Additional Financing Appraisal Environmental and Social Review Summary

Appraisal Stage

(AF ESRS Appraisal Stage)

Date Prepared/Updated: 12/08/2021 | Report No: ESRSAFA299

BASIC INFORMATION

A. Basic Project Data

Country	Region	Borrower(s)	Implementing Agency(ies)
Madagascar	AFRICA EAST	Government of Madagascar	Ministry of Public Health

Project ID	Project Name
P178279	Additional Financing to Support to COVID-19 vaccine purchase and health system strengthening

Parent Project ID (if any)	Parent Project Name
P176841	Support to COVID-19 Vaccine Purchase and Health System Strengthening

Practice Area (Lead)	Financing Instrument	Estimated Appraisal Date	Estimated Board Date
Health, Nutrition & Population	Investment Project Financing	12/2/2021	12/30/2021

Proposed Development Objective

This Project's Development Objective is to support the Government of Madagascar to acquire and deploy COVID-19 vaccines, and to strengthen its immunization services.

Financing (in USD Million)	Amount
Current Financing	100.00
Proposed Additional Financing	41.00
Total Proposed Financing	141.00

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

Yes

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

The Project objectives are aligned to the results chain of the COVID-19 Strategic Preparedness and Response Program (SPRP).

Project DO statement: The PDO of the parent project and this AF is to support the Government of Madagascar to acquire and deploy COVID-19 vaccines, and to strengthen its immunization services.

PDO level indicator: Percentage of the population fully vaccinated, based on prioritized populations as defined in national plan, by gender;

Project Components

The changes proposed for the AF entail scaling up of activities in the parent project Madagascar Support to COVID-19 Vaccine Purchase and Health System Strengthening The PDO will remain unchanged. The costs of the existing components 1 and 2, will be revised . The content of the components and the Results Framework of the parent project are adjusted to reflect the new activities proposed under the AF. The Closing Date remains June 2024.

Component 1: Acquisition of vaccines and medical supplies [originally US$71 million; with proposed AF, US$80 million]

The implementation of the activities under the parent project will continue without any changes. The project will continue to finance: (i) acquisition of vaccines for priority groups defined in NVDP; (ii) acquisition of vaccination supplies needed for activities outlined in the VDDM including diluents, syringes, and medical supplies associated with the vaccination response.

Changes: Under this component, the parent project will be able to procure more doses with the allocated budget than initially planned in the PAD as the country opted for single dose J&J which costs less. That will represent 8 million vaccines to cover 27% of the population. The AF will finance: (i) acquisition of COVID-19 vaccine doses to cover an additional 3 percent of the population and so the total of 9 million doses purchased by the Project will contribute to the government's plan to reach 50.5 percent COVID-19 vaccination coverage by June 2023; and (ii) acquisition of vaccination supplies needed to vaccinate the additional proportion of the population such as diluents, syringes, and all medical supplies associated with vaccination. The country is considering vaccine purchase via COVAX, as the Janssen vaccine is now available through the cost-sharing mechanism. The cost-sharing framework agreement was signed on November 26, 2021. WBG procurement arrangements for vaccines through COVAX are still being finalized.

Component 2: Strengthening health system for the effective deployment of vaccines [originally US$29 million; with proposed AF, US$61 million]

The implementation of the activities under the parent project will continue without any changes. The project will continue to finance: (i) strengthening of vaccine logistics system, cold chain and vaccination sites (storage and transportation); (ii) strengthening surveillance and information systems including vaccine safety and AEFI monitoring; (iii) strengthening planning and coordination capacity including training of health workers/vaccinators and waste management; (iv) communication campaign to address vaccine hesitancy and (v) operating costs.

Changes: Under this component, the AF will finance activities to scale up (i) deployment of health professionals to deliver the additional doses procured through this AF; (ii) purchase of additional equipment for vaccines distribution (cold chain equipment, vehicles and motorbikes) and data reporting (tablets and computers); (iv) additional technical assistance for the deployment of vaccines, including for communication and demand creation based on a geographic mapping of pockets of hesitancy and for utilization of drones for vaccines transportation in remote areas (this will be contracted with private operators specialized in drones utilization)and (v) incentives for community health workers and mobilizators (incentives to be received by community health workers would be linked to number of people referred to vaccination sites. An independent organization will be contracted for the payment and payments will be based on properly validated statements).

Component 3: Contingent Emergency Response

D. Environmental and Social Overview

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

A southern African island state located in the Indian Ocean, Madagascar is the fifth largest island in the world with an area of 587,000km2 and 25.6million inhabitants. Living conditions remain difficult for the vast majority of the population, with a low rate of access to electricity (13%) in particular. Despite abundant natural resources, the country is one of the poorest countries in the world and lags on human capital indicators, including high rates of malnutrition, stunting and out-of-school children.

