

RISK ASSESSMENT AND RISK MANAGEMENT PLAN

Risk Description	Rating	Mitigation Measures	Responsibility
<p>Country Specific Changes in health-seeking behavior, including COVID-19 vaccine acceptance behavior may take a longer time than the project period.</p>	L	MOH is working closely with the World Bank and UNICEF on vaccine communication through various government and social media channels to ensure that COVID-19 vaccine acceptance remains high and information on AEFI will be well-managed.	MOH
<p>Sector Specific Weak implementation capacity of the executing agency relatively new to ADB operations</p>	L	With the positive experience of implementing the ongoing ADB-financed HSEP and the additional resources made available for COVID-19 response in 2020, the most important mitigation factor is to ensure that the HSEP PMU continues as the PMU of the proposed project until the end of the project period in 2024. ADB supervision and monitoring of project implementation will continue. The project will finance technical support (via consultants) directly to the PMU to ensure that all ADB procedures and processes are followed.	MOH
<p>Lack of access to COVID-19 vaccine for target population in high-risk areas.</p>	L	MOH has extensive experience of managing routine vaccination to reach 99% coverage for more than 15 years and is a GAVI graduated country. The Epidemiology Unit also has norms and standards which will mitigate against giving vaccines outside of the priority groups. The medical officer of health area teams are visiting high-risk areas and establishing field immunization centers to ensure that populations in high-risk areas have access to the vaccines.	MOH
<p>Prioritization strategies within NDVP are changed in implementation leading to political risk and loss of public confidence in system.</p>	L	The project will coordinate with Health Promotion Bureau and UNICEF which would implement an appropriate public communication strategy to ensure the rationale is understood.	

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Possible vaccine hesitancy that may prevent the vulnerable populations from getting vaccinated.	L	The national vaccine coverage rate is 99% and there is high acceptance of the national routine vaccination program including the recently launched HPV vaccination. With the launching of the COVID-19 vaccine communication campaign by UNICEF and MOH, the acceptance and knowledge on COVID-19 vaccination will be enhanced.	MOH
Monitoring of the administration of COVID-19 vaccines and adverse events following immunization not effective and efficient.	L	The project is supporting scaling up the COVID-19 Immunization Tracker developed by WHO and MOH to ensure that monitoring of vaccine recipients can be done smoothly.	MOH
Project Specific Inadequate capacity of PMU to cope with the additional workload caused by the project activities.	M	Strengthen the capacity of the PMU. Efficient coordination and ensure the flow of information between the different entities involved in the project implementation.	MOH
Lack of availability of counterpart funds and adequate budget allocations for project implementation.	S	The project reduced the counterpart financing up to all applicable direct local taxes (VAT) and allowed payment of all applicable duties from the loan financing, since vaccine rollout for COVID-19 is a public good. For the payment of VAT, discussions are ongoing to ensure that the required budget allocations are available to avoid delay in project implementation.	MOF
Fiscal Insufficient fiscal space to ensure the sustainability of the project investments due to high public debt constraint.	S	The government has made commitment to allocate adequate fiscal resource and maintain health as a national priority area in its National Policy Framework "Vistas of Prosperity and Splendour". The government will also continue policy dialogue with development partners to ensure adequacy of fiscal resources for implementation of the NDVP.	MOF

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<p>Financial Management The number of financial staff in the existing PMU may not be sufficient to manage the additional workload of the project</p>	M	<p>Appoint an additional finance officer to support the PMU.</p> <p>Provide continuous training to PMU staff in ADB's financial management and disbursement procedures and systems.</p>	<p>MOH and PMU</p> <p>ADB</p>
<p>The asset management, vaccine stock and inventory practices systems of the various entities receiving and storing the medical equipment and vaccines are not fully computerized.</p>	S	<p>Upgrade asset management practices and systems: (i) use of computerized asset register, (ii) periodic inventories and daily vaccine stock take, (iii) reconciliations of the fixed asset register and physical inventories; and (iv) effective and timely reporting.</p>	<p>MOH, MSD, RMSD and Hospitals</p>
<p>Inadequate capacity of the Government's internal audit units to audit the implementation of both the project and the NDVP which may lead to inadequate fixed asset management practices going undetected and lost inventory.</p>	M	<p>Prioritize routine internal audits of the fixed asset management and inventory practices and systems related to the project and the NDVP to ensure proper controls are in place to safeguard the assets. The internal audits are to include a follow-up of past audit observations.</p>	<p>MOH, MSD, RMSD and Hospitals</p>
<p>Delays in submission of audited project financial statements to ADB. Given the importance and scale of the NDVP for COVID-19 vaccines, a regular project financial audit may not be sufficient to provide the required assurances.</p>	S	<p>Coordinate with NAO to ensure: (i) the project is part of NAO's annual audit plan, and the annual project financial statement is submitted to ADB in a timely fashion; and (ii) a performance audit is conducted on the implementation of the NDVP.</p>	<p>MOH, PMU and NAO</p>
<p>Inadequate financial reports or delays in financial reporting may cause bottlenecks and inefficiencies to go unnoticed.</p>	M	<p>Generate periodic financial and physical progress reports and inventory reports to ensure bottlenecks and inefficiencies are identified in a timely fashion.</p> <p>Include comprehensive financial management information including detailed comparison of physical and financial progress in the quarterly progress reports in a format agreed with ADB.</p>	<p>MOH, MSD and RMSD</p> <p>MOH and PMU</p>
<p>Procurement Limited availability of ADB eligible vaccines from manufacturers which leads to long vaccine lead-time.</p>	H	<p>MOH is engaging with key stakeholders (e.g., COVAX, UNICEF, vaccine manufacturers), identifying required vaccines, and entering into contracts with manufacturers as early as possible.</p>	<p>MOH, SPC and ADB</p>

