**Project Administration Manual** 

Project Number: 55082-001 Loan Number: TBD November 2021

India: Responsive COVID-19 Vaccines for Recovery Project under the Asia Pacific Vaccine Access Facility

# ABBREVIATIONS

ADB	_	Asian Development Bank
AIIB	_	Asian Infrastructure Investment Bank
APFS	_	audited project financial statement
APVAX	_	Asia Pacific Vaccine Access Facility
BMW	_	biomedical medical waste
BMWM	_	biomedical medical waste management
CAG	_	Comptroller and Auditor General
CBMWTF	_	common biomedical waste treatment facilities
COVID-19	_	coronavirus disease
	_	
Co-WIN	_	Winning over COVID-19
CSO	_	civil society organization
FMA	_	financial management assessment
GESI	-	gender equality and social inclusion
HLL	_	HLL Lifecare Limited
MOHFW	_	Ministry of Health and Family Welfare
NDVP	_	National Deployment and Vaccination Plan for COVID-19
		Vaccines
PMU	_	project management unit
QPR	_	quarterly progress report
RRC	_	rapid response component
SOE	_	statement of expenditure
SPS	_	Safeguard Policy Statement
ТА	_	technical assistance
UIP	_	Universal Immunization Programme
0.1		

#### NOTES

- (i) The fiscal year (FY) of the Government of India ends on 31 March. "FY" before a calendar year denotes the year in which the fiscal year ends, e.g., FY2021 ends on 31 March 2021.
- (ii) In this report, "\$" refers to United States dollars.

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# **Project Administration Manual Purpose and Process**

The project administration manual (PAM) describes the essential administrative and management requirements to implement the project on time, within budget, and in accordance with the policies and procedures of the government and Asian Development Bank (ADB). The PAM should include references to all available templates and instructions either through linkages to relevant URLs or directly incorporated in the PAM.

The Ministry of Health and Family Welfare (MOHFW) is wholly responsible for implementing the ADB-financed project, as agreed jointly between the borrower and ADB, and according to the policies and procedures of the government and ADB. ADB staff is responsible for supporting implementation including compliance by MOHFW of their obligations and responsibilities for project implementation in accordance with ADB's policies and procedures.

At loan negotiations, the borrower and ADB shall agree to the PAM and ensure consistency with the Loan and Project agreement. Such agreement shall be reflected in the minutes of the loan negotiations. In the event of any discrepancy or contradiction between the PAM and Loan and Project agreement, the provisions of the Loan agreement shall prevail.

After ADB Board approval of the project's report and recommendations of the President (RRP), changes in implementation arrangements are subject to agreement and approval pursuant to relevant government and ADB administrative procedures (including the Project Administration Instructions) and upon such approval, they will be subsequently incorporated in the PAM.

# I. PROJECT DESCRIPTION

1. The Responsive COVID-19 Vaccines for Recovery Project (the project) will provide the Government of India (the government) with financing for procuring safe and effective vaccines against coronavirus disease (COVID-19) through the rapid response component (RRC) of the Asia Pacific Vaccine Access Facility (APVAX).<sup>1</sup> The Asian Infrastructure Investment Bank (AIIB) will provide joint cofinancing to support the procurement of APVAX-eligible vaccines, in full alignment with the project outcome and the policies and procedures of the Asian Development Bank (ADB).

2. The first case of COVID-19 was confirmed in India on 30 January 2020. The COVID-19 vaccination campaign in India began on 16 January 2021. The government aims to inoculate everyone 18 years old and above, which is 68.91% of the population or over 944 million individuals. It is estimated that more than 1,988 million doses of vaccines will be required (assuming 5% wastage rate) for this purpose. As of 12 September 2021, 738.2 million doses have been administered. Of these, 561.1 million first doses were administered covering 40.9% of total population and 177.1 million second doses were administered covering 12.9% of total population.

3. **Impact and outcome**. The project is aligned with the following impact: accelerated health, social, and economic recovery from COVID-19 in India. It will have the following outcome: eligible populations safely vaccinated against COVID-19 in project states.<sup>2</sup>

Output: Safe and effective COVID-19 vaccines supplied for eligible population in 4. project states. The project will support the procurement of safe and effective vaccines against COVID-19 through APVAX's RRC in compliance with ADB's vaccine eligibility criteria. It will procure about 667 million doses of vaccines, which will be administered to about 317 million target population by 2024 following the National Deployment and Vaccination Plan (NDVP) for COVID-19 vaccines and subsequent guidelines. If more doses are procured it will not have any negative effect on the project performance. The eligible vaccines will be procured through bilateral arrangements with vaccine manufacturers or distributors. In addition to the NDVP, the Ministry of Health and Family Welfare (MOHFW) has issued (i) COVID-19 Vaccines Operational Guidelines and (ii) COVID-19 Vaccines Communication Strategy to guide all aspects of the national vaccination program. The Universal Immunization Programme (UIP) has continuously increased capacity and systems for successful national routine vaccination rollout, and those capacity and systems are adapted with enhanced features for the COVID-19 vaccination operation. MOHFW issued several guidelines to states to ensure equitable access to COVID-19 vaccines for the vulnerable groups.

5. ADB's ongoing technical assistance (TA) projects will support the MOHFW with the implementation of the national COVID-19 vaccination program through the following activities: (i) augmenting Immunisation Division's project management capacity through a project management unit (PMU) consultants in coordinating the monitoring, reporting, and evaluation; (ii) supporting field monitoring of vaccination sites; (iii) carrying out dynamic analysis of data by gender, rural and urban, and priority groups to support decision making; (iv) supporting private sector engagement through capacity building and monitoring of compliance with guidelines; (v) supporting vaccination-related biomedical waste management (BMWM) and disposal monitoring;

<sup>&</sup>lt;sup>1</sup> ADB. 2020. <u>ADB's Support to Enhance COVID-19 Vaccine Access</u>. Manila.

<sup>&</sup>lt;sup>2</sup> The project states include Uttar Pradesh, Maharashtra, Bihar, West Bengal, Tamil Nadu, Andhra Pradesh, Madhya Pradesh, Rajasthan, Karnataka, Gujarat, Odisha, Kerala, Jharkhand, Assam, Punjab, Telangana, Haryana, Chhattisgarh, and Delhi (in the order of size of eligible population). The project states may be extended to include states where ADB has ongoing or pipelined operations in case that the loan proceeds are not fully utilized.

(vi) increasing awareness and willingness of vaccination among the vulnerable groups; and (vii) strengthening capacity for monitoring and addressing the adverse events after immunization.<sup>3</sup> These activities are designed to augment the ongoing government efforts at national and state level, creating synergy with the proposed vaccine financing as well as other health sector interventions of ADB. The TA activities are supported by the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) through their respective administrative arrangements with ADB, under the overall coordination of the Immunization Division, MOHFW.

#### II. IMPLEMENTATION PLANS

#### A. Project Readiness Activities

#### Table 1: Project Readiness Activities

			Responsibility			
Indicative Activities	Jan–July	Aug	Sept	Oct	Nov	
Establish project implementation	Х	Х				MOHFW
arrangements						
Advance contracting	Х	Х	Х			MOHFW
actions						
Loan negotiation				Х		ADB, DEA, MOHFW
ADB Board approval				Х		ADB
Loan signing				Х		ADB, DEA, MOHFW
Government legal opinion provided					Х	DEA to coordinate with Solicitor General of India
Loan effectiveness					Х	ADB

ADB = Asian Development Bank, DEA = Department of Economic Affairs, MOHFW = Ministry of Health and Family Welfare.

Source: Asian Development Bank.

<sup>&</sup>lt;sup>3</sup> Activities related (i) to (vii) are supported under TA 6733; and those related to (vii) are supported under TA9550. ADB 2021. <u>Technical Assistance to India for the Supporting COVID-19 Response and Vaccination Program.</u> Manila (TA 6733) and ADB. 2020. <u>Regional Support to Address the Outbreak of Coronavirus Disease 2019 and Potential Outbreaks of Other Communicable Diseases</u>. Manila (TA 9950). The TA paper (TA 6733) and the activities under RETA 9550 are included in Appendix 1.

# B. Overall Project Implementation Plan

6. The project will be implemented until end of 2024. The overall project implementation schedule is in Table 2.

	Table 2: Overall Project Implementation Plan																				
Key Activities	2020			21				22				23				2024	-			25	
	Q4	Q1	Q2	Q3					Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
				Р	repar	atory	activ	ities													
Finalization of the National																					
Deployment and Vaccination																					
Plan																					
Issuing operational guidelines																					
and communication strategy																					
Human resource training																					
Nationwide dry-run																					
						In	nplem	nentat	ion A	ctiviti	es										
Updating vaccination rollout																					
strategy																					
Conduct information,																					
education, and																					
communications campaigns.																					
Co-WIN deployment and																					
upgradation																					
Conducting concurrent																					
monitoring																					
A. DMF																					
1. Safe and effective COVID-																					
19 vaccines supplied for																					
eligible population in project																					
states.																					
1.a.1 Procure the required																					
number of vaccine doses for																					
ADB financing (Q1 2021–Q2																					
2024)																					
1.a.2 Monitor distribution of																					
vaccine doses to project																					
states (Q3 2021–Q3 2024)																					
1.b&c Support, through PMU																					
consultants, MOHFW in																					
vaccination program																					
implementation and project																					
requirements (Q3 2021–Q3																					
2024)																					

Table 2: Overall Project Implementation Plan

	2020		20	21			20	22			20	23			2	2024			20	25	
Key Activities	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
1.d Engage at least 20																					
partners/networks and																					
platforms working with																					
disadvantaged communities,																					
especially women to facilitate																					
outreach of COVID-19																					
appropriate behaviors, other																					
COVID-19 related information																					
and vaccine communication																					
(Q3 2021–Q3 2024)																					
1.e.1 Develop a safe deep																					
burial guidance material (Q4																					
2021)																					
1.e.2 Conduct 10 sessions of																					
training of trainers (Q1 2022)																					
1.e.3 Conduct training on																					
management and safe																					
disposal of BMW for relevant																					
staff (from Q1 2022 to Q2																					
2023)																					
1.e.4 Train NGOs and CSOs																					
on BMWM awareness (Q1																					
2022–Q2 2023).																					
B. Project Management																					
Activities																					
Conduct progress review																					
meetings every two months																					
with TA partners and ADB on																					
the project and TA activities																					
Prepare and submit quarterly																					
and annual progress reports																					
Submit annual audited project																					
financial statements																					
Submit the national																					
vaccination program																					
performance audit report																					
Prepare and submit the																					
project completion report																					

ADB = Asian Development Bank, AEFI = adverse event following immunization, CCE= cold chain equipment, Co-WIN = Winning Over COVID-19, DMF = design and monitoring framework, IT = Information Technology, Q= quarter, RCCE= risk communication and community engagement, TA = technical assistance. Source: Asian Development Bank.

## III. PROJECT MANAGEMENT ARRANGEMENTS

## A. Implementation Arrangement

7. The MOHFW will be the executing agency and the Immunization Division under MOHFW will be the implementing agency. The Immunization Division will coordinate with other MOHFW divisions/units, other agencies, and project states for all aspects of project implementation. Dr. M K Aggarwal, Additional Commissioner, UIP of the Immunization Division will assume the role of the project director leading the implementation activities, assisted by the PMU consultants.

8. The PMU consultant team under the Immunization Division will assist the Project Director in the project specific planning, monitoring and evaluation, reporting, and coordination requirements satisfying ADB project administration requirements and deriving data and information from the overall government's systems related to the national vaccination program. The PMU consultant team will consist of technical experts financed by TA 6733.<sup>4</sup>

# B. Project Implementation Organizations: Roles and Responsibilities

Project Implementation	· · ·
Organizations	Management Roles and Responsibilities
Executing agency:	(i) Oversight of overall project implementation;
Ministry of Health and Family	(ii) Provide guidance and policy directions;
Welfare	(iii) Provide guidance to the implementing agency;
	(iv) Monitor project progress; and
	(v) Recommend course corrections as needed.
Implementing agency: Immunization Division	<ul> <li>Day-to-day project preparation and supervision of project implementation activities;</li> </ul>
(supported by PMU	(ii) Oversight of HLL Lifecare Limited's vaccine contract
consultants)	management;
	(iii) Preparation and submission of withdrawal applications;
	<ul> <li>Submission of the audited annual report and financial statements;</li> </ul>
	(v) Maintaining project accounts and loan financial records;
	<ul> <li>(vi) Keeping supporting documents for project financial statements and project accounts;</li> </ul>
	(vii) Take the lead in implementation of the TA, ensuring complementarity with support provided by others.
	(viii) Conduct bimonthly progress meeting with ADB and TA implementing agencies (WHO and UNICEF);
	(ix) Preparing quarterly progress reports and a project; completion
	report and their timely submission to ADB;
	(x) Facilitate annual internal audit for the project and reporting of
	status of internal audit findings as part of annual progress report;
	(xi) Information disclosure;

Table 3: Project Implementation Roles and Responsibilities

<sup>&</sup>lt;sup>4</sup> The PMU consultants include: vaccine financing expert, senior vaccine regulatory expert, senior vaccine delivery system strengthening expert, senior immunization program design expert, senior public health expert (health security), senior data scientist (health), senior digital tool developer (health), procurement expert, financial management expert, gender specialist, medical waste management specialist, public health management specialists, emergency response and strategic intervention expert (health), and digital health expert/health information technology experts. The terms of reference for these experts are in Linked Document 2 of the TA 6733. The TA will also provide pool of consultants or resource persons up to 10 person-months to meet any emerging need for other technical areas.

	<ul> <li>(xii) Implementation and monitoring of gender equality and social inclusion action plan;</li> <li>(xiii) Coordinate with CAC for the performance audit of the patienal</li> </ul>
	(xiii) Coordinate with CAG for the performance audit of the national vaccination program and submission of the audit report to ADB;
	(xiv) Compliance with loan covenants (social and environment
	safeguards, financial, economic, others) and reporting in the annual report;
	(xv) Monitor biomedical waste management at CVCs and coordinate
	with relevant state department of health and family welfare to
	ensure adequate management and disposal of vaccination wastes; and
	(xvi) Maintain close communication with ADB
ADB	(i) Monitoring and review of the overall implementation of the
	project in consultation with the executing and implementing
	agency, including, but not limited to, progress toward the
	achievement of project outcome, outputs, progress of contract
	award and disbursements, annual project audit, performance
	audit of the national vaccination program, and compliance with loan covenants;
	(ii) Posting on the ADB website of updated project data sheets;
	(iii) Monitor executing/implementing agency's compliance with loan
	covenants (safeguards, financial, gender, and others);
	(iv) Timely processing of withdrawal applications and release of
	funds for eligible expenditures;
	(v) Closely coordinate with AIIB as cofinancing lead to facilitate AIIB
	loan administration requirements and timely disbursement of
	AIIB financing against eligible expenditures;
	(vi) Facilitate periodic joint review missions; and
	(vii) Closely coordinate with TA implementation partners (WHO and
	UNICEF) and other development partners on vaccine program and TA support.

ADB = Asian Development Bank, AIIB = Asian Infrastructure Investment Bank, CAG = Comptroller and Auditor General, CVC = COVID vaccination center, PMU = project management unit, TA = technical assistance, UNICEF = United Nations Children's Fund, WHO = World Health Organization.

