



Report and Recommendation of the President to the Board of Directors

Project Number: 55082-001
November 2021

Proposed Loans and Administration of Loan India: Responsive COVID-19 Vaccines for Recovery Project under the Asia Pacific Vaccine Access Facility

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Asian Development Bank

CURRENCY EQUIVALENTS

(as of 2 November 2021)

Currency unit	–	Indian rupee/s (₹)
₹1.00	=	\$0.01336
\$1.00	=	₹74.8363

ABBREVIATIONS

ADB	–	Asian Development Bank
AEFI	–	adverse event following immunization
AIB	–	Asian Infrastructure Investment Bank
APVAX	–	Asia Pacific Vaccine Access Facility
BMW	–	biomedical waste
BMWM	–	biomedical waste management
CBMWTF	–	common biomedical waste treatment facility
COVID-19	–	coronavirus disease
Co-WIN	–	Winning Over COVID-19
CVC	–	COVID-19 vaccination center
GAVI	–	Gavi, the Vaccine Alliance (formerly Global Alliance for Vaccines and Immunisation)
GDP	–	gross domestic product
GESI	–	gender equality and social inclusion
HLL	–	HLL Lifecare Limited
LIBOR	–	London interbank offered rate
MOHFW	–	Ministry of Health and Family Welfare
NEGVAC	–	National Expert Group on Vaccine Administration for COVID-19
NDVP	–	National Deployment and Vaccination Plan
PAM	–	project administration manual
RRC	–	rapid response component
TA	–	technical assistance
UIP	–	Universal Immunization Programme
UNICEF	–	United Nations Children’s Fund
WHO	–	World Health Organization

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 ended on 31 March 2021.
- (ii) In this report, “\$” refers to United States dollars.

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CONTENTS

	Page
PROJECT AT A GLANCE	
I. THE PROPOSAL	1
II. THE PROJECT	2
A. Rationale	2
B. Project Description	9
III. DUE DILIGENCE	12
A. Economic Viability	12
B. Governance	13
C. Poverty, Social, and Gender	13
D. Environment and Social Safeguards	14
E. Summary of Risk Assessment and Risk Management Plan	15
IV. ASSURANCES AND CONDITIONS	16
V. RECOMMENDATION	16
APPENDIXES	
1. Design and Monitoring Framework	17
2. List of Linked Documents	19

PROJECT AT A GLANCE

1. Basic Data		Project Number: 55082-001	
Project Name	Responsive COVID-19 Vaccines for Recovery Project under the Asia Pacific Vaccine Access Facility	Department/Division	SARD/SAHS
Country Borrower	India India	Executing Agency	Ministry of Health and Family Welfare
Country Economic Indicators	https://www.adb.org/Documents/LinkedDocs/?id=55082-001-CEI		
Portfolio at a Glance	https://www.adb.org/Documents/LinkedDocs/?id=55082-001-PortAtaGlance		
2. Sector	Subsector(s)	ADB Financing (\$ million)	
✓ Health	Disease control of communicable disease		1,500.00
		Total	1,500.00
3. Operational Priorities		Climate Change Information	
✓ Addressing remaining poverty and reducing inequalities		GHG reductions (tons per annum)	0.000
✓ Accelerating progress in gender equality		Climate Change impact on the Project	Low
✓ Tackling climate change, building climate and disaster resilience, and enhancing environmental sustainability			
✓ Fostering regional cooperation and integration		ADB Financing	
		Adaptation (\$ million)	0.00
		Mitigation (\$ million)	0.00
		Cofinancing	
		Adaptation (\$ million)	0.00
		Mitigation (\$ million)	0.00
Sustainable Development Goals		Gender Equity and Mainstreaming	
SDG 1.a		Effective gender mainstreaming (EGM)	✓
SDG 3.8			
SDG 5.c		Poverty Targeting	
SDG 10.2		General Intervention on Poverty	✓
SDG 17.6			
4. Risk Categorization:	Complex		
5. Safeguard Categorization	Environment: C Involuntary Resettlement: C Indigenous Peoples: C		
6. Financing			
Modality and Sources		Amount (\$ million)	
ADB		1,500.00	
Sovereign Asia Pacific Vaccine Access Facility (Regular Loan): Ordinary capital resources		1,500.00	
Cofinancing		500.00	
Asian Infrastructure Investment Bank - Asia Pacific Vaccine Access Facility (Partial ADB Administration)		500.00	
Counterpart		57.77	
Government		57.77	
Total		2,057.77	
Currency of ADB Financing: US Dollar			