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Substantially imbalanced terms of contracts that place large risks on the client.	H	Enter negotiations with multiple firms and prioritize deals with more balanced terms of contracts.	MOH and SPC
Vaccines selected do not subsequently meet APVAX's vaccine eligibility criteria.	L	Identify vaccines that have a defined pathway to meeting APVAX vaccine eligibility criteria.	MOF and MOH
Due to the urgency, the government may prefer for procurement of vaccines on a post-review basis.	L	Vaccine procurement under ADB financing shall be subject to ADB's review and approval. As a minimum, contracts will be required to include ADB's standard anticorruption and audit clause.	MSD, SPC, PMU and ADB
<p>Governance</p> <p>Possible integrity issues might be encountered during procurement, distribution, allocation, and administration of COVID-19 vaccines, and project implementation.</p>	M	<p>ADB's Anticorruption Policy and whistle blowing mechanisms will be introduced to MOH Units, MSD, SPC, and PMU staff engaged under the project to ensure that they are equipped with sufficient knowledge and aware of the policy from the very early stage of project implementation.</p> <p>The project National Steering Committee provides oversight and supervision for the project, and the National Audit Office will conduct both financial and performance audits of the project on a regular basis.</p> <p>ADB under its technical assistance will conduct integrity knowledge management sessions for MOH, MSD, PMU, and other project stakeholders to increase the awareness and compliance with ADB's Anticorruption Policy.</p>	MOH, MSD, SPC, PMU and ADB
<p>Safeguards</p> <p>Temporary increase of immunization waste due to the rollout of COVID-19 vaccine program.</p>	L	Follow the guidelines given in the 2001 draft national policy on health-care waste management and comply with regulatory tools of National Environmental Act on environmental impact assessment, environmental protection license and schedule waste management license supported by standards for discharge and waste disposal	MOH

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		guidelines and international good practices as recommended by WHO. ¹	
Potential temporary and site-specific adverse environmental impacts due to minor civil works related to strengthening and renovation of medical waste management systems in COVID-19 designated hospitals and the establishment of incinerators in satellite hospitals in six selected provinces	L	Adoption of proper mitigation measures in the design, planning, construction, and operations phases. Follow the guidance given in the EARF on screening, categorization, assessment, and mitigation of impacts of the subprojects. Subprojects which are categorized as A for environment will be excluded from project financing.	MOH
<p>Climate Change Sri Lanka's climate risks (i.e., extreme rainfall variability and storminess) can threaten the integrity of COVID-19 treatment hospitals' sewerage systems and cause instability in power supply.</p>	M	Adaptation measures to address climate risks include separation of storm drain from sewerage systems; use of appropriate materials, particularly those near the coastal areas should use corrosion resistant materials; and provision of backup power source. Reduction of greenhouse gas emissions are addressed by more energy-efficient equipment (i.e., incinerators and refrigerator mounted vehicles).	MOH and PMU

H = high, S = substantial, M = moderate, L = low.

ADB = Asian Development Bank, AEFI = adverse event following immunization, APVAX = Asia Pacific Vaccine Access Facility, COVAX = COVID-19 Vaccines Global Access Facility, COVID-19 = coronavirus disease, EARF = environmental assessment and review framework, GAVI = Gavi, the Vaccine Alliance, HPV = human papilloma virus, HSEP = Health System Enhancement Project, MOF = Ministry of Finance, MOH = Ministry of Health, MSD = Medical Supplies Division, NAO = National Audit Office, NDVP = National Deployment and Vaccination Plan for COVID-19 Vaccines, PMU = project management unit, RMSD = Regional Medical Supply Store, SPC = State Pharmaceuticals Corporation of Sri Lanka, UNICEF = United Nations Children's Fund, VAT = value-added tax, WHO = World Health Organization.

Source: Asian Development Bank.

¹ World Health Organization. 2014. *Safe Management of Wastes from Health-care Activities*. Geneva; World Health Organization. 2019. *Overview of Technologies for the Treatment of Infectious and Sharp Waste from Health Care Facilities*. Geneva.