Source: Asian Development Bank.

#### C. **Key Persons Involved in Implementation**

# **Implementing Agency**

Ministry of Health and Family Welfare	Name: Dr. M K Aggarwal Title/Position: Additional Commissioner (UIP) Telephone No. 011- 23062126 Email: <u>mk.aggarwal13@nic.in</u> Address: Immunization Division, Ministry of Health and Family Welfare, Govt. of India,105-D, Nirman Bhawan, New Delhi
	Name: Dr. Veena Dhawan Title/Position: Joint Commissioner (Imm) Telephone No. 011-23063479 Email: veenadhawan65@gmail.com

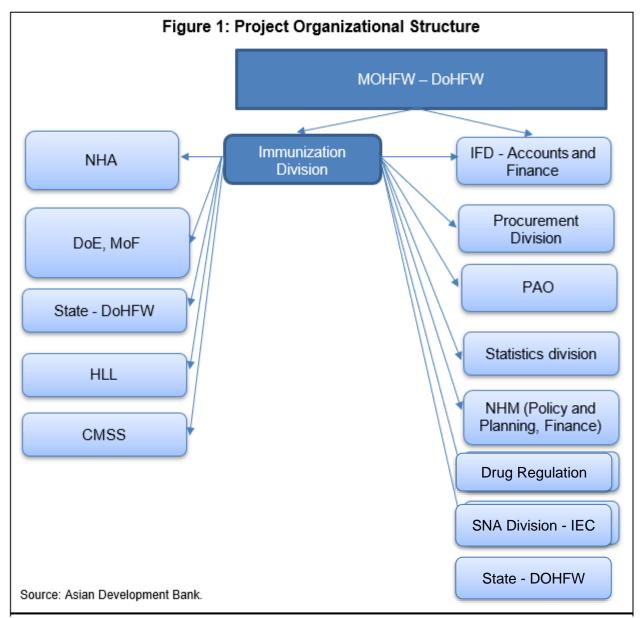
Address: Immunization Division, Ministry of Health and Family Welfare, Govt. of India, 405-D, Nirman Bhawan, New Delhi

	Name: Dr. Ashish B. Chakraborty Title/Position: Assistant Commissioner Telephone No. 011-230621267 Email: <u>ashish.bchakraborty@gov.in</u> Address: Immunization Division, Ministry of Health and Family Welfare, Govt. of India, 105-D, Nirman Bhawan, New Delhi
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### D. Project Organization Structure

9. The MOHFW will be the executing agency and the Immunization Division will be the implementing agency. Other divisions and units within MOHFW will support the Immunization Division in the areas relevant to their respective responsibility, while the Immunization Division will coordinate all project related aspects as the implementing agency. The MOHFW engaged HLL Lifecare Limited (HLL), a government-owned enterprise under the MOHFW, as a procurement agent to provide support on COVID-19 vaccines procurement and contract management. The MOHFW, through the Immunization Division, will ensure the project implementation is well aligned with the national program and will coordinate with state and district level stakeholders.



CMSS = Central Medical Service Society, DOHFW = Department of Health and Family Welfare, HLL = HLL Lifecare Limited, IEC = Information, Education, and Communication, IFD = Integrated Finance Division, MOHFW = Ministry of Health and Family Welfare, NHA = National Health Agency, NHM = National Health Mission, SNA = Swasth Nagrik Abhiyaan.

Source: Asian Development Bank.

### IV. COSTS AND FINANCING

10. The project is estimated to cost \$2,057.77 million, including vaccine costs, tax, physical and price contingencies, and interest during implementation (Table 4).

Table 4: Summary Cost Estimates								
ltem	Description	Amount (\$ million)	Share of Total %					
A.	Base Cost <sup>a</sup>							
	Safe and effective COVID-19 vaccines supplied <sup>b</sup>	1,930.15	93.80%					
В.		69.85	3.39%					
	Subtotal (A+B)	2,000.00	97.19%					
C.	Financial charges during Implementation <sup>d</sup>	57.77	2.81%					
	Total (A+B+C)	2,057.77	100.00%					

COVID-19 = coronavirus disease.

<sup>a</sup> In September 2021 prices and \$1 = 73.00.

<sup>b</sup> Including 5% tax on vaccines procured.

<sup>c</sup> Includes physical and price contingencies, and a provision for exchange rate fluctuation.

<sup>d</sup> Includes interest, commitment charges and front fee, which will be borne by the Borrower.

Source: Asian Development Bank estimates.

11. The government has requested two loans comprising (i) \$500 million loan; and (ii) \$1 billion loan, both from ADB's ordinary capital resources, to help finance vaccine procurement. The first loan will have a 10-year term, including a grace period of 3 years and second loan will have a 5-year term, including a grace period of 3 years; both with interest to be determined in accordance with ADB's London interbank offered rate (LIBOR)-based lending facility; a commitment charge of 0.15% per year; and such other terms and conditions as set forth in the draft loan agreement. For the first loan of \$500 million, the average loan maturity using annuity method based on 30% discount factor, is 7.82 years, and there is no maturity premium payable to ADB. For the second loan of \$1 billion, the average loan maturity using annuity method based on 30% discount factor, is 4.34 years, and there is no maturity premium payable to ADB. ADB will finance the expenditures in relation to procurement of vaccines that meet eligibility criteria.

12. The government has also requested a loan of \$500 million from AIIB, to help finance vaccine procurement.<sup>5</sup> Its terms and conditions will be described in a loan agreement between the government and AIIB. Approval of AIIB loan is expected shortly after ADB's Board approval of the project. ADB will partially administer AIIB financing for the project as per a co-lenders' agreement between ADB and AIIB.

13. The government will provide in-kind contribution, in form of counterpart staff, logistics, cold chain, and various facilities to the ADB project investment. Separate budget codes will be provided for procuring the vaccines for the project. The government has committed that sufficient resources for operational cost will be made available and budget allocation and utilization will be monitored and included in the performance audit of the national vaccination program. The government will also cover interest, commitment charges and front fee. The project financing plan is in Table 5.

<sup>&</sup>lt;sup>5</sup> ADB's partial administration will entail oversight with respect to procurement, safeguards, financial management, and disbursement.

	F	Project	National Vaccination Program <sup>a</sup>				
	Amount	Share of Total	Amount	Share of Total			
Source	(\$ million)	(%)	(\$ million)	(%)			
Asian Development Bank							
Ordinary capital resources	1,500.00	72.89%	1,500.00	19.91%			
Asian Infrastructure Investment							
Bank	500.00	24.30%	500.00	6.64%			
Government of India	57.77 <sup>b</sup>	2.81%	4,542.51°	60.31%			
Others <sup>d</sup>	-	-	989.77	13.14%			
Total	2,057.77	100.00%	7,532.28	100.00%			

#### **Table 5: Summary Project and Program Financing Plan**

<sup>a</sup> The national coronavirus disease (COVID-19) vaccination program is financed through the government's own resources, development partners and other donors. Total program cost was estimated assuming 5% vaccine wastage. Total vaccine costs are estimated at \$6.27 billion and total operational costs of \$1.26 billion.

<sup>b</sup> The government will finance the interest, commitment charges, and front fee.

<sup>c</sup> Including central and state governments contributions, vaccines, ancillary supplies, and operational costs.

<sup>d</sup> Inclusive of contribution from various development partners and donors.

Source: Asian Development Bank estimates.

#### A. Cost Estimates Preparations and Revisions

14. The cost estimates were prepared in September 2021. The cost estimates were discussed and agreed with MOHFW during project processing. The project cost will be reviewed and updated during implementation. The government's detailed vaccine roll-out plan was followed to determine the volume of vaccines to be provided by the project. The vaccine unit costs are derived from the existing contracts. The cost estimates may change following the fluctuating market prices of COVID-19 vaccines. During project implementation, the responsibility for updating the cost estimates will be with MOHFW, guided by the National Expert Group on Vaccine Administration for COVID-19.

#### B. Key Assumptions

- 15. The following key assumptions underpin the cost estimates and financing plan:
  - (i) Exchange rate: ₹73.00 = \$1.00 (as of 1 September 2021).
  - (ii) Price contingencies based on expected cumulative inflation over the implementation period are as follows:

	scalatio	n Rates i	for Price C	ontingency	Calculation	
ltem	2020	2021	2022	2023	2024	Average
Foreign rate of price inflation	-0.5%	1.60%	1.70%	1.70%	1.80%	1.30%
Domestic rate of price inflation	5.5%	5.2%	4.8%	4.5%	4.0%	4.8%

# Table 6: Escalation Rates for Price Contingency Calculation

Source: Asian Development Bank estimates.

#### C. **Detailed Cost Estimates by Expenditure Category**

#### Table 7: Detailed Cost Estimates by Expenditure Category

		(\$ million)			
Items		Local Currency	Foreign Currency	Total Cost	% of Total Cost
Α.	Investment Costs				
	1. Eligible vaccines	1,930.15	0.00	1,930.15	93.80%
	Subtotal (A)	1,930.15	0.00	1,930.15	93.80%
В.	Recurrent Costs				
	1. Other vaccine related costs	0.00	0.00	0.00	0.00%
	Subtotal (B)	0.00	0.00	0.00	0.00%
	Total Project Base Costs	1,930.15	0.00	1,930.15	93.80%
C.	Contingencies				
	1. Physical Contingencies	19.30	0.00	19.30	0.94%
	2. Price Contingencies	50.55	0.00	50.55	2.46%
	Subtotal (C)	69.85	0.00	69.85	3.39%
D.	Financial Charges During Implementation				
	1. Interest during implementation	0.00	57.77	57.77	2.81%
	Subtotal (D)	0.00	57.77	57.77	2.81%
	Total Project Cost (A+B+C+D)	2,000.00	57.77	2,057.77	100.00%

Note: Numbers may not sum precisely because of rounding. Source: Asian Development Bank estimates.

#### Allocation and Withdrawal of Loan Proceeds D.

## **Table 8: Loan Allocations**

	Category		ADB Financing
No.	ltem	Amount Allocated (\$ million)	Percentage and Basis for Withdrawal from the Loan Account
ADB	<b>Ordinary Capital Resource</b>	s Loan of \$500 mill	ion
1	Goods (including vaccines <sup>b</sup> )	482.54	25.0% of total expenditure claimed <sup>a</sup>
2	Unallocated	17.46	
	Total	500.00	
ADB	Ordinary Capital Resource	s Loan of \$1,000 m	illion
1	Goods (including vaccines <sup>b</sup> )	965.07	50.0% of total expenditure claimed <sup>a</sup>
2	Unallocated	34.93	
	Total	1,000.00	
AIIB	Loan of \$500 million		
1	Goods (including vaccines <sup>b</sup> )	482.54	25.0% of total expenditure claimed <sup>a</sup>
2	Unallocated	17.46	
	Total	500.00	

ADB = Asian Development Bank.

<sup>a</sup> Inclusive of taxes imposed within the territory of the borrower.

<sup>b</sup> No withdrawals shall be made from the loan account for financing vaccines until:

ADB has received a letter from the government confirming (i) which COVID-19 vaccine(s) has/have (i) been selected to be financed by the loan proceeds; (ii) which of the Eligibility Criteria has been

satisfied in respect of the selected COVID-19 vaccines; and (iii) that such COVID-19 vaccine(s) has/have received all necessary authorizations, and have been authorized by the Drugs Controller General of India and any other relevant regulatory authorities for distribution and administration within the territory of India; and

(ii) ADB has, based on the information provided in the aforementioned letter, notified the government that the COVID-19 vaccine(s) to be procured are designated as Eligible Vaccines.

Source: Asian Development Bank estimates.

#### **Detailed Cost Estimates by Financier** Ε.

				(\$	million)						
		ADB L	oan 1	ADB L	oan 2	AllE	3	Governm Indi		Total Cost	
		Amount	%	Amount	%	Amount	%	Amount	%	Amount	Tax and Duties <sup>a</sup>
Α.	Investment Costs										
	<ol> <li>Supply contract for eligible vaccines</li> </ol>	482.54	25.00%	965.07	50.00%	482.54	25%	0.00	0.00%	1,930.15	91.91
	Subtotal (A)	482.54	25.00%	965.07	50.00%	482.54	25%	0.00	0.00%	1,930.15	91.91
в.	Recurrent Costs										
	1. Other vaccine related costs	0.00	0.00%	0.00	0.00%	0.00	0%	0.00	0.00%	0.00	0.00
	Subtotal (B)	0.00	0.00%	0.00	0.00%	0.00	0%	0.00	0.00%	0.00	0.00
	Total Project Base Costs	482.54	25.00%	965.07	50.00%	482.54	25%	0.00	0.00%	1,930.15	91.91
C.	Contingencies										
	1. Physical Contingencies	4.82	25.00%	9.65	50.00%	4.82	25%	0.00	5.00%	19.30	0.97
	2. Price Contingencies	12.64	25.00%	25.28	50.00%	12.64	25%	0.00	5.00%	50.55	2.53
	Subtotal (C)	17.46	25.00%	34.93	50.00%	17.46	25%	0.00	5.00%	69.85	3.49
D.	Financial Charges During Implementation										
	1. Interest during implementation	0.00	0.00%	0.00	0.00%	0.00	0%	57.77	3.81%	57.77	0.00
	Subtotal (D)	0.00	0.00%	0.00	0.00%	0.00	0%	57.77	3.81%	57.77	0.00
Tot	al project costs (A+B+C+D)	500.00	24.00%	1,000.00	49.00%	500.00	24%	57.77	3.00%	2,000.00	95.40

Note: Numbers may not sum precisely because of rounding.

<sup>a</sup> Taxes on COVID-19 vaccines is at 5%. Source: Asian Development Bank estimates.

# F. Detailed Cost Estimates by Outputs and/or Components

	Ou	tput				
		% of				
Item	Amount	Category	Total			
A. Investment Costs						
1. Eligible vaccines	1,930.15	100%	1,930.15			
Subtotal (A)						
B. Recurrent Costs						
1. Other vaccine related costs	0.00	0%	0.00			
Subtotal (B)	0.00	0%	0.00			
Total Base Costs (A+B)	1,930.15	100%	1,930.15			
C. Contingencies						
1. Physical Contingencies	19.30	100%	19.30			
2. Price Contingencies	50.55	100%	50.55			
Subtotal (C)	69.85	100%	69.85			
D. Financial Charges During						
Implementation						
1. Interest during implementation	57.77	100%	57.77			
Subtotal (D)	57.77	100%	57.77			
Total Project Cost (A+B+C+D)	2,057.77	100%	2,057.77			

# Table 10: Detailed Cost Estimates by Output

(\$ million)

Note: Numbers may not sum precisely because of rounding. In September 2021 prices. Physical contingencies computed at 1% for COVID-19 vaccines.

Source: Asian Development Bank estimates.