I. THE PROPOSAL

1. I submit for your approval the following report and recommendation on proposed loans to India for the Responsive COVID-19 Vaccines for Recovery Project under the Asia Pacific Vaccine Access Facility (the project).¹ The report also describes the proposed administration of a loan to be provided by the Asian Infrastructure Investment Bank (AIIB) for the project, and if the Board approves the proposed loans, I, acting under the authority delegated to me by the Board, approve the administration of the loan.

2. The project will benefit significantly from an abbreviated consideration period by the Asian Development Bank (ADB) Board of Directors since it supports the Government of India's rapid vaccination rollout to contain the ongoing pandemic and the severity of a possible third wave as well as the loss of lives. The government has already placed orders for Asia Pacific Vaccine Access Facility (APVAX)-eligible vaccines and incurred substantial costs from the accelerated pace of vaccination since August 2021.² Timely ADB support would add value by helping meet urgent financing needs for delivering APVAX-eligible vaccines for priority population, and allow government resources to procure the planned non-APVAX eligible vaccines.³ Vaccine financing would also safeguard essential expenditure on emergency response needs, strengthen the resilience of health systems, and contribute to the country's commitment to an earlier resumption of vaccine export.

3. The project will provide the government with timely financing to procure safe and effective coronavirus disease (COVID-19) vaccines based on an agreed list of eligible expenditures under the rapid response component (RRC) of the APVAX. Ongoing technical assistance (TA) will complement the project by strengthening the vaccine delivery system.⁴

4. The project is aligned with four of the operational priorities of ADB's Strategy 2030: (i) addressing remaining poverty and reducing inequalities; (ii) accelerating progress in gender equality; (iii) tackling climate change, building climate and disaster resilience, and enhancing environmental sustainability; and (iv) fostering regional cooperation and integration. It is consistent with ADB's country partnership strategy, 2018–2022 for India, which prioritizes improvements in quality health care delivery and gender equality.⁵

5. India has met all APVAX access criteria by (i) demonstrating the adverse impact of the COVID-19 pandemic; (ii) completing a needs assessment, including a vaccination allocation and prioritization plan and an incremental medical waste management plan, acceptable to ADB; (iii) providing a governor's letter confirming the government's commitment to implement the plans and ensuring compliance with revised APVAX eligibility criteria for ADB financing;⁶ and (iv) setting up an effective development partner coordination mechanism with a clear role for ADB.

¹ Asian Development Bank (ADB). 2020. [ADB's Support to Enhance COVID-19 Vaccine Access](#). Manila; and ADB. 2021. [Proposed Amendment to ADB's Support to Enhance COVID-19 Vaccine Access](#). Manila.

² Average utilization of doses per week exceeds 60 million in September 2021, incurring expenditures of \$180 million.

³ The Government plans to roll out NRA approved ZyCov-D in the coming weeks to inoculate those below 18 years.

⁴ ADB. 2021. [Technical Assistance: Supporting Covid-19 Response and Vaccination Program](#). Manila (TA 6733, \$4 million for vaccination support); and ADB. 2020. [Technical Assistance for Regional Support to Address the Outbreak of Coronavirus Disease 2019 and Potential Outbreaks of Other Communicable Diseases](#). Manila (TA 9550, around \$4.5 for support for India).

⁵ ADB. 2017. [Country Partnership Strategy: India, 2018–2022—Accelerating Inclusive Economic Transformation](#). Manila.

