the cold chain management, inappropriate temperature storage and handling that can negatively affect the quality and efficacy of vaccines. Poor cold chain management could have an impact on the health and safety of vaccine beneficiaries, or simply diminish the efficacy of the vaccine. In addition, there will also be risks particularly OHS risks to personnel who will be managing and handling storage facility and transportation of vaccines.

Other risks/impacts are linked to waste generated during electronic and electrical equipment management including out of service equipment and inefficient energy consumption from the cold chain equipment.

Minor rehabilitations may also be necessary depending on the state of a given health center and could include adjustments to roofing to allow for natural cooling through cross-breeze, re-painting of exterior walls with lighter colors to increase heat deflection, and installation of solar panels to supplement (or substitute) existing energy consumption. In some cases, it may also be necessary to acquire generators to boost energy supply but this would be determined on a case-by-case basis and depending on the temperature storage needs of the vaccine.

Environmental risks related to minor rehabilitation civil works will be limited to the construction phase, and may include waste generation, hazardous material management, noise and vibration, wastewater discharges and air quality as well as occupational and community health and safety linked to performing these works under COVID 19.

Public Disclosure



MoH has prior experience managing risks and impacts associated with medical waste management. However, there are weaknesses in managing the existing cold chain by the MoH including continuous temperature monitoring systems, and formalization of storage/transport policies and practices.

Social Risk Rating

Substantial

The key social risks associated with the additional financing mostly relate to stakeholder risk, and more specifically to vaccine skepticism and hesitancy, the spread of misinformation, concerns about the government’s prioritization strategy or the performance of the vaccination program, as well as poor buy-in from the general public and key stakeholders in the program. This risk is important as it is key to the successful implementation of the program, which in turn could lead to the control of the pandemic in Tunisia. Other risks include unfair and inequitable vaccine distribution, failure to reach the most socially and medically vulnerable to COVID-19 exposure or severe disease, the potential for the spread of COVID-19 in the course of the vaccine deployment and administration efforts and adverse events following immunization (fatality, life-threatening, adverse event requiring hospitalization or leading to the disruption of normal life). Finally, other risks include uncertainties at this stage regarding the safety and effectiveness of vaccines when it comes to certain vulnerable groups (children, pregnant women, immunocompromised, older adults and individuals previously infected with COVID-19).

In spite of the risks highlighted above, in light of the impressive track record and capacity of the Borrower in implementing vaccination programs and its adoption of a national COVID-19 vaccination strategy that embraces the WHO recommendations, the social risk rating has been assessed as substantial. While these risks are fundamental for the successful implementation of the vaccination program, they do not supersede the risk associated with the no-project alternative, which would leave Tunisia without the means to reach herd immunity in a safe manner and lead to unnecessary death, morbidity and suffering.

B. Environment and Social Standards (ESSs) that Apply to the Activities Being Considered

B.1. General Assessment

ESS1 Assessment and Management of Environmental and Social Risks and Impacts

Overview of the relevance of the Standard for the Project:

The following assessment is based on the review of the COVID-19 Vaccination Strategy (January 2021), the government's communication and stakeholder engagement note (annexed to the preliminary Stakeholder Engagement Plan), meetings with representatives of the MoH working on the COVID-19 Vaccination Program, and good industry international practices, such as the WHO SAGE vaccine allocation and prioritization framework as well as the CDC Interim Program Vaccination Playbook.

The project will have positive impacts as it will improve the capacity of the country’s health systems to reduce COVID-19 morbidities and fatalities. However, environmental and social risks are deemed substantial in light of the nationwide scale of the vaccination program, uncertainties related to the vaccines’ supply levels, the Borrower’s capacity to manage cold chain requirements and waste, and the significant stakeholder risks. More specifically, the risks include biomedical waste generation, the difficulty in ensuring cold chain management, which in turn could lead to a reduced efficacy of the vaccine, health and safety risks in terms of exposure to COVID-19 during vaccine deployment and administration, vaccine disinformation and hesitancy, concerns from the general public on vaccine



prioritization and program performance, failure to reach the most socially and medically vulnerable, as well as the potential for adverse events following immunization. The non-project alternative also entails the risk of not controlling the pandemic that would result in further deaths, severe disease and suffering.

An Environmental and Social Management Framework (ESMF) and Labor Management Procedures (LMPs) were prepared for the parent project (P173945). The two instruments were approved by the Bank and disclosed on the World Bank and the Ministry of Health's (MoH) websites on September 29, 2020. The ESMF includes an Infection Control and Waste Management Plan (ICWMP) and occupational health and safety protocols. At the time of writing, none of the products financed by the Parent Project had been distributed.