#### G. Detailed Cost Estimates by Year

# Table 11: Detailed Cost Estimate by Year (\$ million)

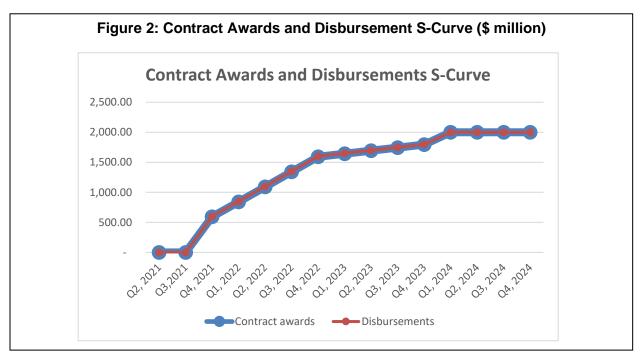
		Total				
ltem		Cost	2021	2022	2023	2024
Α.	Investment Costs					
	1. Supply contract for eligible vaccines	1,930.15	579.04	965.07	193.01	193.01
	Subtotal (A)	1,930.15	579.04	965.07	193.01	193.01
B.	Recurrent costs					
	1. Other vaccine related costs	0.00	0.00	0.00	0.00	0.00
	Subtotal (B)	0.00	0.00	0.00	0.00	0.00
	Total Base Cost	1,930.15	579.04	965.07	193.01	193.01
C.	Contingencies					
	1. Physical Contingencies	19.30	5.79	9.65	1.93	1.93
	2. Price Contingencies	50.55	7.71	25.42	7.55	9.87
	Subtotal (C)	69.85	13.50	35.08	9.48	11.80
D.	Financial Charges During Implementation					
	1. Interest during implementation	57.77	2.84	13.90	19.57	21.46
	Subtotal (D)	57.77	2.84	13.90	19.57	21.46
Total	Project Cost (A+B+C+D)	2,057.77	595.39	1,014.05	222.06	226.27
% Total Project Cost		100%	29%	49%	11%	11%

Note: Numbers may not sum precisely because of rounding.

Source: Asian Development Bank estimates.

### H. Contract and Disbursement S-Curve

16. Figure 2 shows quarterly contract awards and disbursement projections over the life of the project. The S-curve is for ADB financing and ADB administered loan, recorded in ADB's systems and reported through eOps. The projection for contract awards excludes financial charges during implementation.



#### Q = quarter.

Source: Asian Development Bank.

# Table 12: Contract Awards and Disbursement Baseline Projections for ADB Loan 1 (\$ million)

Year	Contract Awards (in \$ million)					Disbursements (in \$ million)				
i eai	Q1	Q2	Q3	Q4	Cum. Total	Q1	Q2	Q3	Q4	Cum. Total
2021	-	-	-	148.14	148.14	-	-	-	150.00	150.00
2022	62.51	62.51	62.51	62.51	398.17	62.50	62.50	62.50	62.50	400.00
2023	12.66	12.66	12.66	12.66	448.80	12.50	12.50	12.50	12.50	450.00
2024	51.20	-	-	-	500.00	50.00	-	-	-	500.00
	Total Contract Awards					Total Disbursements				500.00

Q = quarter.

Source: Asian Development Bank estimates.

					(¥ IIIIIOI	'/				
Year	Contract Awards (in \$ million)					Disbursements (in \$ million)				
Teal	Q1	Q2	Q3	Q4	Cum. Total	Q1	Q2	Q3	Q4	Cum. Total
2021	-	-	-	296.27	296.27	-	-	-	300.00	300.00
2022	125.02	125.02	125.02	125.02	796.35	125.00	125.00	125.00	125.00	800.00
2023	25.31	25.31	25.31	25.31	897.59	25.00	25.00	25.00	25.00	900.00
2024	102.41	-	-	-	1,000.00	100.00	-	-	-	1,000.00
	Т	otal Contr	act Award	s	1,000.00		Total Disb	ursements		1,000.00

# Table 13: Contract Awards and Disbursement Baseline Projections for ADB Loan 2 (\$ million)

Q = quarter.

Source: Asian Development Bank estimates.

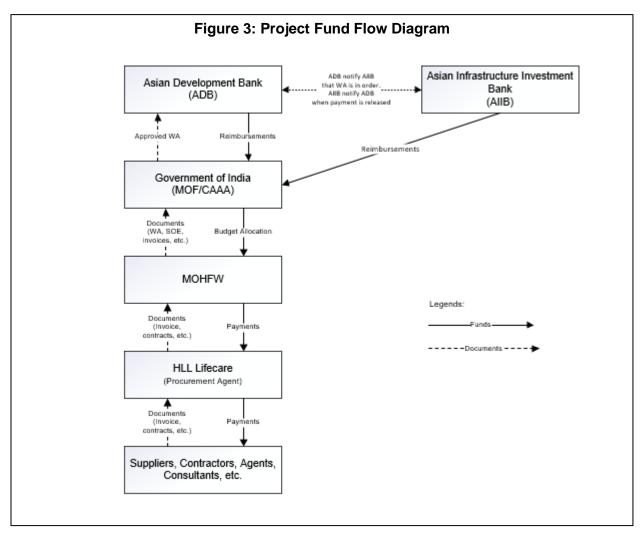
#### Table 14: Contract Awards and Disbursement Baseline Projections for AIIB (\$ million)

(*										
Veer	Contract Awards (in \$ million)					Disbursements (in \$ million)				
Year	Q1	Q2	Q3	Q4	Cum. Total	Q1	Q2	Q3	Q4	Cum. Total
2021	-	-	-	148.14	148.14	-	-	-	150.00	150.00
2022	62.51	62.51	62.51	62.51	398.17	62.50	62.50	62.50	62.50	400.00
2023	12.66	12.66	12.66	12.66	448.80	12.50	12.50	12.50	12.50	450.00
2024	51.20	-	-	-	500.00	50.00	-	-	-	500.00
	Г	otal Contr	ract Award	s	500.00	Total Disbursements				500.00

Q = quarter. Source: Asian Development Bank estimates.

#### I. Fund Flow Diagram

17. The overall project fund flow is illustrated in the figure below.



ADB = Asian Development Bank, AIIB = Asian Infrastructure Investment Bank, CAAA = Controller of Aid Accounts and Audit, MOF = Ministry of Finance, MOHFW = Ministry of Health and Family Welfare. Source: Asian Development Bank.

# V. FINANCIAL MANAGEMENT

# A. Financial Management Assessment

18. A financial management assessment (FMA) was conducted during February and August 2021 in accordance with ADB's Guidelines.<sup>1</sup> The FMA evaluated the MOHFW as the executing agency and the Immunization Division under MOHFW as the implementing agency. The FMA focused on assessing the financial management arrangements such as fund flows, staffing, accounting policies and procedures, internal controls, financial reporting, and internal and external audit for the project. The project is a subset of the ongoing COVID-19 vaccination program of the government, thus, the FMA also covered evaluation of key financial management aspects of the NDVP.<sup>2</sup>

19. The project will use the existing country system. The MOHFW has a well-established implementation arrangements and coordination mechanism from the national to state, district, and block level, which have been operational under the UIP for the routine immunization. The existing systems and mechanisms have been strengthened with additional resources and enhanced systems to cater the unprecedented scale of adult vaccination program. Vaccine supply for public delivery is the central government's responsibility, while inoculation services at state level is the responsibility of states, districts, and block authorities' responsibility under the overall coordination of the states. The central government also provides states with financial resources for operational costs from the COVID-19 Emergency Response and Health System Strengthening package (around \$3,168 million) approved in July 2021.

20. MOHFW has implemented various development partners' projects and is currently implementing an ADB-funded project.<sup>3</sup> The ongoing project's performance and compliance with ADB's financial management requirements is rated "on-track". MOHFW has an Integrated Finance Division which provide budget, finance, and accounting support to various divisions within MOHFW. There is a well-defined and established financial procedures as per the Government Accounting Rules, 1990 and General Financial Rules, 2017. The government also adopts automated budgeting, accounting, and fund management system. Moreover, the Government of India has deployed the electronic Vaccine Intelligence Network platform for integrated inventory management and control of vaccine supplies. This platform's vaccine logistics and supply data can be easily collated with vaccination beneficiary information from the Winning Over COVID-19 (Co-WIN) platform. Co-WIN is an end-to-end vaccination management system which account and report data at every step of the vaccination program process, and therefore can track the vaccine doses to beneficiaries. The FMA found that MOHFW has adequate financial management capacity to (i) record and account the project financial transactions, (ii) operate the statement of expenditure procedures (SOEs), (iii) provide reliable guarterly financial reports and annual audited financial statements, and (iv) safeguard that the funds are used for the purpose intended.

21. The key financial management risks identified include the following: (i) lack of dedicated sub-budget head for the project which may lead to inconsistent financial monitoring and reporting; (ii) non-inclusion of the project in the annual internal audit workplan may result to funds or

<sup>&</sup>lt;sup>1</sup> ADB. 2015. Financial Management Technical Guidance Note: Financial Management Assessment. Manila; ADB. 2020. ADB's Support to Enhance COVID-19 Vaccine Access. Manila; and ADB. 2021. APVAX Preparation Guidance Note. Manila.

<sup>&</sup>lt;sup>2</sup> Government of India. National Development and Vaccination Plan for COVID-19 Vaccines. Delhi.

<sup>&</sup>lt;sup>3</sup> ADB. 2015. <u>Results-Based Loan and Administration of Technical Assistance Grant India: Supporting National Urban</u> <u>Health Mission</u>. Manila.

vaccines misused; and (iii) delay in submission of audited project financial statements (AFPSs) to ADB. The financial management risk will be mitigated through (i) establishment of subbudget/account head for the project prior to loan effectiveness date, (ii) inclusion of the project in the annual internal audit workplan, (iii) MOHFW will prepare the project financial statements timely and submit to Comptroller and Auditor General (CAG) of India for timely audit, (iv) completion of audit and submission of APFSs to ADB within 6 months from end of fiscal year, and (v) regular monitoring and reporting of the project through quarterly progress reports (QPRs) which will include the audit observations and the status of implementation of audit recommendations. The overall pre-mitigation financial management risk for the project is "substantial" primarily due to the unprecedented scale and complexity of the project. The executing and implementing agencies have agreed to implement the financial management action plans detailed in Table 15. The FMA indicates that with the risk mitigation measures and the adoption of the financial management action plan, the financial management systems are acceptable for the proposed project.

	Risk	
Risk Description Inherent Risk	Assessment	Mitigation Measures
Country specific risk. Weaknesses in policy-based budgeting (especially the lack of a multiyear perspective), control in budget execution, internal audit, as well as timeliness of external audits and follow-up on audit findings.	Moderate	ADB will monitor the ongoing implementation of PFM reforms aligned with Second Administrative Reform Commission's recommendations.
<b>Program specific risk.</b> Delay of vaccine availability. The high global demand for COVID-19 vaccines exceeds global supply for approved vaccines. This may delay the COVID-19 vaccination rollout of GOI due to limited vaccines availability.	Moderate	The government has engaged HLL Lifecare Limited as procurement agent with purchasing and negotiation power to secure the vaccines. The government will source the vaccines both from domestic and international sources.
Overall Inherent Risk	Moderate	
Project Risk	-	
<b>Funding.</b> Significant financing is needed to deploy the COVID-19 vaccines to the target population. Delays in allocation and release of budget may lead to inadequate project financing and implementation delays.	Moderate	For FY2021–2022 budget, the government has approved and allocated >50% of the total program cost. MOHFW shall regularly review and monitor the annual budget and coordinate with MOF on timely allocation of adequate budget for COVID-19 vaccination program.
Vaccine inventory management. Vaccine lost, misused, or misappropriated.	Low	As the risk is "Low", no mitigation measure required.
Accounting and financial reporting. Dedicated sub-budget head that will ring- fence the project financing and expenditures from other financial transaction of the ministry has yet to be created. This may lead to inconsistent financial monitoring and reporting.	Substantial	MOHFW will create sub-budget head for the Project. This will ease tracking of budget, accounting, and financial reporting of the project. Also, MOHFW, with the support from ADB's TA, will engage a dedicated financial management consultant which will be responsible to prepare the project financial reporting for submission to ADB. QPRs will be produced and submitted to ADB within 45 days from end of each quarter.

Table 15: Financial Management, Internal Control and Risk Assessment

Assessment	
	Mitigation Measures
Substantial	The project will be included in the internal
	audit plan and adequate experienced staffs
	will be assigned to conduct the audit.
Substantial	MOHFW needs to work with the external
	auditor to ensure that audited project
	financial statements are submitted within 6
	months after the end of the fiscal year.
	CAG will conduct the audit in accordance
	with the terms of reference agreed with
	ADB.
	MOHEW will submit the APES to ADB
	within 6 months from end of the fiscal year.
Substantial	wann o monaio nom ond or the isoar year.
Substantial	
S	Substantial

ADB = Asian Development Bank, APFS = audited project financial statement, CAG = Comptroller and Auditor General, COVID-19 = coronavirus disease, FY = fiscal year, GOI = Government of India, MOF = Ministry of Finance, MOHFW = Ministry of Health and Family Welfare, NDVP = National Deployment and Vaccination Plan, QPR= quarterly progress report, TA = technical assistance.

Source: Asian Development Bank.

22. The executing agency and the implementing agency have agreed to implement an action plan that describes the key measures to improve financial management, detailed in Table 16.

	Table 16. Financial Management	Action Plan	
Area	Action Item	Period	Responsibility
1. Funding	a. Update the budget for COVID-19 related activities including cost of vaccines, logistics, cold chain, etc. and the financing plan to address the same on a regular basis.	Quarterly	MOHFW
	b. Draw up the fund requirement plan for the next FY and submit to MOF.	Annually in accordance with the budget circular timeline of MOF	MOHFW
2. Accounting and financial reporting	a. Create a dedicated sub-budget head for the project (reflecting ADB and AIIB as funding sources).	By end October 2021	MOHFW
	b. With the support from ADB's TA, engage a dedicated financial management consultant which will be responsible to prepare the unaudited project financial statements for financial	By end October 2021	MOHFW and ADB

# Table 16. Financial Management Action Plan

Area	Action Item	Period	Responsibility
	reporting to ADB in accordance with templates (Cash basis) suggested in terms of reference document used in audit of ADB assisted projects for timely submission and qualitative reporting to ADB. <sup>4</sup>		
	c. Produce and submit the QPRs to ADB within 45 days from end of each quarter.	45 days from end of each quarter	MOHFW
3. Internal audit	a. Include the project in the internal audit plan for the period of the project.	Annually (by June of each year)	MOHFW
	b. Monitor resolution of internal audit observations.	Quarterly	MOHFW
	c. Include the internal audit observations and recommendations and actions taken by MOHFW in QPRs and submitted to ADB quarterly.	Quarterly	MOHFW
4. External audit	a. Notify CAG on the requirement for the audit of the project in accordance with the terms of reference agreed with CAG for ADB funded projects.	Annually	MOHFW
	b. CAG to conduct audit on an annual basis for the period of the project.	Annually	CAG
	c. Monitor resolution of audit observations and actions needs and include them in QPRs for ADB.	Quarterly	MOHFW
	d. Submit audited APFS within 6 months from end of FY.	Annually	MOHFW
5. Performance audit	a. Jointly finalize and agree the terms of reference for the performance audit.	By inception date	CAG and ADB
	b. CAG to conduct the performance audit of the national COVID-19 vaccination program	By Q4 2023	CAG
	c. Copy of the performance audit report submitted to ADB.	By Q3 2024 or 1 month from completion whichever is earlier ^	MOHFW and CAG

ADB = Asian Development Bank, APFS = audited project financial statement, CAG = Comptroller and Auditor General, FY = fiscal year, MOF = Ministry of Finance, MOHFW = Ministry of Health and Family Welfare, QPR= quarterly progress report.