Madagascar declared a state of health emergency due to the global COVID-19 pandemic (decree 2020-359 of March 21, 2020) and has since then alternated health emergency and “regular” situations. The first health emergency was lifted on October 18, 2020. It was reinstated early April 2021 due to the second wave (decree 2021-390 of April 03, 2021) and lifted again on September 04, 2021. As of November 3, 2021, Madagascar reported 42,935 cases and 964 official deaths from Covid-19 since the start of the outbreak. The first cases (three imported) were confirmed on March 20, 2020 and a first peak was reached in July/August 2020 (number of cases multiplied by four in a month), with the highest number of new cases per day at 360. While the capital city of Antananarivo was impacted the most, all 22 regions of the country were affected. The epidemiological situation worsened with the second wave with presence of the South-African variant, that hit Madagascar in March-April 2021, with over 600 new daily cases (and peak on April 14, 2021 with 854 new cases). The death rate (now estimated at 2.12 percent compared to 1.4 percent in 2020) has also increased.

Madagascar began its vaccination campaign on May 10, 2021. As of November 2, 2021, 1,898,990 vaccine doses have arrived, of which 547,311 doses have been administered, and 346,823 individuals (1.2 percent of the total population) have been fully vaccinated. Additional 2,622,400 doses are expected to come over the next months, which will be complemented by those procured under this AF.

The AF would support the costs of expanding activities of the Madagascar Support to COVID-19 Vaccine Purchase and Health System Strengthening (P176841). The primary objectives of the AF are to enable affordable and equitable

access to COVID-19 vaccines and help ensure effective vaccine deployment in the Madagascar through vaccination system strengthening, and to further strengthen preparedness and response activities under the parent project. The AF will allow the government to acquire and deploy doses to cover an additional 17 percent of the population and contribute to reach the government's ambition to reach 50 percent COVID-19 vaccination coverage by June 2023. The proposed AF will form part of an expanded health response to the COVID-19 pandemic and maintain government's commitment to provide free of charge COVID19 vaccines in public and private health facilities using national Expanded Program of Immunization (EPI) vaccine delivery system.

The new activities under the AF that may have E&S impact are: (i) technical assistance for use of drones for vaccines transportation in remote areas, communication, evaluation of information system; (ii) purchase medical equipment such as scanners and ambulances for the COVID-19 response; (iii) strengthening cold chain logistic; (iv) increasing access to, and use of, medical facilities and associated generation of medical waste.

Identification of target groups was informed by (i) the WHO SAGE recommendations in terms of prioritization of vulnerable populations; (ii) recommendations from the Scientific Committee supporting the Government in the COVID-19 response, and (iii) local epidemiological data.

The Government of Madagascar revised the National Deployment Vaccination Plan (NDVP) in September 2021 after careful review of local and international evidence and lessons:

- Change to the Covid-19 vaccination strategy: Initially, it was planned to vaccinate the priority target populations first during the first immunization campaign, and then move on to the other categories. However, statistics showed that the populations outside the priority categories were the most active. Therefore, it was decided to open up vaccination to people aged 18 and over, but to vaccinate the priority targets first at the vaccination sites. This flexibility is maintained for the rest of the Covid-19 vaccination, which will now be done in routine mode.
- Changes to the vaccine deployment strategies: Basic health facilities with a doctor and a functioning refrigerator (solar or electric) will be identified as a vaccination site. Vaccination will be carried out closer to the targets by increasing the number of fixed sites, including health centers, advanced and mobile strategies. The mobile and advanced strategies will be adopted for the vaccination of populations far from fixed sites, particularly in rural areas, on the one hand, and groups of more than 50 people in urban and peri-urban areas, on the other. The participation of private health facilities in the vaccination against Covid- 19 contributed to the achievement of the objectives during the first vaccination campaign. This good practice will be maintained and developed.

To strengthen national vaccine pharmacovigilance capacity, a notification form and specific Adverse Event Following Immunization (AEFI) case definitions related to the administration of the Covid-19 vaccine were developed by the central level following the guidelines established by the WHO.

Regarding the cold chain, the current vaccine logistics system and cold chain have significant weaknesses. The project will alleviate some of the constraints by providing support at all levels of the system. Support for cold chain improvements may include procuring and installing warehouses, cold rooms, fridges, freezers, cold boxes, vaccine carriers to focus not just on COVID-19 vaccine but the upgrade of the entire cold chain (including routine vaccines) should lead to energy efficiency savings as facilities are modernized or fitted with more energy efficient equipment resulting in reductions in energy savings and positive GHG reducing impacts. In the case of cold chain equipment, this means procuring and installing Solar Direct Drive Refrigerators and WHO PQS certified climate friendly refrigerators/freezers.

The Project will be nationwide, including urban, rural and peri-urban areas. Interventions will involve all health access levels from the national, through regions-districts-communes, to the community level. The exact locations of the project activities are not known at this stage but the interventions are nationwide. The AF will be covered by existing E&S instruments that were developed for the parent project, considering the necessary updates.