These documents will be updated to take into account the activities of the additional financing, their associated risks and impacts and proposed mitigation measures. The updated ESMF will include the procedures to be followed in case of activation of the CERC, an updated Infection Control and Waste Management Plan (ICWMP) taking in account the new vaccine activities and proposed vaccination sites. The updated ESMF will also include the description of the rationale behind the prioritization and allocation of vaccine as reflected in the strategy. The ESMF will outline the avenues being explored by the MoH to reach priority groups who live in remote areas, such as the use of mobile clinics, going through non-governmental organizations that take care of vulnerable groups such as illegal migrants or the homeless, as well as ensuring that vaccination premises include facilities with universal design features. The document will highlight the pollution and energy consumption efficiency measures, as well as the standards that will be used to ensure the reliability of the cold chain.

The revised ESMF will address the current capacity of the Borrower to monitor adverse events following immunization. In case of low capacity, the Borrower will establish an effective system designed and implemented in line with the WHO Global manual on Surveillance of Adverse Events Following Immunization as one example of GIIP.

The updated ESMF will follow the generic mitigation measures associated with the proposed minor civil works, as outlined in the Parent Project ESMF. The instrument will outline the public health measures proposed to minimize the exposure to and propagation of SARS-CoV-2 during the implementation of project activities. The ESMF will be updated to define vaccine cold chain transport and storage temperature monitoring and reporting plan in line with GIIP such as the CDC toolkit Vaccine storage and handling and WHO vaccine management Handbook How to monitor temperatures in the vaccine supply chain.

Finally, the instrument will describe the monitoring mechanisms that will be put in place monitor vaccine administration, such as reminder for second doses, vaccine registries and vaccination cards. The ESMF will follow good international practices, such as the recommendations from the WHO SAGE vaccine allocation and prioritization framework as well as the CDC Interim Program Vaccination Playbook.

The updated LMP will reflect the new categories of workers associated with the additional financing, additional risks and mitigation measures and new training requirements.

Given the considerable stakeholder risks associated with the vaccination program, a stand-alone Stakeholder Engagement Plan (SEP) will be prepared for the AF. The MoH is hiring a communication firm and agencies specialized in digital media, press and media relations and marketing to support information, stakeholder engagement and outreach associated with the vaccination campaign. At this stage, a preliminary SEP, specific to the additional



financing, was prepared and will be disclosed on the MoH and World Bank websites prior to appraisal. The document, based on the Vaccination Strategy and government notes on the proposed information and stakeholder engagement campaign, identifies the key project stakeholders, provides the main orientations for the updated SEP, key objectives, messages on vaccine prioritization, deployment and phasing, health and safety, and public health measures, as well as requirements for grievance management. An updated SEP will be disclosed on the MoH and World Bank websites prior to effectiveness to take into account the latest developments in terms of project design, such as the establishment of the toll free number and grievance redress mechanism, new features of the communication strategy and document the stakeholder engagement activities that will have taken place by then.

Given the urgency to support the Borrower to secure vaccination products and prepare for the vaccination program, the instruments have been deferred to effectiveness. Key operational documents that were required for the update of these instruments, such as the vaccination strategy, were only approved in early January 2021, and many protocols and systems are still in the process of being formulated at the time of writing. In the meantime, the project will use existing instruments prepared under the COVID-19 parent project and preliminary SEP for all activities that are covered under these documents. These conditions are outlined in the Environmental and Social Commitment Plan (ESCP).

ESS10 Stakeholder Engagement and Information Disclosure

The commencement of an effective stakeholder engagement and information disclosure process before the availability of COVID-19 vaccines are essential to the success of the COVID-19 vaccination program. In a context of vaccine hesitancy and skepticism, coupled with low or uneven vaccine supply, enabling the public to have confidence in the vaccine's safety and informing the government's allocation priorities is fundamental.

The national COVID-19 Vaccination Strategy recognizes that transparency, information disclosure and stakeholder engagement are key factors in the success of the vaccination program. The MoH plans to hire a communication/public relations firm and specialized agencies in digital communication, marketing and media relations to help them lead a comprehensive outreach campaign and engage key stakeholder to ensure their buy-in in COVID-19 vaccination program.