^ Date indicative and subject to discussion during inception.

Source: Asian Development Bank.

<sup>&</sup>lt;sup>4</sup> TOR document duly agreed with comptroller and auditor general (C&AG) of India office and approved by the department of economic affairs available in DEA website.

# B. Disbursement

# 1. Disbursement Arrangements for ADB and AllB Funds

23. The loan proceeds from ADB and AIIB will be disbursed in accordance with ADB's *Loan Disbursement Handbook* (2017, as amended from time to time),<sup>5</sup> and detailed arrangements agreed upon between the government, ADB, and AIIB. ADB will review submitted withdrawal applications and pay its share of financing against confirmed withdrawal application and advise AIIB on their share of financing disbursement. Online training for project staff on disbursement policies and procedures is available.<sup>6</sup> The PMU staff and consultants are encouraged to avail of this training to help ensure efficient disbursement and fiduciary control.

24. The Immunization Division under the MOHFW will be responsible for (i) preparing disbursement projections, (ii) requesting budgetary allocations for ADB and AIIB and counterpart funds, (iii) collecting and retaining supporting documents, (iv) preparing withdrawal applications, and (v) submission of withdrawal applications and other relevant documents through the Controller of Aid Accounts and Audit to ADB. The Immunization Division will be supported by the Integrated Finance Division and other relevant divisions and units of the MOHFW for the project implementation.

25. Eligible expenditures under the project will follow the indicative master list of eligible items and agreed list of acceptable expenditure items ('positive list') for ADB financing under the rapid response component (Appendix 2).

26. **Reimbursement procedure** will be used where ADB pays from the loan account to the borrower's account, for eligible ADB's share of expenditures which have been incurred and prefinanced by the government out of its budget allocation or its own resources.

27. **Advance fund procedure.** The government opted not to avail for advance fund procedure for this project.

28. **Retroactive financing.** Loan proceeds can be withdrawn to reimburse or finance the eligible expenditures incurred under the project before the loan effective date, subject to a maximum amount equivalent to 30% of the RRC financing amount, provided that the expenditures have been incurred not earlier than 12 months before the date of the loan agreements.

29. Use of the disbursement procedures in the PAM shall remain flexible and switching between modes may be done as per the request of the borrower to account for the uncertainty in the supply timeline and related payment modes.

30. **Statement of expenditure procedure.** <sup>7</sup> The SOE procedure may be used for reimbursement of eligible expenditures. The ceiling of the SOE procedure is the equivalent of \$100,000 per individual payment. Supporting documents and records for the expenditures claimed under the SOE should be maintained and made readily available for review by ADB's disbursement and review missions, upon ADB's request for submission of supporting documents on a sampling basis, and for independent audit. Reimbursement in excess of the SOE ceiling should be supported by full documentation when submitting the withdrawal application to ADB.

<sup>&</sup>lt;sup>5</sup> ADB. 2017. *Loan Disbursement Handbook*. Manila. The handbook is available electronically from the ADB website.

<sup>&</sup>lt;sup>6</sup> Disbursement eLearning. <u>http://wpqr4.adb.org/disbursement\_elearning.</u>

<sup>&</sup>lt;sup>7</sup> SOE forms are available in Appendix 7B and 7D of <u>ADB's Loan Disbursement Handbook</u> (2017, as amended from time to time).

31. Before the submission of the first withdrawal application, the borrower should submit to ADB sufficient evidence of the authority of the persons who will sign the withdrawal applications on behalf of the borrower, together with the authenticated specimen signatures of each authorized person. The minimum value per withdrawal application is stipulated in the *Loan Disbursement Handbook* (2017, as amended from time to time). Individual payments below such amount should be paid by the MOHFW and subsequently claimed to ADB through reimbursement. The borrower should ensure sufficient category and contract balances before requesting disbursements. Use of ADB's Client Portal for Disbursements system is mandatory for submission of withdrawal applications to ADB.<sup>8</sup>

32. **Disbursement of AIIB Financing.** The borrower shall submit the original withdrawal application and copies of supporting documents to ADB, and concurrently one identical copy of such withdrawal applications and copies of supporting documents to AIIB. ADB shall review each withdrawal application, in accordance with ADB disbursement procedures and guidelines and advise AIIB to make the necessary payment, if any, subject to approval by AIIB. AIIB's approval shall be made in accordance with the AIIB loan agreement and other applicable guidelines and procedures. AIIB will promptly inform ADB once payment has been made. In case AIIB rejects the payment requested in the withdrawal application, it shall promptly inform ADB and the borrower in writing of its decision and the basis of such decision. ADB shall not be held liable for any decision made by AIIB with respect to payments requested in withdrawal applications or any delay in disbursement outside of ADB's control.

# 2. Disbursement Arrangements for Counterpart Fund

33. Disbursement for counterpart funds, if any, will be carried out according to the government's guidelines and practices. The government counterpart funds will be sufficiently allocated in the budget annually. The Immunization Division will prepare disbursement projections and request budgetary allocations for counterpart funds to the Ministry of Finance. The Immunization Division will submit to ADB annual project contract awards and disbursement projections at least a month before the start of each calendar year, if applicable.

# C. Accounting

34. The Immunization Division will maintain separate project accounts and records by funding source for all expenditures incurred on the project. The project accounts will follow the government accounting standards. The Immunization Division will prepare project financial statements in accordance with government accounting laws and regulations.

35. The expenditure categories and output used in the financial reports will be aligned with the structure outlined in the PAM. Moreover, to allow for timely and efficient monitoring, the Immunization Division will ensure that comprehensive financial information is included in the QPRs to be submitted to ADB within 45 days after the end of each reporting period. The financial information to be included in the progress report is included in Appendix 3.

36. **Variance analysis.** The Immunization Division will examine the differences between budgeted vs. actual expenditures.

<sup>&</sup>lt;sup>8</sup> Client Portal for Disbursements. <u>https://cpd.adb.org/</u>. Online guide can be accessed at <u>https://www.adb.org/documents/client-portal-disbursements-guide</u>.

37. **Periodic reconciliations**. To ensure the correctness and completeness of the project's books of accounts and financial reports, the Immunization Division shall conduct biannual reconciliation of the project book of accounts, and ADB's disbursement data available in the Loan Financial Information System and report this as part of QPRs.

38. Any discrepancies and/or reconciliation items will be followed up to ensure these are resolved in a prompt manner. The differences between amounts claimed from ADB and the amounts disbursed by ADB will be disclosed and explained in the withdrawal application register to be included in the financial reports.

# D. Auditing and Public Disclosure

39. **Internal audit.** The project will be covered by a regular internal audit of the MOHFW. The Immunization Division will actively liaise with the internal audit of the MOHFW to ensure that the recommendations related to the project (if any) are addressed in a timely manner. The status of the internal audit recommendations will also be regularly monitored by MOHFW.

40. **Financial audit.** The MOHFW will cause the detailed project financial statements to be audited in accordance with auditing standards promulgated by the CAG of India. The APFS together with the auditor's opinion will be presented in the English language to ADB within 6 months from the end of the fiscal year.

41. The audit report for the project financial statements will include a management letter and auditor's opinions, which cover (i) whether the project financial statements present a true and fair view or are presented fairly, in all material respects, in accordance with the applicable financial reporting standards; (ii) whether the proceeds of the loan were used only for the purpose(s) of the project; and (iii) whether the borrower or executing agency was in compliance with the financial covenants contained in the legal agreements (where applicable). The management letter will include from the second year onwards, a follow-up on previous years audit observations. In case the auditor does not issue a management letter, the auditor must issue a written confirmation that no internal control issues were identified as part of the audit.

42. Compliance with financial reporting and auditing requirements will be monitored by review missions and during regular project oversight, and followed up regularly with all concerned, including the external auditor.

43. The government and the MOHFW have been made aware of ADB's approach to delayed submission, and the requirements for satisfactory and acceptable quality of the audited project financial statements.<sup>9</sup> ADB reserves the right to require a change in the auditor (in a manner consistent with the constitution of the borrower), or for additional support to be provided to the

<sup>&</sup>lt;sup>9</sup> ADB's approach and procedures regarding delayed submission of audited project financial statements:

<sup>(</sup>i) When audited project financial statements are not received by the due date, ADB will write to the executing agency advising that (a) the audit documents are overdue; and (b) if they are not received within the next 6 months, requests for new contract awards and disbursement such as processing of new reimbursement, and issuance of new commitment letters will not be processed.

<sup>(</sup>ii) When audited project financial statements are not received within 6 months after the due date, ADB will withhold processing of requests for new contract awards and disbursement such as processing of new reimbursement, and issuance of new commitment letters. ADB will (a) inform the executing agency of ADB's actions; and (b) advise that the loan may be suspended if the audit documents are not received within the next 6 months.

<sup>(</sup>iii) When audited project financial statements <u>are not received within 12 months after the due date</u>, ADB may suspend the loan.

auditor, if the audits required are not conducted in a manner satisfactory to ADB, or if the audits are substantially delayed. ADB reserves the right to verify the project's financial accounts to confirm that the share of ADB's financing is used in accordance with ADB's policies and procedures.

44. Public disclosure of the APFS, including the auditor's opinion on the project financial statements, will be guided by ADB's Access to Information Policy 2018.<sup>10</sup> ADB will disclose the APFS and the opinion of the auditors on the project financial statements no later than 14 days of ADB's confirmation of their acceptability by posting them on ADB's website. Management letter and additional auditor's opinions will not be disclosed.<sup>11</sup>

45. **Performance audit.** The performance audit for the COVID-19 national vaccination program shall be conducted by CAG in accordance with auditing standards promulgated by the CAG of India to ensure economy, efficiency, and effectiveness of vaccine program. The findings will help further strengthening pandemic preparedness and health system strengthening. The performance audit will be carried out before end of the project. The indicative scope of the performance audit is in Appendix 4. The performance audit report in English shall be shared with ADB by Q3 2024 or 1 month from completion of the report, whichever is earlier.

# VI. PROCUREMENT AND CONSULTING SERVICES

# A. Advance Contracting and Retroactive Financing

46. All advance contracting and retroactive financing will be undertaken in conformity with ADB's Procurement Policy (2017, as amended from time to time)<sup>12</sup> and Procurement Regulations for ADB Borrowers (2017, as amended from time to time).<sup>13</sup> The borrower, executing agency, and implementing agency have been advised that approval of advance contracting and retroactive financing does not commit ADB to finance the project.

47. **Advance contracting.** Advance contracting will apply for all contracts for procurement of COVID-19 vaccines which will be subject to APVAX eligibility criteria (footnote 1).

48. **Retroactive financing.** Retroactive financing refers to ADB's financing of project expenditures incurred by the borrower prior to the effectiveness of the loan agreement but not earlier than 12 months prior to the signing of the loan agreement. Except as otherwise agreed with ADB, the expenditures incurred for procurement of COVID-19 vaccines that are eligible for advance contracting will be eligible for retroactive financing of up to 30% of the ADB RRC financing amount.

# B. Procurement of Goods, Works, and Consulting Services

49. All procurement of goods and services will be undertaken in a manner consistent with the simplified and expedient procedures permitted under the ADB Procurement Policy (2017, as amended from time to time) (footnote 12) and Procurement Regulations for ADB Borrowers (2017, as amended from time to time) (footnote 13).

<sup>&</sup>lt;sup>10</sup> ADB. 2018. <u>Access to Information Policy</u>. Manila.

<sup>&</sup>lt;sup>11</sup> This type of information would generally fall under access to information policy exceptions to disclosure. ADB. 2018. <u>Access to Information Policy</u>. Manila. Paragraph 17 (viii) and (ix).

<sup>&</sup>lt;sup>12</sup> ADB. 2017. <u>ADB Procurement Policy</u>. Manila.

<sup>&</sup>lt;sup>13</sup> ADB. 2017. <u>Procurement Regulations for ADB Borrowers. Goods, Works, Nonconsulting and Consulting Services</u>. Manila.

50. The procurement of vaccines against COVID-19 will be undertaken through the RRC, in conformity with its APVAX vaccine eligibility criteria. Procurement under the RRC is restricted to the purchase of vaccines, its associated international logistics costs necessary for their delivery to the final destinations, and some specific consulting services.

51. The MOHFW has engaged HLL as a procurement agent funded by the government budget to handle various aspects of COVID-19 vaccines procurement, contract management and delivery (para. 9). HLL is a well performing government-owned enterprise under the MOHFW. HLL has been undertaking large procurement for MOHFW of all COVID-19 related emergency purchases of materials like N95 surgical masks, personal protective equipment kits, gloves, face shields, etc. Procurement capacity assessment of HLL was undertaken during due diligence of project preparation. HLL has extensive procurement expertise using both national and international competitive bidding procedures, vast delivery network, and experience in managing cold chains and multi-modal logistics and distribution oversight to final destinations. HLL work based on Procurement Manual<sup>14</sup> and Integrity Pact Policy<sup>15</sup> which are in line with the policy and procedures of the government including ministry directives and requirements of Central Vigilance Commission.<sup>16</sup> This arrangement will free up MOHFW resources to focus on implementing vaccine roll out and measured to arrest the spread of COVID-19 and to try and contain any possible third wave.

52. The procurement of vaccines and related services will be done by direct contracting method of DGCI approved vaccines that meet APVAX eligibility criteria. MOHFW will decide on the vaccines to be procured based on the proposal submitted by vaccine manufacturer, and to be priced on a fixed-term basis inclusive of GST. HLL will subsequently negotiate terms of the contract, and sign and manage the contract on behalf of MOHFW. HLL will ensure that the vaccine is pre-inspected and tested by authorized national drug testing laboratory<sup>17</sup> for delivery as per agreed delivery method, schedule, tranches, quantity, and destination. The manufacturer shall provide full warranty throughout the vaccine's shelf life and pay liquidated damages for delays. Terms of payment may include high advance payment against an irrevocable Bank Guarantee valid for contract period plus shelf life plus other predetermined period. ADB loan will finance contracts for Covishield by Serum Institute of India, which is eligible under APVAX, and Covaxin by Bharat Biotech when it meets APVAX eligibility criteria. With eased regulatory, procurement from international vaccines manufacturers<sup>18</sup> remains an option under the project. Following ADB's APVAX policy (footnote 1), ADB's member country procurement eligibility restrictions will be waived, and universal procurement will apply.

53. Majority of the vaccines to be financed under the project have been procured through advance contracting. To be eligible for ADB financing, the MOHFW will issue a side letter to these

<sup>&</sup>lt;sup>14</sup> Softcopy is available for reference.

<sup>&</sup>lt;sup>15</sup> Available through this link.

<sup>&</sup>lt;sup>16</sup> The Central Vigilance Commission is the apex Indian governmental body created to address governmental corruption.

<sup>&</sup>lt;sup>17</sup> For example: Central Drugs Laboratory in Kasauli, Himachal Pradesh, and the Indian Institute of Biologicals in Uttar Pradesh's Noida.