The parent project has been declared effective in September 2021, and the ES risk management instruments, were approved by the RSA and published in October. The PIU has implemented WB safeguard measures satisfactorily for several years under the project PARN (P160848) including AF for COVID-19 response measures. They have successfully implemented medical waste management procedures in urban and rural health facilities and have in place procedures for COVID vaccine deployment through the parent project.

D. 2. Borrower's Institutional Capacity

Like the parent project, this AF will be implemented by the UCP (Unité de Coordination de Projets) with the Ministry of Public Health (MPH) in Madagascar, which is also implementing the Improving Nutrition Outcomes using the Multiphase Programmatic Approach-PARN (P160848) with its 2 additional financings (Covid-19 response-CERC replenishment and P174669- Improving Nutrition Outcomes using the Multiphase Programmatic Approach PEF Covid 19), and also financing from other partners (GAVI and Global Fund). The MPH has more than 15 years of experience working with World Bank Safeguards, but less experience in ESF implementation.

Current E&S staff at the UCP covering all WB health projects are: 01 senior E&S safeguard specialist, 01 environmental safeguard specialist, 01 social safeguard specialist (social mobilisation, communication and SEA-SH) and a technical team of MPH assisting on medical waste management. At the national level, there is the national office for the environment (ONE - Office National pour l'Environnement). ONE's missions are prevention of environmental risks in public and private investments and pollution control, management of the environmental information system, monitoring and evaluation of the state of the environment to support environmental assessment and better decision making at all levels and environmental labelling and certification.

The results of the capacity assessment and the respective capacity building plan are included in the parent project ESMF; staffing and capacity building obligations are included in the ESCP. The parent project was effective on July 26, 2021 and has not yet made any disbursements, so is at an early stage of implementation. The implementation progress of the parent project has been satisfactory so far. The UCP had filled E&S staffing positions, carried out communication campaigns and consultations, operationalized the grievance mechanism (GM), and also put in place COVID-19 safety measures in accordance with the Stakeholder Engagement Plan, ESMF, and Labor Management Procedures.

An MoU to clarify the roles of the various agencies (WHO, UNICEF, etc.) involved should also be considered. Agencies involved to support project activities will follow the Project's ESMF and comply with all relevant ESSs.

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

A. Environmental and Social Risk Classification (ESRC) Substantial

Environmental Risk Rating Substantial

The environmental risk rating remains substantial given that AF activities will be the same of parent project, with no addition new activities or components, but just scaling up existing components. Each of the various stages of the vaccine deployment and vaccination processes are likely to entail occupational health and safety (OHS), environmental and social issues, and mass vaccination centers may pose risks for vaccinators, especially when performed in non-traditional settings and in high volumes. The main environmental risks identified are related to: (i) Occupational Health and Safety issues as workers in healthcare facilities and laboratories that may be exposed to infectious disease contagion, including use and disposal of medical supplies and chemicals for cleaning and disinfection; (ii) medical and pharmaceutical waste management issues related to waste handling and collection, transportation and disposal of hazardous and infectious healthcare and laboratory waste, (iii) community health and safety related risks such as increased risk of COVID-19 or other infectious disease transmission. In addition, vaccine transportation and distribution will entail road safety risks. Standards for vaccine management including chain cold infrastructure are required because COVID-19 vaccine products are temperature-sensitive. The current vaccine logistics system and cold chain have weaknesses and may present a risk to the safety of services which could affect the quality and effectiveness of vaccines. The use of drones for transportation generates others specific issues as licences requirements as well as additional environmental risks related to its drone crash and public health issues and the risk of leakages due to substandard packaging materials. There may also be additional risks related to public perception (or lack of awareness) arising from the use of drones. Other risks associated with the project activities include community health and safety risks from incorrect vaccine storage, handling and transportation practices leading to vaccine quality deterioration. Another factor within the environmental risks is the Borrower's E&S capacity to manage E&S risks and impacts. Their capacity is being assessed and appropriate capacity building measures will be included in the project and outlined in the ESMF. Moreover, Component 2 will enhance capacity of implementation which will be undertaken through technical assistance activities (including immunization system strengthening including the strengthening capacities of key personnel in logistics, cold-chain, human resources, etc.) that have diffused and induced impacts, often playing out over a longer term. To mitigate the above risks and impacts, the parent project has prepared, consulted upon, and disclosed an Environmental and Social Management Framework (ESMF) and a National Medical Waste Management Plan (NMWMP) and a LMP. The ESMF covers a broad range of environmental aspects including: ESS1 – environmental risks screening forms, Environmental and Social management Plans (ESMPs), and training requirements (vaccine delivery and health care waste management); ESS2 – occupational health and safety measures as per the WHO, CDC, WB Environment Health and Safety (EHS) Guidelines and other Good International Industry Practice (GIIP); ESS3 – pollution, water and energy resource consumption and management of the WASH facilities and equipment of the cold chain; ESS4 – infection control and prevention measures to limit the spread of COVID-19 during the vaccination activities and Emergency Response Plan. The AF does not make relevant any new ESSs or brings new environmental risks and impacts to the parent project.