The Ministry of Health has already launched consultations with key stakeholders, such as public and private health care professionals, specialized agencies and local government institutions and multilateral agencies such as the WHO, to define the approach of the COVID-19 Vaccination Strategy, which includes the definition of prioritization criteria. Moreover, the MoH conducts regular briefings and updates on its website, Facebook page as well as main television channels. Moreover, in order to have a better understanding of the perceptions of the general public regarding the pandemic and the performance of the communication of the government, the MoH commissioned a perception survey in October 2020. The survey confirmed that while 90% understood and supported the public health measures, 45% of surveyed individuals deplored the poor communication efforts from the government.

For the purpose of the additional financing, the MoH has prepared a preliminary Stakeholder Engagement Plan (SEP) based on the national COVID-19 vaccination strategy and other documents produced by the Ministry of Health, that identifies the key stakeholders, outlines the engagement mechanisms, and looks at options for managing grievances and requests for information. The SEP will be disclosed on the MoH and World Bank's websites prior to appraisal and



will serve as one of the reference documents for the preparation of the SEP update to be prepared prior to effectiveness as well as any other COVID-19 vaccination stakeholder engagement and communication activities.

The preliminary SEP identifies the following main stakeholder groups: (i) affected stakeholders, which include: vaccine beneficiaries that have been defined for this first phase and listed among the priority groups outlined above, future vaccine beneficiaries who are not yet included in the early phases of the vaccination program (and who may perceive themselves as negatively affected), vaccination agents who will be identified by the MoH among health staff from the public sector, the Ministry of Health and other technical and local agencies involved in the implementation of the early phases of the vaccination campaign, and finally vaccine manufacturers from whom acquisitions will be made; (ii) concerned stakeholders: this group includes various government agencies across sectorial lines and local administrations, health staff from the public and the private sector, the federation of private health services, as well as other private groups and organizations (e.g. community leaders, mass media, NGOs), and the general public; (iii) vulnerable stakeholders, who cut across both groups mentioned above, and include the illiterate, the elderly living alone, illegal migrants, the homeless, and individuals in the priority groups who are disabled or live in remote areas.

The key objectives of the preliminary SEP are to (i) inform the general public, the priority groups and health care workers about the vaccination program, its phases and implementation calendar; (ii) communicate in a uniform and transparent manner about the efficacy and safety of the vaccine(s) proposed to be administered, their side effects, the associated environmental and social impacts of their deployment and administration, and about the recommendations of public health authorities; (iii) explain the prioritization rationale; (ii) provide clear, uniform and coherent communication about the vaccination program and in particular during the early phases; and (vi) put in place a system for managing complaints and request for information.

Moreover, the preliminary SEP outlines indicative messages ranging from practical information about the vaccination activities timelines and locations to the importance of maintaining public health measures (i.e. masks, social distancing, etc.). The preliminary SEP highlights the rationale for the vaccine strategy prioritization and allocation, proposes mechanisms to dispel disinformation, outreach strategies for second-dose reminders, and outlines the framework for a mechanism to address grievances and requests for information. This mechanism will also be reflected in the updated ESMF.

Given the contagious nature of the disease, the preliminary SEP advocates for a precautionary approach that favors the use of information technology and limits public meetings with a large number of participants. Any face-to-face interactions will require mask wearing and social distancing. Among potential engagement mechanisms listed in the preliminary SEP are the use of surveys and mass media (radio, television, newspapers) for daily press conferences, articles and awareness campaigns; the use of social media (e.g. Facebook, Twitter); the publication of information on a dedicated website or a dedicated page on the MoH website; and the use of visual support materials such as billboards, posters and pamphlets.

The MoH is looking at different options for the grievance redress mechanisms. Of late, the ministry is considering setting up a toll-free number dedicated to the vaccination program. The toll-free number would have different functions, including responding to questions from the general public, registering citizens for their vaccination appointment, as well as receiving grievances. The details on how the grievances will be dispatched to the responsible entities or timeframe for addressing grievances have not yet been specified, but the MoH is aware that any



mechanism will have to allow for anonymous grievances to be submitted and the capacity to manage sensitive grievances such as GBV/SEA incidents.

Stakeholder Engagement activities, including the implementation of the SEP, and communication and outreach activities will be financed by the project. Communication activities may also be supported by other donors and multilateral agencies.

B.2. Specific Risks and Impacts

A brief description of the potential environmental and social risks and impacts relevant to the Project.

ESS2 Labor and Working Conditions

The key workers directly associated with the project include the five members of the UGPO who are all civil servants. Other direct workers include around 10 individual consultants that will be hired to support the day-to-day activities of the UGPO. The number of employees from contracted workers is not known at this stage, but is expected to include the personnel from the communication firm and companies who will be working on the vaccination communication campaign. Contracted workers include the employees to be hired to perform the minor civil works associated with the cold storage facilities. The project may rely on volunteers according to the national strategy.