<sup>&</sup>lt;sup>18</sup> The Government of India has also eased regulatory pathways and approved vaccines which have been granted emergency approval for restricted use by the US Food and Drug Administration, European Medicines Agency, UK Medicines and Healthcare Products Regulatory Agency, Pharmaceuticals and Medical Devices Agency Japan, or which are listed in WHO (Emergency Use Listing Procedure). To fast-track imports, the government also waived the requirement of a bridging trial for well-established foreign vaccines on 27 May 2021.

contracts to incorporate ADB Anticorruption and Integrity provisions as well as other pertinent information to meet APVAX eligibility criteria, such as information on vaccine manufacturing location. All contracts for any remaining vaccines to be procured under the project shall include the same provisions and be subject to prior review by ADB.

54. Value for money in procurement will be achieved through (i) selecting candidate vaccine types that are best suited to the domestic logistics supply chain and distribution mechanisms; (ii) identifying vaccines that will efficiently meet the project disbursement conditions; (iii) engaging with manufacturers who have advantageous vaccine availability and delivery timelines; and (iv) entering into agreements on terms and conditions that are reasonable, noting the currently constrained market for vaccines globally. Advance contracting carried out by MOHFW has thus far resulted in competitive vaccine price in the market and value for money.

# C. Procurement Plan

55. The procurement plan (Appendix 5) is prepared in accordance with need of the procurement. The procurement plan indicates procurement method, review procedures, procurement of goods, and contract packages. The procurement plan provides (i) a list of contract packages that will be processed over the next 18 months; (ii) the proposed methods for procurement of such contracts that are permitted under the loan agreement; and (iii) the related ADB review procedures. A delay in loan effectiveness, other start-up delays, and delays during implementation will require an unscheduled procurement plan update. ADB will review each updated procurement plan prior to its publication. Current procurement plan mostly captures information on advance contracting of vaccines procurement.

## VII. SAFEGUARDS

56. **Environment safeguards (C)**. The project will support procuring safe and effective vaccines against COVID-19 utilizing the RRC of APVAX. The procurement of COVID-19 vaccines is not anticipated to result in any significant adverse environmental impacts. Due diligence assessed the current legal and regulatory framework, BMWM plan for the COVID-19 vaccination drive, capacity for BMWM, and projected biomedical waste (BMW).

57. India's longstanding UIP has adopted clear legal and regulatory frameworks for BMWM accompanied by comprehensive guidelines. BMWM Rules 2016 provides clear guidance on BMWM to minimize risk to health care workers and the community. Further, COVID-19 Vaccines Operational Guidelines, 2020 issued by MOHFW provides guidelines for BMWM during COVID-19 vaccination drive. Guidelines on BMWM under the UIP (2021) provides additional guidance for BMWM from COVID-19 immunization program. Due diligence confirmed that the amount of BMW expected to be generated from the COVID-19 immunization program is guantified as nominal in comparison to the overall BMW generation in the country. Majority of BMW is treated by common biomedical waste treatment facilities (CBMWTF) following Central Pollution Control Board guidelines. The due diligence report on BMW generation calculates the incremental load from COVID-19 vaccination to be 50 tons/day or 4.21% of total BMW generation. Of the 19 states which will be the focus of the project: (i) 10 states are utilizing less than 70% BMW capacity and have 18 additional CBMWTF under construction, (ii) five states are utilizing less than 90% BMW capacity and have 10 additional CBMWTF under construction, and (iii) four states are utilizing over 90% BMW capacity with three of the states having additional CBMWTF under construction.<sup>19</sup>

<sup>&</sup>lt;sup>19</sup> COVID-19 Immunization Waste Management Assessment (accessible from the list of linked documents in Appendix 2 of the report and recommendation of the President).

For one state, its state pollution control board has undertaken a gap assessment and plans to establish at least one additional CBMWTF which will have an incinerator, autoclave, shredder, and effluent treatment plant. In addition to waste treated in CBMWTF, the state also has 362 captive treatment facilities with 27 incinerators. This state will also utilize deep burial in compliance with BMWM Rules 2016 (and subsequent amendments) in rural and remote areas where there is no access to a CBMWTF. Thus, the project is classified as category 'C' for environment.

58. ADB TA projects have been supporting the COVID-19 response and vaccination program. One of the TA outputs is for improving management and safe disposal of immunization waste. It will strengthen monitoring of BMWM through field level monitors of vaccination sites and in improving the tracking of the disposal process and record keeping. It will also (i) develop standard operating procedures and various information materials for dissemination; (ii) support capacity building of over 2,000 health care and frontline workers and 200 civil society organizations (CSOs) and nongovernment organizations (NGOs); as well as (iii) develop guidance on improved BMW disposal practices such as deep burial or incineration. It will demonstrate best practice examples through hand-holding support in 10 vaccination centers in three selected states including Delhi, Rajasthan, and Tamil Nadu. Findings will be shared widely through webinars for possible scaling up and adoption across other states. Together, these activities would help sustain focus on BMW.

59. **Involuntary resettlement (category C).** The project will not require any land acquisition or lead to any involuntary resettlement impacts. Improved medical waste management will not result in civil works under the project. Should any civil works or other investments become necessary that could potentially result in impacts on land and resource, those impacts will be screened and if necessary, avoided, reduced, mitigated, or compensated in line with international best practice and/or the ADB Safeguard Policy Statement (SPS) (2009).

60. **Indigenous peoples (category C)**. While the indigenous people communities are present in the country, they will not be targeted as distinct and vulnerable indigenous peoples as a group, as defined by ADB's indigenous peoples safeguard policies, but may benefit as individual indigenous peoples. The project will ensure that members of indigenous people's groups will not be excluded and will not suffer any disadvantages in targeting due to the fact of belonging to an indigenous peoples group. The proposed loan is not expected to have any direct or indirect impacts on the dignity, human rights, livelihood systems, or culture of indigenous peoples, or the territories or natural or cultural resources that indigenous peoples own, use, occupy, or claim as an ancestral domain or asset.

61. **Prohibited investment activities.** Pursuant to ADB's SPS (2009), ADB funds may not be applied to the activities described on the ADB Prohibited Investment Activities List set forth at Appendix 5 of the SPS (2009).

# VIII. GENDER AND SOCIAL DIMENSIONS

62. **Gender equality and social inclusion.** The project is categorized *effective gender mainstreaming*. A gender equality and social inclusion (GESI) action plan has been agreed with the MOHFW. Monitoring of the GESI action plan implementation will be done jointly with the Immunization Division and AIIB, supported by the PMU consultants. The project aims to achieve vaccination of around 360 million population including 47.5% female at the outcome level, with reporting per age group, geographical location (by region/rural/urban) and sex. The GESI action plan targets include (i) 50% increase in knowledge on prevention and management of COVID-19

and COVID-19 vaccines among vulnerable people (including poor, women, older people, persons with disabilities, residents in rural and remote areas, and other disadvantaged minority groups) in 10 states; (ii) at least 20 partners/networks and platforms working with disadvantaged communities, especially women trained as master trainers to facilitate outreach of COVID-19 appropriate behaviors, other COVID-19 related information, and vaccine communication; (iii) at least 2,000 (including at least 40% women) medical and paramedical, auxiliary, and treatment and disposal facility staff are trained on BMWM (at least 40% women) and at least 200 CSOs and NGOs are trained for amplifying the message of environmentally sound biomedical waste management; and (iv) dynamic analyses of data (disaggregated by rural/urban, women/men/others, and priority vulnerable groups) generated from Co-WIN dashboard to support timely policy formulation and decision making. The lessons learned and best practices from COVID-19 vaccination especially in GESI aspects will also be compiled and disseminated for system strengthening and future pandemic response. The resources, including consultant services and financial resources are allocated for GESI action plan implementation and monitoring and will come from TA 6733. The GESI action plan is in Table 17.

		Responsible			
Activities	Indicators/Targets	Agency	Timeframe		
Output 1. Safe and effective COVID-19 vaccines supplied for eligible population in project states					
<ol> <li>Integrate a GESI lens in the dynamic analysis of data generated by Co-WIN dashboard to inform decision making on vaccine deployment (TA<sup>a</sup> output 1.3)</li> </ol>	<ul> <li>(i) A gendered analysis (disaggregated by region/rural/ urban, and priority vulnerable groups) of the vaccination data generated by Co-WIN dashboard conducted.<sup>b</sup></li> <li>(ii) An action/policy brief prepared based on the above analysis and disseminated to states and other stakeholders to support timely decision making.</li> </ul>	MOHFW, PMU consultants/ WHO	2022		
<ol> <li>Compile lessons and best practices from COVID-19 vaccination to enhance the UIP systems and mechanisms, including GESI aspects for future pandemic response (TA output 1.4)</li> </ol>	<ul> <li>(iii) Lessons learnt and best practices from COVID-19 vaccination especially in gender equality and social inclusion aspects compiled and disseminated to states and other stakeholders for system strengthening and future pandemic response.</li> <li>(iv) A (one) workshop organized to share lessons learnt and best practices with a focus on equitable access to vaccines.</li> </ul>	MOHFW, PMU consultants/ WHO	2022		
<ol> <li>Build the capacity of people engaged in BMWM including women. (TA output 3.6)</li> </ol>	<ul> <li>(v) Various modes of training programs developed</li> <li>(online/classroom/shop floor) to reach out different professional groups.</li> <li>(vi) At least 2,000 medical and paramedical, auxiliary and treatment and disposal facility staff including at least 40% women trained on BMWM.</li> </ul>	MOHFW, PMU consultants/ WHO	2023		
4. GESI-sensitive branding and messaging for COVID-19 appropriate behaviors and vaccination information are	(vii) GESI sensitive awareness <sup>c</sup> raising materials made visible at vaccination centers and in rural catchment areas.	MOHFW, PMU consultants/ UNICEF	2023		

#### Table 17. Gender Equality and Social Inclusion Action Plan

		r
disseminated through vaccination centers and rural catchment areas (TA output 5.1)	<ul> <li>(viii) Baseline for the awareness among vaccination center visitors and catchment area population established</li> <li>(ix) Effect of the visible messages assessed through a sample survey biannually.</li> </ul>	
5. Strengthen the capacities of services providers including campaigners, vaccination teams, elected representatives, local influencers, women groups and CSOs in RCCE outreach activities to target excluded and vulnerable groups. (TA output 5.2)	<ul> <li>(x) At least 20 partnerships/ networks including from local CSOs, NGOs, CBOs, women's groups, SHGs and their federations including those representing women and other vulnerable groups trained as master trainers<sup>d</sup></li> <li>(xi) The partners/networks and platforms<sup>e</sup> working with vulnerable groups, especially women facilitate outreach of CAB, CAB+ and vaccine communication.</li> <li>(xii) Sex disaggregated baseline established on the knowledge on prevention and management of COVID-19 and COVID-19 vaccination among vulnerable people including women in 10 states.</li> <li>(xiii) Vulnerable people report improved knowledge on the prevention and management of COVID-19 and COVID-19 vaccination in 10 states.</li> <li>(xiii) Vulnerable people report improved knowledge on the prevention and management of COVID-19 and COVID-19 vaccines in 10 states targeting a 50% increase (of 50% at least 20% are women<sup>f</sup>)</li> </ul>	ints/
Project management Support		
<ol> <li>Recruit a GESI specialist in the PMU. (TA output 1.1)</li> </ol>	<ul> <li>(xiv) GESI specialist provides input and relevant data on all GESI commitments set out in the project.</li> <li>(xv) GESI-AP progress reports</li> </ul>	/, 2021 onwards.
BMWM = biomedical waste management,	submitted biannually. CAB = COVID-19 appropriate behaviors, CAB+	= COVID-19 related

BMWM = biomedical waste management, CAB = COVID-19 appropriate behaviors, CAB+ = COVID-19 related information, CBO = community-based organization, COVID-19 = coronavirus disease, CSO= civil society organization, GESI = gender equality and social inclusion, MOHFW = Ministry of Health and Family Welfare, NGO = nongovernment organization, PMU=project management unit, RCCE = risk communication and community engagement, SHG = self-help group, TA = technical assistance, UNICEF = United Nations Children's Fund, UT=union territory.

Note: Consultations, meetings, and training programs to be either organized virtually and/or follow the state government guidelines for social distancing and pandemic protocols. All trainings to include post training assessment to measure/evaluate learning gains.

<sup>a</sup> ADB 2021: Technical assistance to India: <u>Supporting COVID-19 Response and Vaccination Program</u>. Manila (TA 6733).

<sup>b</sup> Including poor, women, older people, persons with disabilities, residents in rural and remote areas, and other disadvantaged minority groups)

<sup>&</sup>lt;sup>c</sup> GESI sensitive awareness raising material includes but not limited to gender and socially inclusive materials promoting equality and inclusion and avoiding bias and stereotyping in the development and dissemination of material including amongst others in consideration of the following: (i) equal representation of women and men, girls and boys along with representation of PwDs, elderly and other vulnerable groups in visual and verbal communications; (ii) avoid gender stereotypical portrayal of women and men in all forms of communications including pictorial representations.

- <sup>d</sup> The master trainers can be community leaders, teachers, frontline workers, accredited social health activists, auxiliary nurse midwife, NGOs, CBOs, and women groups leaders and private service providers.
- <sup>e</sup> New networks may include: (i) Community Led Local Entitlements and Claims Tracker (an NGO working on social accountability system strengthening, engaging marginalized communities through a network of CBOs, CSOs and individuals across 75–100 districts); (ii) CSOs and NGOs working with persons with disabilities; and (iii) rural banking networks which run access to financing programs for the poor and cover over 230 million households in semi-urban and rural areas.

<sup>f</sup> Out of 50% people with increased knowledge on prevention of COVID-19, 20% are women which means that of those reporting improved knowledge, 40% are women.

Source: Asian Development Bank.

# IX. PERFORMANCE MONITORING, EVALUATION, REPORTING, AND COMMUNICATION

## A. Project Design and Monitoring Framework

63. The project design and monitoring framework for the project is in Appendix 7.

### B. Monitoring

64. Project performance monitoring. Overall monitoring of project progress will be undertaken by the government, which will review regular progress reports on implementation of the national vaccination program, which is supported by the project, as submitted by MOHFW. The concerned line ministries, acting on behalf of the government, will monitor progress, procurement, quality, and contract management. ADB, AIIB, and the implementing agency will conduct semiannual joint reviews throughout the implementation of the project and will regularly monitor the (i) project output quality, (ii) implementation arrangements, (iii) implementation progress, (iv) disbursements, and (v) implementation progress of the vaccination program. The pre-wrap-up of the joint review mission will be chaired by the additional commissioner (UIP) MOHFW. Performance for the project will be monitored based on indicators and targets stipulated in the design and monitoring framework. Disaggregated baseline data for output and outcome indicators gathered during project processing will be updated and reported on guarterly basis through the implementing agency's QPRs and after each joint review mission. Results will feed into ADB's project performance monitoring system in eOps (reported during guarterly validation exercise).

65. The APVAX policy (footnote 1) requires additional information on vaccine procurement and the national vaccine program implementation in QPRs. The indicative format of the progress report is available in Appendix 3.

66. **Compliance monitoring.** The loan agreements specify the undertakings and covenants that will be monitored through regular review missions and discussed with the executing agency/implementing agency. Compliance with undertakings and loan covenants, social and environmental safeguards, gender, and financial management aspects will be jointly monitored by ADB, AIIB, and the executing agency/implementing agency. Any noncompliance issues will be specified in the QPRs together with remedial actions.