Social Risk Rating Substantial

In line with the World Bank ESF guidelines, the social risk rating has been determined to be Substantial. It is expected that project activities will have essentially positive social impacts by supporting the country's specific

needs in preventing the spread of the Covid-19 and limiting immediate socioeconomic losses, as well as strengthening public health and essential medical care structures and operations to build resilience and reduce the risk from emerging and re-emerging pathogens. Project activities consist mainly of purchasing medical equipment and inputs, technical assistance and capacity building; and will not involve involuntary resettlement and cultural heritage issues. In addition, the AF activities will involve the use of drones to ensure the effective deployment of vaccines to the very remote areas. The main social risk are (i) that vulnerable and high-risk social groups, first targets of the vaccination campaign, are unable to access the Covid-19 vaccination, due to lack of information, distance from health centers, and possible elite capture, (ii)Covid vaccination (safety and efficacity) is still a subject of debate, so very sensitive to communicate, and presents a risk of non-acceptance which could lead to social unrest and tensions (iii)-related risks such as increased risk of COVID-19 transmission (including through inadequate medical waste management) and adverse events following immunization, as well as (iv) risks resulting from inadequate or conflictual public engagement and inadequate consultation Given that there is limited experience with drone use in-country especially in hard to reach areas, significant efforts need to be made to educate communities especially those within the drone path or corridor to ensure acceptance. Project implementation will also involve different types of workers including PIU staff, health civil servants, local CSOs staff, and community health workers which may raise OHS concerns. In addition to OHS concerns, healthcare workers and researchers may face reprisals and retaliation. Finally, the PCU has limited capacity and experience in managing social risks under the ESF.

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:

Similar to the parent project, ESS1 is assessed as relevant for the AF. The project is not expected to involve any activities that could generate significant and irreversible environmental and social impacts. Nonetheless, there are wide-ranging environmental and social risks and impacts that will need to be assessed and managed through a risk-based approach.

Activities under component 1 will acquire and deploy Covid-19 vaccines, and could present environmental, social, health and safety risks for the project workforce and communities. Key E+S risks include: (i) OHS issues as workers in healthcare facilities and laboratories that may be exposed to infectious disease contagion; (ii) medical and pharmaceutical waste management issues related to waste handling and collection, transportation and disposal of hazardous and infectious healthcare and laboratory waste; (iii) vaccine transportation and distribution from storage will entail road safety risks; (iv) community health and safety related risks. All project activities, ranging from operation of health centers and vaccine distribution to community engagement interactions, present a risk of transmission in the community. The operation of health centers have a high potential of infecting the wider population if not systematically managed and well controlled; (v) potential risks around exclusion of vulnerable groups to access project supported services and facilities and/or vaccines, and risk of elite capture. Real or perceived inequities also have the potential to lead to conflicts and citizen unrest; and (vi) SEA/S-H risks. The project will put in place recommended SEA/SH mitigation measures, including code of conduct for all workers.

The activities of the AF will include, in component 2, the use of drones to deliver vaccines to remote areas of Madagascar which may induce several risks such as: (i) risk of drone crash and public health issues. Since these are vaccines and not specimen samples there is limited risk of exposure to the active virus in the event of any drone crash; (ii) risk of leakages due to crash or substandard packaging materials if the vaccines are not well packaged; (iii) risk of disruption to other airspace users and people and property on the ground; (iv) risk of crashes in areas that could have a negative impact on biodiversity conservation and sustainable management of living natural resources; (v) risks related to privacy and security, this risk might be moderate where the drone is not programed to take pictures and video ; and (vi) Stakeholder Engagement risk given that there is limited experience with drone use in-country, especially in hard to reach areas and efforts for community education, especially those within the drone path, to ensure acceptance will be undertaken. Due to limited information that is available at this stage, E&S impacts / risks related to the use of drone must be properly addressed in the ESMF, including but not limited to noise nuisance, people injury due to drone malfunction/fall from height, potential damage to Flora / Fauna etc..

Prior to the activity implementation, licenses will be acquired to ensure that drone operations are in compliance with regulations of national civil aviation authorities and GIIP.

As the project plans to provide vaccination against Covid-19 to specific/identified beneficiaries of the population, certain hesitancies remain regarding efficiency, side effects, geographical distribution and choice of target groups to be vaccinated, safety storage and transport and social acceptability. The introduction of the Covid-19 vaccine can in this case cause social controversy and tension on a large scale. The project will implement a SEP to ensure appropriate stakeholder engagement, proper awareness raising and timely information dissemination.
The following categories are considered disadvantaged or vulnerable: elderly people living alone, illiterate people, people with reduced mobility, people among prioritized categories for vaccination living in remote areas, people with disabilities, homeless people, registered and unregistered migrants and women, especially victims of GBV. The main barriers disadvantaged or vulnerable may encounter are: lack of access to information, lack of or inadequate travel means (including financial) and constraints in accessing health care services (due to distance or reduced mobility). Measures to address those barriers are set out into the SEP and the SIA in the ESMF.