Primary suppliers are expected to be international pharmaceutical manufacturers undergoing Phase 3 trials (e.g. Pfizer, Moderna, Astrazeneca, Johnson and Johnson, Novavax) approved by the SRAs and from which the Tunisian government will acquire the vaccine products, companies producing vaccine administration supplies (e.g. needles, syringes, alcohol pads, vaccines refrigerators) and cold chain equipment suppliers. A retainer contract has already been secured by the Ministry of Health with Pfizer for two million doses. In the contract conditions, the vaccine products will be delivered up to the all the main vaccination sites by Pfizer directly. This is expected to differ with other vaccine manufacturers that the MoH may purchase.

During the first phases of the vaccination program, it is expected that all COVID-19 vaccination agents will come from the public sector and be pre-authorized by the MoH. They will include staff from public hospitals and health centers as well as civil servants physicians working in various Ministries (e.g. Ministries of Education, Social Affairs, Defense). These vaccination agents currently work as civil servants and will not have direct contractual obligations with the project.

Overall, the key risk associated with ESS2 is the risk of exposure of the project workers to the virus during vaccine deployment and administration. Other risks relate to stress management. The project is not expected to generate labor influx or lead to the risks of child or forced labor.

The LMP of the parent project was approved by the Bank and disclosed on the World Bank and Ministry of Health websites in September 2020. The LMP outlines the COVID-19 health and safety and infection control protocols developed by the MoH in line with the World Health Organization's (WHO) guidelines. The LMP of the parent project also highlights the grievance mechanisms (i.e. "Shocroom") available to health care workers that have been put in



place at the national level. This grievance mechanism allow workers to quickly inform management of labor issues, such as a lack of PPE and unreasonable overtime.

Healthcare workers play a critical role in outbreak response and are the backbone of a country's defenses to limit or contain the spread of disease. They face higher risks of potential COVID-19 infection in their efforts to protect the greater community and are exposed to hazards such as psychological distress, fatigue and stigma. They will be prioritized for early vaccination.

Worker safety: Healthcare associated infections due to inadequate adherence to occupational health and safety standards can lead to illness and death among the staff from public hospitals and health centers as well as civil servants physicians working in various Ministries (e.g. Ministries of Education, Social Affairs, Defense). The Vaccine centers to be supported by the project will process COVID-19 and will therefore have the potential to cause serious illness or potentially lethal harm to the staff and to the community, so effective administrative and containment controls will be put in place to minimize these risks. Environmentally and socially sound health facilities management will require adequate provisions for minimization of occupational health and safety risks, proper management of hazardous waste and sharps, use of appropriate disinfectants, proper quarantine procedure for COVID-19, appropriate chemical and infectious substance handling and transportation procedures, etc. These measures are covered in the ICWMP contained in the updated ESMF and are based on the national healthcare delivery standards and norms set by the MoH in addition to WHO guidance.

The LMP will be updated to take into account the activities of the additional financing, and reflect the new categories of workers to be included, the COVID-19 mitigation measures to limit transmission among the project workforce during the vaccine deployment and administration as well as the training requirements in the administration of the COVID-19 vaccine. For some activities under the AF, the Parent Project LMP will be used until the finalization of the updated instrument.

ESS3 Resource Efficiency and Pollution Prevention and Management

The AF vaccine activities will generate medical wastes from vaccines centers that could include infected materials (lab solutions and reagents, syringes, etc.) and which would require special handling and awareness, as they may pose an infectious risk to healthcare workers in contact or handling the waste, chemicals and other hazardous materials. These could have substantial impact on the environment and human health.

Each beneficiary medical facility/lab, following the requirements of the updated ESMF, WHO COVID-19 guidance documents, and other good international practices, will prepare and follow the updated Infection Control and Medical Waste Management Plan (ICMWP) outlined in the updated ESMF to prevent or minimize such adverse impacts. The updated ESMF will include the biomedical management plans for the vaccination sites that do not have an ICMWP in place, such as schools. The updated ESMF will include guidance related to transportation and management of vaccines and medical goods or expired chemical products as recommended in healthcare infections control practices in line with United States CDC and WHO environmental infection control guidelines for medical facilities.