67. **Safeguards monitoring.** No standalone safeguards monitoring report is required since the project is categorized C for all safeguards (environment, involuntary resettlement, and indigenous peoples). However, the Q4 progress report (in lieu of consolidated annual reports) and the project completion report stated below shall report in compliance with the loan agreements, including those clauses pertaining to safeguards. The reports shall also document

and assess the COVID-19 immunization waste management system's adequacy, quality of performance, and corrective actions planned to improve its effectiveness, as needed.

68. **Gender and social dimensions monitoring.** The GESI action plan will be routinely monitored by the implementing agency. The agency will ensure that GESI progress and achievements are reflected in monitoring and evaluation formats and reports. GESI action plan implementation and periodic reporting will be included in the QPRs in accordance with the GESI action plan monitoring and reporting format in Appendix 6 and submitted to ADB and AIIB. ADB and AIIB will also assess the progress of these activities during the joint review missions. In addition, the inclusion and compliance with labor standards, health, and gender aspects will be monitored through review of bidding documents, contract awards, and progress reports. The GESI action plan monitoring format is in Appendix 6.

69. **Performance audit of the national vaccination program.** A performance audit will be conducted within the project period (indicatively in Q4 2023) and will monitor the performance of the national vaccination program from procurement to distribution of the vaccines in accordance with the NDVP for COVID-19 and any subsequent policies. The performance audit will evaluate governance, financial accountability, and transparency. The main objective of performance auditing is constructively to promote economical, effective, and efficient governance and contribute to accountability and transparency, and to contribute towards health system strengthening, especially for any future emergency response or national vaccination efforts. The performance audit report will be submitted to ADB and other development partners by Q3 2024 or 1 month after completion of the report, whichever is earlier.

## C. Evaluation

70. An ADB inception mission will be fielded within 3 months after the loans are declared effective; thereafter, ADB and AIIB, and the TA implementation partners (i.e., UNICEF and WHO) will conduct regular joint semiannual review missions to review and discuss progress, and report on the project and TA performance. As necessary, special loan administration missions and a midterm review mission will be fielded, under which any changes in scope or implementation arrangements required to ensure the achievement of project objectives will be discussed. Within 6 months of physical completion of the project, the MOHFW will submit a project completion report to ADB and AIIB.

71. The latest QPR (with the cumulative achievements in outcome and output performance indicators and any issues emerged during the report period along with any backlog of unresolved issues) before the review missions will inform review, special administration, or midterm review missions.

## D. Reporting

72. The Immunization Division/MOHFW will provide ADB and AIIB with QPRs in a pre-agreed format which will meet the requirements of the ADB's project performance reporting system, no later than 45 days after end of each quarter. The QPRs should include (i) financial and disbursement information, variance analysis of physical and financial progress, details of utilization of funds and reconciliation with ADB Loan Financial Information System, and status of resolution of audit findings; (ii) cumulative progress in achieving outcome and output performance indicators; (iii) key implementation issues and solutions. QPR for Q2 and Q4 will additionally include COVID-19 immunization waste management status and the status of compliance with

loan covenants. QPR for Q4, which will serve as consolidated annual report, will also include updated procurement plan, and updated implementation plan for the next 12 months. A project completion report will be submitted within 6 months of physical completion of the project.

## E. Stakeholder Communication Strategy

73. The project will comply with the transparency and accountability policy of the Access to Information Policy (ADB. 2018. Access to Information Policy. Manila). To do so, it will establish a communications strategy that will ensure an efficient and continuous two-way communication about ADB projects with stakeholders, focusing on managing stakeholders' expectations during all phases of implementation. The strategy will follow the following approaches:

- (i) Stakeholders. Critical stakeholders include people affected by COVID-19, and women and vulnerable groups. Other key stakeholders include, but are not limited to, MOHFW as executing agency, government officials at national and sub-national levels, interested community-based organizations, interested civil society organizations, interested private sector entities, and interested development partners.
- (ii) Disclosure. MOHFW will disclose on its website all information relevant to this project, including the scope, cost, financial and institutional arrangements, the annual progress reports, progress on procurement, and the APFS. The website will provide the contact details of implementing agency staff in English, Hindi and other widely used languages in India and a link to the webpage of ADB's Office of Anticorruption and Integrity (OAI) at <u>http://www.adb.org/Integrity/report-violations</u> for reporting allegations of corrupt and fraudulent practices, and other integrity violations arising out of the project and/or project activities.
- (iii) Communication focal point. The Immunization Division under MOHFW will be responsible for implementation and monitoring of information dissemination and disclosure of information related to the project and project activities. The Immunization Division will also designate a focal person within the PMU for information dissemination and disclosure, who will also serve as the custodian of all information relevant to the project.

74. The government developed the COVID-19 Vaccine Communication Strategy to support the national vaccination program by raising awareness on new vaccines, addressing vaccine hesitancy, and promote COVID-19 appropriate behaviors. Guided by the strategy and under the overall coordination of MOHFW and state authorities, several development partners, and numerous NGOs and CSOs have been supporting risk communication and community engagement efforts for the COVID-19 vaccination. The Immunization Division will closely work with UNICEF and WHO in the risk communications and community engagement activities under TA 6733.

## X. ANTICORRUPTION POLICY

75. ADB reserves the right to investigate, directly or through its agents, any violations of the Anticorruption Policy (1998, as amended to date) relating to the project.<sup>20</sup> All contracts financed by ADB shall include provisions specifying the right of ADB to audit and examine the records and accounts of the executing and implementing agencies and all project contractors, suppliers, consultants, and other service providers. Investigation of government officials, if any, will be

<sup>&</sup>lt;sup>20</sup> ADB. 1998. *Anticorruption Policy*. Manila.

requested to be undertaken by the government. Individuals and/or entities on ADB's anticorruption debarment list are ineligible to participate in ADB-financed, -administered, or - supported activities and may not be awarded any contracts under the project.<sup>21</sup>

76. To support these efforts, relevant provisions are included in the loan agreement, project agreement, the bidding documents, and contracts for the project, as applicable. ADB's Anticorruption Policy and ADB's Integrity Principles and Guidelines (2015, as amended from time to time) were explained to and discussed with the MOHFW and the Immunization Division. Specifically, the MOHFW and the Immunization Division should gain access to ADB's Complete Sanctions List (https://www.adb.org/site/integrity/sanctions) to confirm that no bidder, contractor, supplier, individual consultant, consulting firm, and its team members (as applicable) are currently subject to ADB sanctions during bid/proposals evaluation, prior to shortlisting, contract award, and contract variations, extensions or modifications. The MOHFW and the Immunisation Division should access <a href="https://www.adb.org/integrity/report-violations">https://www.adb.org/integrity/report-violations</a> so that they are aware about where, how and what to report if there is an integrity concern or allegation of integrity violation on ADB-related activity.<sup>22</sup>

77. OAI is the initial point of contact for all allegations of fraud, corruption, or other integrity violations in any ADB-financed, administered, or supported projects. Complaints may be reported to the Office of Anticorruption and Integrity through one of the following methods:

by online complaint form at https://www.adb.org/integrity/report-violations#accordion-0-0 by e-mail at integrity@adb.org or anticorruption@adb.org by phone at +63 2 8632 5004 by fax to +63 2 8636 2152 by mail at the following address (Please mark correspondence Strictly Confidential):

Office of Anticorruption and Integrity Asian Development Bank 6 ADB Avenue, Mandaluyong City 1550 Metro Manila, Philippines

78. Transparency International ranked India 80th out of 180 countries on its Corruption Perception Index in 2019. India, with a score of 41/100, is ranked much higher than its neighbors in South Asia and several countries in Southeast Asia. Nevertheless, given the increasing expectation of citizens for improved governance, the implementation of the anticorruption mechanisms clearly needs to be strengthened.

79. **Procurement probity**. All central and state government employees are required to commit to conduct, discipline, and appeal rules, which include a commitment to the statement of ethics. The public procurement rules and policies and the general conditions of contract clearly define situations of conflict of interest. The rules also stipulate that anyone involved in the procurement process should declare any potential conflict of interest. Further, rule 37 of the General Financial Rules states that an officer will be held personally responsible for any loss sustained by the government through fraud or negligence. The government has an elaborate institutional framework for checking probity in public procurement. Apart from the CAG, the Central Vigilance Commission, Central Bureau of Investigation, and Competition Commission of India examines anticompetitive elements and can impose a penalty if it finds evidence for

<sup>&</sup>lt;sup>21</sup> ADB's Anticorruption Sanctions List: <u>https://www.adb.org/site/integrity/sanctions.</u>

<sup>&</sup>lt;sup>22</sup> Reporting integrity violations: <u>https://www.adb.org/integrity/report-violations.</u>

involvement in anticompetitive activities such as bid rigging, collusive bidding, cartelization, or abuse of power. Apart from the institutional mechanism, state governments have put in place procedures for blacklisting of bidders. State governments upload blacklisting details on their eprocurement portals.

80. **Vaccination program oversight and monitoring mechanism**. Specific to the national vaccination program, there are high level of government oversight and public scrutiny. The National Expert Group on Vaccine Administration for COVID-19 has been constituted at the central level to advise on all aspects of the COVID-19 vaccine including vaccine trials, vaccine selection, equitable distribution of vaccines, procurement, financing, delivery mechanisms, prioritization, safety surveillance and vaccine communication strategy. Further, there is direct oversight from the Prime Minister's office where regular meetings are undertaken with states which might be lagging in performance or pertaining to technical issues such as vaccine wastage. In addition to this, the Supreme Court of India has required explanation from the MOHFW on several aspects of deployment, thus providing oversight to the vaccine rollout strategy and implementation. Robust digital platforms deployed for the management of vaccine doses. All vaccine doses are tracked from manufacturers to beneficiaries, including wastages.

81. **Grievance redressal mechanisms.** MOHFW has been operating a toll free 24x7 national helpline '1075' and another helpline (011-23978046) for addressing queries related to the COVID-19 pandemic, vaccine rollout and the Co-WIN software. In addition to 1075, a technical helpline (0120-4473222) has been established to specifically handle Co-WIN software-related queries. Any technical issue which is not resolved by 1075 is directed to the Technical Helpline for resolution. MOHFW has also created an email id (ncov2019@gov.in) for addressing COVID-19 related queries and grievances in addition to providing a repository of state COVID-19 helplines and website links for relevant resources, on its website - https://www.mohfw.gov.in/. State 104 helplines have been augmented to address queries on COVID-19 vaccination including grievance redressal related to vaccination process as well as linking to concerned facilities for management of any adverse event. As per guidelines, all grievances are to be reviewed at regular intervals at the level of state task force, district task force, urban task force, and block task force.

## XI. ACCOUNTABILITY MECHANISM

82. People who are, or may be in the future, adversely affected by the project may submit complaints to ADB's Accountability Mechanism. The Accountability Mechanism provides an independent forum and process whereby people adversely affected by ADB-assisted projects can voice, seek a resolution of their problems, and report alleged violations of ADB's operational policies and procedures. Before submitting a complaint to the Accountability Mechanism, affected people should try in good faith to solve their problems by working with the concerned ADB operations department. Only after doing that, and if they are still dissatisfied, should they approach the Accountability Mechanism.<sup>23</sup>

### **Contact details:** Secretary Compliance Review Panel Asian Development Bank 6 ADB Avenue Mandaluyong City

<sup>&</sup>lt;sup>23</sup> Accountability Mechanism. <u>https://www.adb.org/who-we-are/accountability-mechanism/main</u>.

1550 Metro Manila, Philippines

Tel + 63 2 632 4149 Fax +63 2 636 2088 E-mail: <u>crp@adb.org</u> Web: <u>www.compliance.adb.org</u>

## XII. RECORD OF CHANGES TO THE PROJECT ADMINISTRATION MANUAL

83. The first draft of PAM has been prepared and agreed upon at the loan negotiations in October 2021. All revisions/updates including the revision to contract awards and disbursement S-curves during implementation will be retained in this section to provide a chronological history of changes to implemented arrangements recorded in the PAM.

	Date	Revisions
First revision		
Second revision		

## **TECHNICAL ASSISTANCE**

1. The Technical Assistance (TA) grant support is provided by Asian Development Bank (ADB) through two TA projects. These include the following:

- (i) TA 9950-Regional Support to Address the Outbreak of Coronavirus Disease (COVID-19) and Potential Outbreaks of Other Communicable Diseases (\$3 million); and
- (ii) TA 6773-India: Supporting COVID-19 Response and Vaccination Program (\$7 million).

2. Activities under TA 9950 includes (i) strengthening points of entry for enhanced screening of the passengers; (ii) 'War room' support to the Ministry of Health and Family Welfare for ensuring and active surveillance of the COVID-19 cases and response; development of Winning for COVID-19 dashboard and planning of ancillary supply; (iii) strengthening capacity for pandemic preparedness through back-end support on financial management and information technology tools. (iv) strengthening of facility level monitoring of vaccinations being undertaken (and adherence to operational guidelines) including close support to monitoring of adverse events following immunization given the increased pace of vaccination

- 3. Activities under TA 6773 includes the following for COVID-19 vaccination program:
  - (i) Support national vaccine program implementation through operationalizing a program management unit (PMU) in Immunization Division for improved guidance to states; field level monitoring of vaccination sites and cold chain points, including of adverse events following immunization; dynamic data analysis with improved disaggregation (on gender, rural and urban and priority groups vaccination status) from digital platforms to inform decision making; distilling learnings from current vaccination program, including those on inclusion, for future pandemic response or national vaccination programs (through ADB-hired consultants under PMU).
  - (ii) Support improved engagement of private sector through capacity building on national guidelines; provide practical guidance on various vaccine management and administration, and support monitoring of national guidelines adherence within the private sector. The TA will facilitate regular reporting on adherence of national guidelines within the private sector (through WHO).
  - (iii) Support improved vaccination waste management through strengthening of the monitoring of biomedical waste management; improved tracking of biomedical waste management; developing relevant guidelines and standard operating procedures; capacity building of various stakeholders, including nongovernment organizations and civil society organizations on environmentally sound biomedical waste management (BMWM) practices; developing case study and demonstration sites where best practices in BMWM is undertaken and share knowledge within various stakeholders. (through WHO).
  - (iv) Strengthen awareness of COVID-19 and vaccination program among disadvantaged groups through improving visibility of COVID appropriate behavior related communication at service delivery points; improved risk communication and community engagement outreach with focus on poor, women, older people, persons with disabilities, residents in rural and remote areas, and other disadvantaged minority group; leverage alternate community networks and frontline workers from other national health programs, rural services (e.g. banks), and local self-government mechanisms such as panchayats (through UNICEF).