The NVDP includes measures to ensure fair, equitable and inclusive access to vaccines for target groups, including pre-registration at the Fokontany level and collaboration with health professional boards or the diabetes association. In rural and hard-to reach regions, community health workers will sensitize target populations. In the south of Madagascar, the population displaced by the humanitarian crisis will be particularly considered.

The NVDP also highlights distribution platforms, including storage and conservation, demand promotion to reach eligible populations by June 2023 with free and voluntary vaccines, monitoring and evaluation mechanisms to capture complete, timely, and accurate COVID-19 data for evidence-based decision making, and tools and mechanisms for implementation management and pharmacovigilance, specifically vaccine safety monitoring, Adverse Events Following Immunization management and injection safety. Protocols for consent to vaccinations are established. Individual consent form is signed at registration.

Component 2 will focus on technical assistance and capacity building and the development of procedures for better surveillance and supply and distribution of Covid-19 vaccines. There are limited civil works expected in this project

related to cold chain improvement, the activities will take place in the existing area of health services and vaccination centers. Any potential risks related to those civil works will be detailed in the ESMF.

Under component 3 (CERC), the project will facilitate access to rapid financing by allowing reallocation of uncommitted project funds in the event of a natural disaster or a state of emergency. Prior to the start of emergency response activities, the request to activate this part shall come from the implementer with prior No Objection from the Association. The ESMF includes a section to screen an indicative list of activities related to emergencies likely to occur in the country. If proposed activities fall within the scope of the positive list agreed in the CERC Manual, and considered in the Project ESMF, no additional E&S work is needed. If not, the Borrower must update this section to conduct an E&S assessment of emergency activities before they are initiated. In this case, the updated ESMF shall be consulted upon and disclosed.

Increased technical capacity for testing, vaccine distribution, use of medicines or medical waste could lead to downstream risks; these will be managed through the implementation of the NMWMP and guidance on destruction of expired medicines.

To assess and manage these risks and impacts consistent with the ESF, the Project will update the ESMF of the parent project that outlines the procedure for screening, classifying, assessing, monitoring and reporting each project activity, commensurate to the risk. The ESMF describes all the practices for handling, storing, treating, and disposing of hazardous and non-hazardous waste, as well as types of worker training required including training of staff to be aware of all hazards they might encounter. The ESMF also evaluates and addresses any risks associated with cold chain in managing hazardous/medical materials or agents as needed. The updated ESMF will consider risks related to the use of drone.

All project activities shall be subject to environmental and social screening and where necessary specific instruments shall be prepared before commencement of applicable project activities and outlined in site-specific ESMPs. This will provide for the application of best practices in COVID-19 diagnostic testing, vaccine distribution and handling the medical supplies and disposing of the generated waste. Safe work protocols shall be developed and implemented for hazardous tasks. Health screening and COVID-19 prevention measures for workers will be incorporated into the OHS procedures outlined in the ESMPs. Emergency response and handling procedures shall be developed to handle any accidents on site.

The management of medical and biomedical waste is addressed in the existing NMWMP. The NMWMP that has been prepared and disclosed for the PARN Project (P160848) in April 2020 was updated to include particular measures related to COVID-19 vaccines such as risks related to the transport, storage, handling and disposal of vaccines. The updated ESMF needs to reflect and adress the cumulative impacts due to waste generation from several locations that could lead to additional stress on existing waste management facilities.

Measures will also be taken to support citizen engagement, including the existing GM, and to address SEA/SH. Community sensitization and capacity building activities will be carried out in order to engage the project's key stakeholders in E&S risks management and to ensure project ownership. For the AF, the SEP of the parent project has been updated to include the new stakeholders of the AF and the specific measures needed to ensure that the flight

maintain a high standard of cultural sensitivity and cause minimum disruption to the lives of populations under the flight path.

The Borrower has updated : (i) the ESCP and SEP (including GM). The AF will use the updated NMWMP, and the ESMF (including SIA, SEA-H action plan, a capacity assessment and a capacity building action plan) and the LMP will be updated, disclosed, consulted and adopted as conditions of disbursement.

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ESS10 Stakeholder Engagement and Information Disclosure

Like for the parent project, ESS10 is assessed as relevant for the AF. The project's Stakeholder Engagement Plan (SEP) outlines a structured approach to engagement with stakeholders that is based upon meaningful consultation and disclosure of project information, considering the specific challenges associated with COVID-19 with consultation and communication methods adapted in the light of the pandemic. For the AF, the SEP has been updated and has been disclosed prior to appraisal.