The updated ESMF will include mitigation measures related to the pollution management of electrical and electronic wastes (EEW) and the energy resource consumption of the equipment of the cold chain. The updated ESMF will propose a waste management plan for the EEW and will develop the best practices available in the cold chain sector concerning energy consumption. The updated ESMF will propose waste management plan related to the small works for the rehabilitation of cold storage facility as well as management of risks/impacts linked to Occupational Health and Safety, community Health and safety, management of dust, noise and effluents during these rehabilitation works. The updated ESMF will also prohibit the use of equipment with cooling gases attacking the ozone layer as stipulated in Montreal protocol and Tunisian national legislation.

ESS4 Community Health and Safety

In terms of community health and safety, only vaccines that were approved by SRAs in three regions or WHO prequalified and approved by 1 SRA will be considered. Given the scale of the vaccination program, there is a risk for possible adverse side effects following immunization. Another risk is the exposure of beneficiaries to COVID-19 while waiting in line or during vaccine administration. Increased exposure could also result from COVID-19 vaccinated individuals failing to follow public health measures following immunization in a context where the vaccine is not highly efficacious or does not have the capacity to neutralize the transmission of the virus. Other exposure risks are related to the poor management of infectious medical waste that could potentially infect the wider community.

Another key community health and safety risk is the poor management of vaccines cold chain storage, which could lead to lower vaccine efficacy. The poor management of vaccine registries has also been identified as a risk, as a poor management system could lead to mix-ups or limitations to successfully administer second doses. This in turn could lead to harmful drug interactions or reduced efficacy. In terms of gender based violence and sexual exploitation and abuse (SEA), the risks directly associated with the additional financing are low. Outside the potential for incidents associated with the use of mobile clinics, which numbers are not yet known at this stage, all vaccination activities will be administered in vaccination sites, such as regional sites, primary schools, hospitals, and basic health centers, and are conducted with an open door policy.

The project will use the military physicians to vaccinate military personnel and to secure vaccine deployment activities and vaccination centers. The military in Tunisia is highly professional and enjoys the trust and support of the population. There are no known incidents of SEA involving members of the military. It has stayed neutral and protected civilians in the latest upheavals of the Tunisian revolution. Based on the above and the fact that the military's involvement is yet to be confirmed at this stage, SEA risks associated with the military is rated as low.

The updated ESMF will clarify additional measures that will be put in place by the MoH if necessary to (i) monitor serious adverse post immunization effects. The surveillance system of the adverse events following Immunization in line with WHO guidelines would be established and elaborated in the updated ESMF ; (ii) protocols to confirm consents from individuals to be vaccinated; (iii) minimize the risk of exposure during vaccine administration (i.e. masks wearing, physical distances and limitation of public and social gathering); (iv) ensure that the cold chain management meets the vaccine requirements by establishing a vaccine cold chain transport and storage temperature monitoring measures in line with WHO/CDC guidelines as example of GIIP. (v) maintain registries to monitor vaccine allocations; (vi) propose measures in case of incidents involving the military and systems for incident monitoring and



(vii) ensure vaccine administration is done publicly with an open door policy. The SEP will include messaging that emphasize the importance of keeping public health measures throughout the vaccination program as well as remind vaccinated individuals of their second dose date. The infection control and waste management plan is already included in the original ESMF of the Parent Project and will be updated to cover the new vaccination activities.

ESS5 Land Acquisition, Restrictions on Land Use and Involuntary Resettlement

NA

ESS6 Biodiversity Conservation and Sustainable Management of Living Natural Resources

NA

ESS7 Indigenous Peoples/Sub-Saharan African Historically Underserved Traditional Local Communities

NA

ESS8 Cultural Heritage

NA

ESS9 Financial Intermediaries

NA

C. Legal Operational Policies that Apply

OP 7.50 Projects on International Waterways No

OP 7.60 Projects in Disputed Areas No

B.3. Reliance on Borrower’s policy, legal and institutional framework, relevant to the Project risks and impacts

Is this project being prepared for use of Borrower Framework? No

Areas where “Use of Borrower Framework” is being considered:

None

IV. CONTACT POINTS

Public Disclosure



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Borrower/Client/Recipient

Borrower: Republic of Tunisia

Implementing Agency(ies)

Implementing Agency: Ministry of Health

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VI. APPROVAL

Task Team Leader(s):	Fatima El Kadiri El Yamani, Denizhan Duran
Practice Manager (ENR/Social)	Pia Peeters Cleared on 29-Jan-2021 at 10:43:53 GMT-05:00
Safeguards Advisor ESSA	Gael Gregoire (SAESSA) Concurred on 01-Feb-2021 at 10:08:14 GMT-05:00

Public Disclosure