### INDICATIVE MASTER LIST OF ELIGIBLE ITEMS AND AGREED LIST OF ACCEPTABLE EXPENDITURE ITEMS ('POSITIVE LIST') FOR ADB FINANCING UNDER THE RAPID RESPONSE COMPONENT

- 1. The eligible items agreed for financing will include:
  - advance market commitments and/or payments or procurement costs for vaccines acquired through the COVID-19 Vaccines Global Access Facility (irrespective of whether India eventually procures vaccines through the facility);
  - (ii) vaccines that meet any of the eligibility criteria outlined in the linked document: Eligibility Criteria for Use of Funds under the Rapid Response Component.<sup>1</sup>
    - (a) Vaccines that meet at least one of the eligibility criteria and will be potentially financed by the Asian Development Bank such as, Pfizer/Moderna vaccine, Oxford/AstraZeneca vaccine manufactured by the Serum Institute of India (SII), and Johnson & Johnson's Janssen vaccine manufactured by authorized manufacturers, etc.
    - (b) Vaccines being explored for procurement which may also be financed by the Asian Development Bank <u>if they meet one of the eligibility criteria</u> are COVAXIN vaccine manufactured by Bharat Biotech International Limited; COVOVAX vaccine manufactured by the SII; SPUTNIK V vaccine manufactured by Gamaleya Research Institute of Epidemiology and Microbiology, by Dr. Reddy's Laboratories, by SII, or by Panacea Biotech (and others); COBERVAX manufactured by Bio E; and ZyCOV-D manufactured by Zydus Cadila and others;
  - (iii) advance payments for vaccines that meet one of the eligibility criteria, and that will be procured from vaccine manufacturers and distributors (see item ii);
  - (iv) international logistics and related services required for the transportation of eligible vaccines to designated delivery points in India; and
  - (v) indirect management fees, with reasonable percentage normally below 10% of the loan amount managed, charged as required by the United Nations agencies' financial regulations or similar authoritative guidelines.

<sup>&</sup>lt;sup>1</sup> Eligibility Criteria for Use of Funds Under the Rapid Response Component (accessible from the list of linked documents in Appendix 2 of the report and recommendation of the President).

## OUTLINE QUARTERLY PROGRESS REPORT FORMAT

### **General Instructions**

1. The quarterly progress reports (QPRs) should follow the format outlined below and are to be submitted to ADB within 45 days after each quarter. In case of delays or incomplete information, ADB will submit a reminder to the executing agency/implementing agency. Repeated delays or incomplete information may have a negative impact on the project performance ratings and may be discussed during review missions.

2. For specific ADB reporting purposes the progress report will contain the following information:

## Section A. Introduction and Basic Data

- i. ADB/AIIB loan number, project title, borrower, executing agency, implementing agency
- ii. total estimated project cost and financing plan;
- iii. status of project financing including availability of counterpart funds;
- iv. dates of approval, signing, and effectiveness of ADB/AIIB loans;
- v. original and revised (if applicable) ADB/AIIB loan closing date and elapsed loan period based on original and revised (if applicable) loan closing dates; and
- vi. date of last joint review mission and or progress review meeting.

## Section B. Utilization of Funds (ADB Loan, and Counterpart Funds)

- i. Cumulative contract awards financed by the ADB/AIIB loan, and counterpart funds (commitment of funds to date), and comparison with time-bound projections (actual contract award achievement against projected targets in the PAM). Include an analysis of significant variances between projected and actual contract awards;
- ii. Cumulative disbursements from the ADB/AIIB loan, and counterpart funds (expenditure to date), and comparison with time-bound projections (actual disbursement against the projected disbursement targets in the PAM). Include an analysis of significant variances between projected and actual disbursements; and
- iii. Re-estimated costs to completion, need for reallocation within ADB/AIIB loan categories, and whether an overall project cost overrun is likely.
- iv. Reconciliation of project records and ADB disbursement records (LFIS/GFIS) and AIIB records for the reporting period and cumulative from project inception to end of the reporting period. Explain reasons for discrepancies and outline follow-up actions required (if any). Attach a detailed reconciliation by withdrawal application as per <u>Appendix C.</u>

## Section C. Project Purpose

- i. status of project progress towards outcome and output performance indicators compared with those in design and monitoring framework, and whether major changes have occurred or will need to be made;
- ii. an assessment of the likelihood that the outcome and output performance indicators will be met in part or in full, and whether remedial measures are required based on the current project scope and implementation arrangements; and
- iii. an assessment of changes to the key assumptions and risks that affect attainment of the development objectives.

## **Section D. Implementation Progress**

- i. provide a brief summary assessment of progress or achievements in implementation since the last progress report;
- ii. assessment of the progress of each project component, such as (a) procurement of goods and (b) the performance of suppliers, manufacturers, and contractors for goods contracts;
- iii. assessment of progress in implementing the overall project to date in comparison with the original implementation schedule—quantifiable and monitorable target, (include simple charts such as bar or milestone to illustrate progress, a chart showing actual versus planned expenditure, S-curve graph showing the relationship between physical and financial performance, and actual progress in comparison with the original schedules. Include an analysis of significant variances between physical and financial progress; and,
- iv. an assessment of implementation challenges and any need to change any part of implementation arrangements.

## Section E. Major Project Issues and Problems

3. Summarize the major problems and issues affecting or likely affect implementation progress, compliance with covenants, and immediate development objectives. Recommend actions to overcome these problems and issues (e.g., changes in scope, changes in implementation arrangements, and reallocation of loan proceeds).

# Section F. Compliance with Safeguards and Covenants (reporting twice a year, for Q2 and Q4 reports)

- i. review the borrower's compliance with policy loan covenants, and, where relevant, provide any reasons for any noncompliance or delay in compliance;
- ii. provide a summary assessment of compliance with resettlement and environmental safeguards, if any;
- iii. provide a summary assessment of COVID-19 immunization waste management; and,
- iv. Summarize the status of financial covenants (if any) as outlined in the loan and project agreement.

## Section G. Financial Management

- i. Summarize the status of financial management in the project including: a) any problems in the existing financing management arrangements and /or flow of funds and b) any significant changes occurred during the reporting period (e.g. staff turnover, implementation of new financial systems, emerging financial management related risks etc.);
- ii. Summarize the status of: a) the financial management action plan outlined in the PAM, b) recommendations and actions raised by ADB as part of the APFS review (if any) and c) financial management related recommendations agreed during ADB review missions (if any); and
- iii. Summarize the status of past audit observations (resolved/ pending).

# Section H. Updated Procurement Plan and Implementation Plan (reporting once a year, for Q4 reports)

i. Updated procurement plan for the next 12 months.

ii. Updated project implementation plan for the next 12 months.

## Appendixes

4. Attach the following appendixes to the QPR when submitting it to ADB (using the forms provided in the PAM, as applicable):

- A. Summary Loan Covenant Review
- B. Statement of Cash Receipts and Payments by Category
- C. Detailed reconciliation (by Withdrawal application) of project records and ADB disbursement records (LFIS/GFIS) for the fiscal year to date and cumulative
- D. List of signed contracts
- E. Status of external audit observations (resolved/ pending)
- F. Status of internal audit observations (resolved/ pending)
- G. Status of FM action plan (complied/ongoing)
- H. Status of FM related actions agreed during ADB review missions (if any).
- I. Financial vs. physical progress
- J. Information on project administered vaccines

## QUARTERLY PROGRESS REPORT APPENDIXES

### Appendix A: Summary Loan Covenant Review

Loan Agreement Ref.	Description	Status of Compliance as of xx	

Appe	ndix B: Statement of C	ash Receipts and Paym	ents by Category					
	Reporting Period (Tri- annually/annually)	Year to date	Cumulative	Hard commitments (contracts signed not paid)				
	In the currency of the finar	he currency of the financial statements						
Cash receipts								
ADB Advance/Replenishments	Q	Q*	Q^					
ADB Reimbursement/Retroactive Financing	U	U*	U^					
AIIB Advance/Replenishments	м	M*	М^					
AIIB Reimbursement/Retroactive Financing	ο	O*	0^					
Government	S	S*	S^					
Total	T=Q+P +U+M+N+0+S	T*=Q*+P* *+U*+M*+N*+O*+S	T^=Q^+P^+U^+M^+N^+O^+S ^					
Payments								
Vaccines costs	А	A*	A^	A**				
Consultancy services	В	B*	В^	B**				
Project administration	С	C*	C^	C**				
Other related costs	D	D*	D^	D**				
Total expenditures	E=A+B+C+D	E*=A*+B*+C*+D*	E^=A^+B^+C^+D^	E**=A**+B**+C**+D **				
Opening cash balance	н	H*	Н^					
Closing cash balance	K=H+T-E	K*=H*+T*-E*	K^=H^+T^-E^					

Appendix B: Statement of Cash Receipts and Payments by Category

WA Details			Per project records/APFS (Amount recorded in the project Financial statements as reimbursement, etc)				records	isbursement LFIS/GFIS Il Paid) <sup>1</sup>		
Withdrawal application No (WA)	Disbursement method (reimbursement, etc)	Time period covered in the WA	Date	In local currency (as recorded in project records/ financial statements)	exchange rate	USD equivalent (A)	Value date	In USD (B)	Difference (A-B)	Reason for difference (i.e. timing forex. Pending rejected)
1		I		1	I		I			I
3										
etc										
Total										

### Appendix C. Detailed Reconciliation (by Withdrawal Application) of Project Records and ADB Disbursement Records (LFIS/GILFIS)

#### for the Fiscal Year to Date and Cumulative

<sup>1</sup> Shall include ADB and AIIB which are both reflected in ADB Disbursement Records (LFIS)

	Appendix D: List of Signed Contracts								
Contract Info	rmation								
Description	Contract	Contract Start	Contract End	Supplier/Contractor Name	Contract No.	Total Contract Value	Total Contract Amount Invoiced to date	Total Disbursed on Contract	Total Undisbursed Amount
1. Vaccine contracts									
2: Other related expenditures									
3. xxxx									
Total									

### Appendix E: Status of External Audit Observations - Cumulative from Inception to End of Reporting Period

 endation/ oservation	External Audit Recommendation	Date of the Recommendation	Planned Actions to Address the Recommendation	Responsibility	Current Status of the Planned Action (pending /resolved)	Remarks

#### Appendix F: Status of Internal Audit Observations – Cumulative from Inception to End of Reporting Period

Recommendation/ Audit Observation	External Audit Recommendation	Date of the Recommendation	Planned Actions to Address the Recommendation	Responsibility	Current Status of the Planned Action (pending /resolved)	Remarks

### Appendix G: Status of Financial Management Action Plan

Key Risk	Risk Mitigating Activity			Current status (implemented/Pending)	Remarks (including an action plan in case of noncompliance)

#### Appendix H: Status of Financial Management Action Plan During Mission

Issue	Agreed Action	ed Action Timeline Responsible Entity		Current status (implemented/Pending)	Remarks (including an action plan in case of noncompliance)	

	Financial vs Physical progress: detailed report												
No	Contract description	Contact Number	Contract amount	Amount disbursed to date	Outstanding balance	Vaccine Lot Number	Quantity of vaccines ordered	Quantity of vaccines received	Remaining quantity of vaccines to be received	Quantity of vaccines in stock	Quantity of vaccines administered / used	Reconciliation items e.g. vaccine wastage etc.	Remarks/ Analysis
			А	В	C=A-B		D	Е	F	G	Н	I=E-G-H	
			(Currency)	(Currency)	(Currency)		#	#	#	#	#	#	
1													
2													
3													
4													
5													

### Appendix I: Financial vs. physical progress - Cumulative

### Appendix J: Information on Project Administered Vaccines

State	Contact Number	Vaccine	Vaccine Lot Number	Quantity of vaccines received	Quantity of vaccines administered/ used	Quantity of vaccines in stock	Remarks/Analysis

## INDICATIVE PERFORMANCE AUDIT TERMS OF REFERENCE

1. **Objective of the assignment.** The primary objective of this assignment is to conduct a performance audit of the Government of India's National COVID-19 Vaccination Program (the Program). The performance audit should be an independent, objective, and reliable examination of whether government undertakings, programs, systems, operations, activities and/or organizations involved in the implementation of the Program are operating in accordance with the principles of economy, efficiency and/or effectiveness and whether there is room for improvement.<sup>1</sup>

2. **Scope of work**. The auditor's review should include an audit of the systems and overall operating procedures for the efficient implementation of the National Vaccination Plan. The auditor review shall include an analysis of:

- (i) Economy. Aims at "keeping the cost low". It focuses on how the audited entities succeeded in minimizing the cost of resources (input), taking into account the appropriate quality of these resources. The auditor should conclude on whether the vaccines were available in due time and of appropriate quantity and quality.<sup>2</sup>
- (ii) Efficiency. Seeks "making the most of available resources". It evaluates whether the inputs have been put to optimal or satisfactory use, or whether the same or similar outputs (in terms of quality and turnaround time) could have been achieved with fewer resources. In other words, it answers the following question: "Are we getting the most output in terms of quantity and quality – from our inputs and actions?". The auditor should conclude whether the available resources and vaccines have been fully utilized and delivered to appropriate recipients and wastage was minimized.
- (iii) Effectiveness. Pursues "Achieving the stipulated aims or objectives". It deals with results by focusing on whether and how the NDVP is meeting its goals. It can be split in two aspects: (a) the attainment of specific objectives in terms of outputs (also called efficacy); and (b) the achievement of intended results in terms of outcomes. The auditor should conclude whether the targeted groups to receive the vaccine were completed and in a timely manner.

3. **Specific areas for audit**. Based on the preliminary risks identified and prioritization made by the auditor, the scope of the audit may include the following areas.

- (i) Assess the sufficiency and timeliness of budget allocation and availability of funds.
- (ii) Review procurement contracts and compliance with these supply agreements.
- (iii) Analyze the coverage of actual vaccination including dropouts and assess whether it complies with the NDVP in terms of quantity and timeliness.
- (iv) Review the availability of resources necessary for the administration of vaccines including syringes, PPEs, etc.
- (v) Analyze vaccine wastage throughout the supply chain.

<sup>&</sup>lt;sup>1</sup> In accordance with auditing standards promulgated by CAG of India.

<sup>&</sup>lt;sup>2</sup> Quality, for the purposes of the 'Economy' analysis, means the opportunity-cost analysis to be made by the government when choosing which vaccine to procure for the purposes of quickly and effectively vaccinate the target population at the lower cost possible. It should confront, for each available option, the benefits of getting the vaccine at a certain cost against the economic costs of not vaccinating the target population.

- (vi) Assess the sufficiency and proper operation and maintenance of cold chain and transportation facilities from the port of entry to distribution at provincial hubs to hospitals or health centers.
- (vii) Assess the availability and capacity of the health workers tasked to administer the vaccines.
- (viii) Evaluate the information system and accuracy of data used for reporting and monitoring.
- (ix) Assess the effectiveness of the communication plan.
- (x) Other areas depending on the risk assessment of the auditor.
- 4. **Documentation**. In undertaking the audit, the audit shall review the following document<sup>3</sup> (including any update to such documents):
  - (i) National Plan for COVID-19 Vaccination in India;
  - (ii) Vaccination projects documents from ADB and other donors financing NDVP;
  - (iii) Legal Agreements from ADB and other donors;
  - (iv) Monthly or quarterly activity reports (programmatic as well as financial);
  - (v) Important correspondence pertaining to implementation matters of the NDVP;
  - (vi) Internal audit reports relevant to the expenditures or any systems, governance or other issue which may impact the NDVP program;
  - (vii) Other relevant documents and data.

5. **Conduct of audit.** The performance audit should follow the auditing standard promulgated by CAG of India or International Standards on Audit (e.g., ISSAI 3000). These standards require that the auditor comply with ethical requirements and plan and perform the audit to obtain sufficient, appropriate evidence and provide a reasonable basis for the findings and conclusions based on the audit objectives.