A range of stakeholders have been identified in the SEP (affected groups and other groups), among which disadvantaged or vulnerable groups who have barriers to access to health services or health information campaigns, groups who may have distrust of government health programs, groups who may be hesitant of health interventions such as vaccinations for cultural reasons and affected populations under the drone's trajectory.

Consultations were carried out during the preparation phase, which identified inputs which will inform the design and implementation of the project. The SEP also provides clear strategy and actions for information disclosure, consultation and stakeholder engagement. The SEP included guidelines to ensure that the risk of spread of COVID-19 among stakeholders during consultations is minimized. It focuses on clear and accessible messaging on safety of vaccines, principles of fair, equitable and inclusive vaccines access and allocation, as well as rationale for prioritizing certain groups.

An important part of stakeholder engagement activities are communication campaigns and behavioral change interventions to address vaccine hesitancy and inequitable distribution of vaccines.

The AF will use the GM that the parent project has built on the GRM of the PARN project. Thus, the SEP outlines an updated Grievance Mechanism (GM) with specific consideration to vaccination. The GM integrates GBV-sensitive measures, including multiple channels to initiate a complaint and specific procedures for SEA/SH, such as confidential and/or anonymous reporting with safe and ethical documenting of GBV and SEA/SH cases. After 4 months implementation, the GM of the vaccine project has recorded 102 complaints, a third of which concern the lack of information, more precisely, the inadequacy of clear guidance on the availability of vaccines, the characteristics of these vaccines and the nearest vaccination site.

Through the SEP, the project will ensure that information is meaningful, timely, and accessible to all affected stakeholders and, particularly, populations that are most at risk, project sites, neighboring community, health workers, waste handlers and the project workers. A Communication and Social Mobilization specialist has therefore been engaged for the project.

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

ESS2 is relevant for the parent project and AF. The project activities will be carried out by a Project Implementation Unit (PIU) under the Ministry of Public Health. The PIU team will include direct workers, which could be civil servants and consultants hired to support the technical areas for which weak institutional capacities were assessed. The project workforce is also expected to include regional primary caregivers, health administrators, contractors and subcontractors, including potential workers from nearby communities, primary supply workers and other partners (local CSOs). Workers can be exposed to a wide variety of risks such as (i) occupational health risks at the workplace due to hazardous chemicals, unsafe machines; (ii) occupational safety risks from work-related accidents; (iii) pathogen exposure, infection and associated illness, death (iv) passing on infections to family and community (v) non-respect of workers' rights, illegal and untenable overtime, psychological distress, fatigue, occupational burnout and (vi) SEA/SH risks. The government will ensure that all project workers are adequately instructed and trained, on a regular basis, on prevention and reporting procedures available for SEA-H as set out in ESMFand SEP.

To manage risks related to Project workers, a Labor Management Procedures (LMP) was prepared for the parent project and disclosed which (i) respond to the specific health and safety issues posed by COVID-19, and (ii) protect workers' rights as set out in ESS2. The terms and conditions of the contracts of all the workers involved in the project need to be made in accordance with the national labor law and meet the requirements described in ESS2 to ensure that working conditions be acceptable. The LMP includes the terms and conditions of employment, non-discrimination and equal opportunities, workers' organizations, measures to prohibit child labor and forced labor, grievance redress mechanisms for labor disputes, and occupational safety and health measures for the workers, including SEA/SH for both direct and contracted workers. OHS measures will be included in activity/site specific ESMPs, while for contract workers common risks and impacts will be assessed in the ESMF and an OHS management program will be implemented in according to guidance outlined in the ESMF and subproject instruments, e.g. ESMPs. There are OHS risks associated with the project including elevated risks of COVID-19 transmission and transmission of other communicable diseases due to pricks from sharps. The risks will be managed through OHS guidance outlined in the ESMF, and site/activity specific ESMPs, and in GIIP. The LMP will be updated, as a disbursement condition, to address activities under the AF.

ESS3 Resource Efficiency and Pollution Prevention and Management

This ESS3 standard is relevant for the parent project and AF. Pollution prevention and management – specifically medical waste management – will be a particularly important under the project activities in accordance with good international practices. Medical and pharmaceutical wastes (including water, reagents, infected materials, etc.) are expected to be generated from health facilities to be supported (vaccines, supplies and medical equipment). Additionally the project will generate a high volume of sharps. The improper handling, transporting, and disposal of these medical waste streams may result in adverse impacts to human health and the environment. Liquid contaminated waste may find its way to the soil or any nearby water body if not properly managed. This project will support the Borrower in the preparation of procedures and management of medical waste for the collection and transport of COVID-19 and other related medical waste to disposal sites. All activities related to the waste management (handling, transporting and disposal) should be conducted in accordance with the ESMF and the NMWMP.Regarding the cold chain, the current vaccine logistics system and cold chain have critical weaknesses. The project will alleviate some of the constraints by provide support at all levels of the system. Support for cold chain improvements may include procuring and installing warehouses, cold rooms, fridges, freezers, cold boxes, vaccine carriers to focus not just on COVID-19 vaccine but the upgrade of the entire cold chain (including routine vaccines) should lead to energy efficiency savings as facilities are modernized or fitted with more energy efficient equipment resulting in reductions in energy savings and positive GHG reducing impacts. In the case of cold chain equipment, this means procuring and installing Solar Direct Drive Refrigerators and WHO PQS certified climate friendly refrigerators/freezers to reduce greenhouse gas emissions from fossil fuels. In any activities to install cold-chain equipment in healthcare facilities, emphasis will be place in using clean energy solutions (such as solar and battery systems) to provide continuous power to health facilities and cold-chain equipment, and to reduce operating costs. Analysis of the cold chain management will be included in the ESMF.

The installation of equipment will be required to follow the requirements of site specific ESMPs for the Project, COVID-19 guidance note documents, and other best practices to prevent or minimize such adverse impacts. New site specific ESMPs will be prepared for screened activities that require them. The ESMP will include guidance related to transportation and management of samples and medical goods or expired chemical products. Any activities that have been screened for environmental and social risks will not be carried out until a completed, consulted and disclosed ESMP is prepared. Resources (water, air, etc.) used in the facilities and labs will follow standards and measures in line with guidelines on the management of medical waste. A hazardous waste management plan will be annexed to the ESMF to ensure appropriate management of pollution that may contaminate the air, water or soil. The NMWMP supports national legislation such as the environmental Law 005-2008 related to the measures for environmental permitting and other legislations related to pollution and dangerous substances.

In order to manage hazardous waste, infectious waste, non-hazardous and non-infectious medical waste a National Medical Waste Management Plan (NMWMP) has been prepared. The NMWMP outlines procedures for sorting, handling and disposing of medical waste and also for managing waste generated in response to Covid-19 based on WHO and WB guidance. It was revised and redisclosed in April 2020 and again revised in October 2021 to reflect the implementation of Covid-19 vaccination campaigns and appropriate medical waste management procedures. It will be updated to include particular measures related to Covid-19 vaccines such as risks related to the transport, storage, handling and disposal of vaccines. Technical capacity of the Borrower to manage hazardous and medical waste in line with GIIP i.e. infrastructure, facilities and specialized companies for collection and treatment of hazardous and

medical waste which operate in the country, will be assessed, improved accordingly and addressed as part of the updated NMWMP as outlined in the ESMF an in order to be in line with the GIIP. The project will support the Borrower to address identified gaps and minimize potential impacts on environment and community health and safety. It will support the Borrower (i) to optimize plans and processes for collection and transportation of COVID-19 and other related medical waste to disposal sites and (ii) to additionally develop and implement guidelines and staff training to improve climate friendly medical waste management at the facility level with a focus on waste management in flood prone areas. Key waste management inputs will also be procured through the project (bags to collect waste, bins).

GHG Emissions and Energy Efficiency. The Project is not anticipated to generate significant quantities of GHG emissions. However, the project will include, where possible, measures to increase efficiency of energy use. In the case of cold chain equipment, this means procuring and installing Solar Direct Drive Refrigerators and WHO PQS certified climate friendly refrigerators/freezers to reduce greenhouse gas emissions from fossil fuels. In any activities to install cold-chain equipment in healthcare facilities, emphasis will be place in using clean energy solutions (such as solar and battery systems) to provide continuous power to health facilities and cold-chain equipment, and to reduce operating costs.

There is no procurement of pesticides foreseen in the project, and the project is not considered to be significant user of water.

ESS4 Community Health and Safety

Similar to the parent project, ESS4 is relevant for the AF, to the project components because it is equally important to ensure the safety of communities from disease infection. Medical waste and general waste from health centers, as well as from vaccine distribution, have a high potential of carrying micro-organisms that can infect the community at large if they are not properly disposed of. There is a possibility for infectious microorganisms to be introduced into the environment and the surrounding communities if not well contained within the laboratory or due to accidents and/or emergencies. Medical/health centers will thereby have to follow respective procedures with a focus on appropriate waste management of contaminated materials, as well as protocols on the transport of samples and workers cleaning before leaving the workplace back into their communities. Additional risks concern increased risk of COVID-19 transmission, adverse events following immunization, forced vaccination. The use of drones represents (i) risk of drone crash, (ii) risk of leakages due to crash or substandard packaging materials and (iii) risk related to privacy and security . To address those risks, the ESMF includes elements on: (i) how project activities will be carried out in a safe manner with low incidences of accidents and incidents in line with Good International Industry Practice, WHO guidelines, (ii) emergency preparedness measures will also be developed and implemented to manage unlikely cases of laboratory accidents and/or emergencies, (iii) procedures protocols and other measures to ensure voluntary consent/no forced vaccination and due process in case of mandatory vaccination, (iv) capacity of the national system to monitor, investigate and respond to adverse events following immunization, (v) available infrastructure and capacity of the Borrower to established and implement vaccine cold chain temperature monitoring and (iv) measures to mitigate community health and safety risks related to the use of drones.