6. **Audit report.** All reports must be presented in the English language by Q3 2024 or within 1 months from completion of the audit. The auditors are expected to produce a report which should contain, at the minimum, the following information:

- (i) Background Covering the objective, scope, and history of the NDVP Program, the legal and government framework, information on financing and cash and inkind donations, status of implementation of the NDVP program, etc.
- (ii) Roles and Responsibilities For maintaining records, monitoring, and reporting the use of funds and for the implementation of the NDVP program.
- (iii) Audit objectives and Methodology used Informing the (a) subject matter, (b) audit objective(s) and/or questions, (c) audit criteria and its sources, (d) audit-specific methods of data gathering and analysis applied, (e) time period covered, and (f) sources of data.
- (iv) Limitations to the data used.

<sup>&</sup>lt;sup>3</sup> Project documents are available at <u>http://www.adb.org/projects/documents</u>. ADB's guidelines are available at <u>http://www.adb.org/publications/guides</u>.

- (v) Audit Findings This part should cover the main findings and responses obtained.
- (vi) Conclusions This should contain the professional opinions based on the objectives and results of the audits, following applicable international auditing standards.
- (vii) Recommendations This part should provide the recommended measures to help strengthen the NDVP processes and procedures. Additionally, this section should identify gaps and possible actions to strengthen country health sector systems to prepare the Government for future pandemics.

## **PROCUREMENT PLAN**

Basic	Basic Data								
Project Name: Responsive COVID-19 Vaccines for Recovery Project under the Asia Pacific Vaccine Access Facility									
Project Number: 55082-001 Approval Number: TBD									
Country: India	<b>Executing Agency:</b> Ministry of Health and Family Welfare								
Procurement Risk: Substantial	Implementing Agency: Immuniz	zation Division							
Project Financing Amount: \$2,057.77 million ADB Financing: \$1,500.00 million Cofinancing (ADB Administered): \$500.00 million	Project Completion Date: 31 D	ecember 2024							
Date of First Procurement Plan: 6 September 2021 Date of this Procurement Plan: 28 Octo									
Procurement Plan Duration: 18 months	Advance Contracting: Yes	e-GP: No							

## A. Methods, Review and Procurement Plan

Except as the Asian Development Bank (ADB) may otherwise agree, the following methods shall apply to procurement of goods, works, non-consulting services, and consulting services.

Procurement of Goods, Works and Non Consulting Services			
Method Comments			
Direct Contracting (DC)	All vaccine contracts to be financed by the project will be subject to direct contracting and shall meet the eligibility criteria under APVAX.		

## B. List of Active Procurement Packages (Contracts)

The following table lists goods, works, non-consulting, and consulting services contracts for which the procurement activity is either ongoing or expected to commence within the procurement plan's duration.

Goods, Works, and Non consulting Services							
Package Number	General Description	Estimated Value (\$m)	Procurement Method	Review	Bidding Procedure	Advertisement Date	Comments
G01	Procurement of COVID-19 vaccines through bilateral deals	2,000.00		Prior Review	N/A	N/A	No. of Contracts: multiple Domestic Preference: No Advance Contracting: Yes High Risk Contract: Yes COVID-19 Response: Yes Other: For contracts that have already been placed, prior review will consist of review of signed contract and issuance of side letter as per ADB requirement.

COVID-19 = coronavirus disease, DC = direct contracting, NA= not applicable.

## GENDER EQUALITY AND SOCIAL INCLUSION ACTION PLAN MONITORING FORMAT

	Prog	Issues and	
	FIOG	ress to Date Cumulative Progress	Challenges
	Progress for the	(Progress (qualitative and	(Please include
	Quarter	quantitative updates	reasons why
	(Progress for the	including sex-	an activity was
	current quarter-	disaggregated data) from	not fully
	qualitative and	the start of the	implemented,
	quantitative updates	implementation of the GAP	targets fall
	(sex-disaggregated	to the previous quarter's	short, reasons
Activities, Indicators, Targets	data))	progress report.)	for delay, etc.)
Output 1. Safe and effective COVID-19 v	//		
Activity1 Integrate a GESI lens in the			
dynamic analysis of data generated by			
Co-WIN dashboard to inform decision			
making on vaccine deployment (TA			
output 1.3)			
Responsibility: MOHFW, PMU,			
consultants/ WHO			
Time Frame: 2022			
Indicator/target			
i. A gendered analysis			
(disaggregated by region/rural/			
urban, and priority vulnerable			
groups <sup>a</sup> ) of the vaccination data			
generated by Co-WIN			
dashboard conducted.			
ii. An action/ policy brief prepared			
based on the above analysis			
and disseminated to states and			
other stakeholders to support			
timely decision making.			
Activity 2 Compile lessons and best			
practices from COVID-19 vaccination to			
enhance the UIP systems and			
mechanisms, including gender equality			
and social inclusion aspects for future			
pandemic response. (TA output 1.4)			
Responsibility: MOHFW, PMU,			
consultants/ WHO			
Time Frame: 2022			
Indicator/target			
iii. Lessons learnt and best			
practices from COVID-19			
vaccination especially in gender			
equality and social inclusion			
aspects compiled and			
disseminated to states and			
other stakeholders for system			
strengthening and future			
pandemic response			
iV. A (one) workshop organized to			
share lessons learnt and best			
practices with a focus on			
equitable access to vaccines.			
Activity 3 Build the capacity of people			
engaged in BMW management including			
women. (TA output 3.6)			
		1	

_			,
	nsibility: MOHFW, PMU,		
	tants/ WHO		
	rame: 2023		
Indica	tor/target		
٧.	Various modes of training		
	programs developed		
	(online/classroom/shop floor) to		
	reach out different professional		
	groups.		
vi.	At least 2,000 medical and para		
	medical, auxiliary and treatment		
	and disposal facility staff		
	including at least 40% women		
	trained on BMWM.		
	y 4 GESI-sensitive branding and		
	ging for COVID-19 appropriate		
	ors and vaccination information		
	seminated through vaccination		
	s and rural catchment areas (TA		
output			
	nsibility: MOHFW, PMU,		
	tants/ UNICEF		
	Frame: 2023		
	tor/target		
vii.	GESI sensitive awareness		
	raising materials made visible at		
	vaccination centers and in rural		
	catchment areas.		
viii.	Baseline for the awareness		
	among vaccination center		
	visitors and catchment area		
	population established.		
ix.	Effect of the visible messages		
	assessed through a sample		
	survey bi-annually.	 	
	y 5 Strengthen the capacities of		
	es providers including		
	igners, vaccination teams, elected		
	entatives, local influencers, women		
	and CSOs in RCCE outreach		
	es to target excluded and		
	able groups. (TA output 5.2). •nsibility: MOHFW, PMU,		
	tants/ UNICEF		
	Frame: 2021–2023		
	tor/target		
Х.	At least 20 partnerships/		
	networks including from local		
	CSOs, NGOs, CBOs, women's		
	groups, SHGs and their		
	federations including those		
	representing women and other		
	vulnerable groups trained as master trainers. <sup>b</sup>		
vi			
xi.	The partners/ networks and		
	platforms <sup>c</sup> working with		
	vulnerable groups, especially		
	women facilitate outreach of		
	CAB, CAB+ and vaccine		
	communication.	L	

-			
xii.	Sex disaggregated baseline		
	established among vulnerable		
	groups on the knowledge on		
	prevention and management of		
	COVID-19 and COVID-19		
	vaccination among vulnerable		
	people including women in 10		
	states.		
xiii.	Vulnerable people report		
	improved knowledge on the		
	prevention and management of		
	COVID-19 and COVID-19		
	vaccines in 10 states targeting a		
	50% increase (of 50%, 20% are		
	women <sup>d</sup> ]		
Projec	t Management Support		
Activit	y 7 Recruit a GESI specialist in		
	IU. (TA output 1.1)		
Respo	nsibility: MOHFW, PMU		
Time F	Frame: 2021 onwards		
Indicator/target			
xiv.	GESI specialist provides input		
	and relevant data on all GESI		
	commitments set out in the		
	project.		
xv.	GESI-AP progress reports		
	submitted biannually.		

BMWM = biomedical waste management, CAB = COVID-19 appropriate behaviors, CAB+ = COVID-19 related information, CBMWTF = common biomedical waste treatment facility, CBO = community-based organization, COVID-19 = coronavirus disease, CSO = civil society organization, GESI = gender equality and social inclusion, HCW = health care worker, MOHFW = Ministry of Health and Family Welfare, NGO = nongovernment organization, PMU = project management unit, RCCE = risk communication and community engagement, SHG = self-help group, TA = technical assistance, UIP= Universal Immunization Programme, UNICEF = United Nations Children's Fund, UT = union territory, WHO = World Health Organization.

- <sup>a</sup> Including poor, women, older people, persons with disabilities, residents in rural and remote areas, and other disadvantaged minority groups)
- <sup>b</sup> The master trainers can be community leaders, teachers, FLW/ASHAs, ANMs, NGOs, CBOs, and women groups leaders and private service providers.
- <sup>c</sup> New networks may include: (i) community-led local entitlements and claims tracker (an NGO working on social accountability system strengthening, engaging marginalized communities through a network of community-based organizations, CSOs and individuals across 75–100 districts); (ii) CSOs and NGOs working with persons with disabilities; and (iii) rural banking networks which run access to financing programs for the poor and cover over 230 million households in semi-urban and rural areas.
- <sup>d</sup> Out of 50% people with increased knowledge on prevention of COVID-19, 20% are women which means that of those reporting improved knowledge, 40% are women.

Source: Asian Development Bank.

DESIGN AND MONITORING FRAMEWORK					
Impact the Project is Aligned with Accelerated health, social, and economic recovery from COVID-19 in India (NDVP for COVID-19 Vaccine) <sup>a</sup>					
		Data Sources and	Risks and		
Results Chain	Performance Indicators	Reporting Mechanisms	Critical Assumptions		
Outcome Eligible populations safely vaccinated against COVID-19 in project states	By 2024: a. At least 317 million target populations (at least 47.5% women) vaccinated with at least two doses against COVID-19 in project states <sup>b,c</sup> (Baseline as of 16 Aug 2021: Male: 52.6%, Female: 46.8%, Others: 0.6%) (OP 1.1)	a. Co-WIN and MOHFW project progress reports	A: Sufficient resources to cover operational costs made available on time by government and development partners. A: Adequate and effective awareness- raising campaigns ensure that priority populations are willing to get vaccinated.		
Output Safe and effective COVID-19 vaccines supplied for eligible population in project states.	1a. By 2024, at least 667 million doses of COVID-19 vaccine procured and delivered to the project states <sup>d</sup> (2021 baseline: 0) (OP 1.1.2)	1a. MOHFW project progress report and Co- WIN dashboard	A: Adequate Supply of vaccine that meet APVAX eligibility criteria R: Changing priorities of the implementing agency		
	[Under TA support] 1b. Co-Win dashboard generated reports disaggregated by rural/urban, women/men/others, age made available throughout project implementation. (2021 baseline: Co-WIN dashboard operational)	1b. Co-WIN dashboard and TA monitoring reports			
	<ul> <li>1c. By 2022, lessons learnt and best practices from COVID-19 vaccination especially in gender equality and social inclusion aspects compiled and disseminated for system strengthening and future pandemic response (2021 baseline: N/A)</li> <li>1d. By 2023, vulnerable people<sup>e</sup> reporting improved knowledge on the prevention and management of COVID-19 and COVID-19 vaccines in 10 states increased by 50% (out of 50% increased target at least 20% are women<sup>f</sup>) (2021 baseline to be established by December 2021) (OP 2.5.1)</li> </ul>	1c-e. MOHFW project progress reports, and TA monitoring reports			
	1e. By 2023, at least 2,000 medical and paramedical, auxiliary, and treatment and disposal facility staff (of which				

## DESIGN AND MONITORING FRAMEWORK

	40% are women) have		
	acquired knowledge of BMWM (2020 Baseline: 0) (OP 3.3.2)		
Key Activities with Mi			
	COVID-19 vaccines supplied for		
	ed number of vaccine doses for AE oject states (Q3 2021–Q3 2024)	DB financing (Q1 2021–Q2 202	24) and monitor distribution
	arough PMU consultants, MOHF	W in vaccination program in	plementation and project
requirements (Q3 2021	–Q3 2024)		
to facilitate outreach	partners/networks and platforms wo of COVID-19 appropriate behavi		
communication (Q3 20	21–Q3 2024) ep burial guidance material (Q4 202	21) conduct 10 sessions of tra	ining of trainers ( $01.2022$ )
conduct training on ma	nagement and safe disposal of BM MWM awareness (Q1 2022–Q2 20	1W for relevant staff (from Q1 2	
Project Management			
	arterly progress reports (Q1 2022 of		
Submit annual audited	performance audit of the national v project financial statement (Q2 202 from the completion of the report,	22 onwards) and program perfo	
	tion report (by Q1 2025).	whichever is earlier).	
Inputs			
ADB: \$1,500 million (lo			
AIIB: \$ 500 million (loa			
ADB: \$ 4 million (TA gr	ant) <sup>n</sup> Asian Development Bank, AIIB = A		
19 = coronavirus diseas Health and Family Welfa	BMWM = biomedical waste mana e, Co-WIN = Winning over Covid- ire, NDVP = National Deployment a c, PMU = project management unit	19, CSO = civil society organiz and Vaccination Plan, NGO = r	ation, MOHFW = Ministry of ongovernment organization,
	k III of the National Deployment and	d Vaccine Allocation Plan (acc	essible from the list of linked
documents in Append			
	ciaries will depend on the price of ate. We have assumed 5% wastag		
<sup>c</sup> The project states incl Pradesh, Rajasthan, Chhattisgarh, and I million eligible populat	lude Uttar Pradesh, Maharashtra, E Karnataka, Gujarat, Odisha, Ke Delhi (in the order of size tion, which is 18 years or olde state may be extended to include	erala, Jharkhand, Assam, Pu of eligible population). Thes er people. Combined, they c	njab, Telangana, Haryana, se states have over 10 over over 95% of eligible
<sup>d</sup> The number of doses	will depend on the actual price of ve assumed \$3/dose with two dose		
<ul> <li>Vulnerable people refe areas, and disadvanta</li> </ul>	er to women, income poor, older pe aged minority groups. Women tar siding in rural and remote areas, ar	ople, persons with disabilities, gets will include poor women	residents in rural and remote , older women, women with
f Out of 50% people w	ith increased knowledge on preve ved knowledge, 40% are women.		
	establish baseline for visible messa	aging would be developed by U	NICEF with inputs from ADB
to undertake baseline <sup>h</sup> Support will be covered	assessment and biannual survey ved by ongoing TA from ADB. 202	would assess against the same 1. <u>Technical Assistance to Ind</u>	e indicators established. ia for Supporting COVID-19
Reduction (\$5 million)	ination Program. Manila (TA 673 and TA Special Fund (\$2 million).		le Japan Fund for Poverty

### Contribution to ADB Strategy 2030 Operational Priorities:

Expected values and methodological details for all OP indicators to which this project will contribute results are detailed in the Contribution to Strategy 2030 Operational Priorities (accessible from the list of linked documents in Appendix 2 of the Report and Recommendation of the President). In addition to the OP indicators tagged in the design and monitoring framework, this operation will contribute results for OP 7.3.3 measures to improve regional public health and education services supported in implementation by supporting India's national vaccination program which contributes towards reduction of transmission of COVID-19 in South Asia region and beyond.