Road safety risks may increase during transport and distribution of vaccines and this concern should be taken into account by this project. The ESMF has developed minimal technical standards including the general requirements

for the vehicles, minimal standards for safe journey, road safety awareness with defensive driving elements, requirements for drivers (age and experience; training requirement, medical fitness; roles and responsibilities, etc.).

The government has a protocol to monitor adverse events following immunization (AEFI) that is part of the national vaccine deployment plan that was finalized and adopted in 2021. The ESMF referred to the measures to be applied in the course of the project outlined in the AEFI.

In line with the WB SEA/SH Good Practice Note, the Bank has undertaken a SEA/SH risk screening of potential risks and impacts induced by the project, and the risk has been classified as moderate. Indeed, SEA/SH may be an obstacle to acceptability of reproductive health services. To mitigate those risks, the project will ensure the avoidance of any form of SEA/SH by relying on code of conduct all workers implementing the project. The government will ensure that all project workers are adequately instructed and trained, on a regular basis, on prevention and reporting procedures available for SEA and SH as set out in ESMF and SEP. The community neighboring will also be made aware of the GM that can be utilized to raise concerns or complaints regarding the conduct of project related workers, and also GM specifically for SEA/SH. The borrower should ensure that a Risk Hazard Assessment (RHA) for the activities that have the potential to generate emergency event. Based on the results of the RHA, they should prepare an Emergency Response Plan (ERP) in coordination with the relevant local authorities and the affected communities to handle any accidents on site. The drafted SEA/SH Prevention and Response Action Plan (including a mapping of existing service providers) that has been annexed to the ESMF should be updated.

No military forces will be used for activities implemented under the proposed project. Military doctors and nurses are providing vaccines to military forces in military health facilities.

Madagascar faces several climate hazards due to its increasingly variable and changing climate change environment. The project will support the country to deal with these vulnerabilities and enhance climate resilience and adaptation, through the following activities such as (I) expansion of vaccination efforts by including mobile outreach services to reach target beneficiaries, including those most impacted by climate shocks, (ii) purchase of reusable tents, tables, chairs, and beds to make vaccination sites resilient to climate risks, (iii) support data collection and data infrastructure to improve and monitor COVID-19 and other vaccine distribution, like vaccines to prevent diseases induced or exacerbated by climate shocks. (iv) conduct an assessment to identify gaps in preparedness for climate-related emergencies, particularly floods and drought, and opportunities for promoting climate-friendly planning in vaccine deployment and delivery, (v) develop contingency plans for safe vaccine delivery in case of climate emergencies, particularly flooding and drought, (vi) provide training and guidelines for health workers preparedness and response to climate shocks, including specific modules and materials on preparedness and response to climatic shocks, particularly flooding and droughts. In order to ensure safe cold chain management during power outages and natural disasters, the project will support the acquisition and use of clean energy solutions (such as the solar system) to provide continuous power to health facilities and cold-chain equipment

ESS5 Land Acquisition, Restrictions on Land Use and Involuntary Resettlement

This ESS5 standard is not relevant. Project activities will not induce land acquisition and/or physical or economic displacement of affected people. Land acquisition is not expected even the project might involve a small rehabilitation of the existing facilities such as the cold chain infrastructure under the component 2

ESS6 Biodiversity Conservation and Sustainable Management of Living Natural Resources

The standard is considered relevant. The use of drones for delivery of vaccine may lead to crashes in areas that could have a negative impact on biodiversity conservation and sustainable management of living natural resources. Flight paths will be established to avoid sensitive ecological areas and waterways nevertheless the risk persists. Walkthrough surveys with analysis of satellite images should be conducted to determine the drone flight path to ensure that their routes avoid sensitive ecological areas and waterways.

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

ESS7 is not relevant for the project. There are no Indigenous Peoples/Sub-Saharan African Historically Underserved Traditional Local Communities that meet the criteria of IP/SSHAUTLCs, per the requirements of this Standard, in the project area.

ESS8 Cultural Heritage

ESS8 is not relevant to the Project currently as the limited civil works within existing facilities are unlikely to affect tangible or intangible cultural assets.

ESS9 Financial Intermediaries

The ESS9 Standard is not currently relevant to the Project as Financial Intermediaries will not be used.

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:

The use of borrower framework is not being considered for this project.

IV. CONTACT POINTS

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Borrower/Client/Recipient

Borrower: Government of Madagascar

Implementing Agency(ies)

Implementing Agency: Ministry of Public Health

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VI. APPROVAL

Task Team Leader(s):	Maud Juquois
Practice Manager (ENR/Social)	David Seth Warren Cleared on 08-Dec-2021 at 13:09:52 GMT-05:00
Safeguards Advisor ESSA	Peter Leonard (SAESSA) Concurred on 08-Dec-2021 at 15:01:13 GMT-05:00