⁶ Country National Vaccination Prioritization and Allocation Plan (accessible from the list of linked documents in Appendix 2).

Table 1: Compliance with Criteria–Asia Pacific Vaccine Access Facility

Access Criteria	ADB Staff Assessment
Demonstrated adverse impact of COVID-19	The COVID-19 pandemic has led to 34.37 million infections and 461,389 deaths in India. ^a The pandemic disrupted routine health services and adversely affected mental well-being. Institutional deliveries declined by 22% so far in 2021, compared with the same period in 2019, as per the health management information system. India's economy contracted by 7.3% in fiscal year 2021 ^b and its gross domestic product is expected to remain below its pre-pandemic path. COVID-19 significantly impacted lives and livelihoods. Unemployment increased to 20.9% in April–June 2020, from 9.1% in the previous quarter. ^c The impact on women has been severe because more women lost jobs than men, and women also faced a greater burden of family care and domestic violence.
Needs assessment completed	A needs assessment using WHO's vaccine introduction readiness assessment tool highlighted India's high level of readiness for COVID-19 vaccination. ^d In addition, the government developed detailed COVID-19 vaccine operational guidelines and a comprehensive communication strategy for COVID-19 vaccine deployment to guide the national vaccination program. ADB due diligence identified the need for further strengthening in BMWM, risk communication and community engagement, private sector engagement, and monitoring and evaluation systems.
National vaccination allocation plan	The National Deployment and Vaccination Plan, approved on 12 January 2021, prioritizes health care workers, other essential frontline workers, and older people—in line with the WHO SAGE framework. ^e The National Expert Group on Vaccine Administration for COVID-19 and the National Technical Advisory Group on Immunization provide guidance for priority population groups based on emerging epidemiological evidence and global best practices. The government adopted a dynamic mapping model considering the availability of vaccines and coverage of priority groups.
Incremental BMWM	The BMWM Rules 2016 outline the requirements for BMWM. The guidelines on BMWM under the Universal Immunization Programme 2021 provide additional guidance for immunization activities. Further, the CPCB issued detailed guidelines for COVID-19 immunization focusing on reduction, segregation, disinfection, and transport of waste; and disseminated them to states and union territories on 23 December 2020. The CPCB monitors COVID-19-related BMW and introduced a mobile application to track COVID-19 BMW, which a Supreme Court order made mandatory for all health facilities.
Governor's letter	ADB has received the governor's letter confirming the government's commitment to implement its prioritization plan, and compliance with the APVAX vaccine eligibility criteria. ^f
Effective development partner coordination mechanism with clear role for ADB	Partners engaged in the COVID-19 response coordinate through WHO-led Health Development Partner Group meetings. ADB has been an active member and worked with several partners for synergies. A vaccine subgroup consisting of ADB; Gavi, the Vaccine Alliance; United Nations Development Programme; United Nations Children's Fund; WHO; and the World Bank coordinates vaccine deployment related technical assistance.

ADB = Asian Development Bank, APVAX = Asia Pacific Vaccine Access Facility, BMW = biomedical waste, BMWM = biomedical waste management, COVID-19 = coronavirus disease, CPCB = Central Pollution Control Board, SAGE = Strategic Advisory Group of Experts on Immunization, WHO = World Health Organization.

^a Government of India, [Ministry of Health and Family Welfare](#) (accessed 10 November 2021).

^b Government of India. 2021. [Provisional estimates of Annual National Income](#). Delhi.

^c Government of India, Ministry of Statistics and Program Implementation. 2021. [Quarterly Periodic Labour Force Survey October-December 2020](#). Delhi. Unemployment estimates are based on current weekly status.

^d Key focus areas are (i) the national vaccine allocation plan, (ii) planning and coordination, (iii) cold chain and logistics, (iv) service delivery, (v) pharmacovigilance, (vi) BMWM, (vii) monitoring and evaluation, (viii) advocacy and communication, (ix) private sector engagement, and (x) regulatory preparedness.

^e World Health Organization (WHO). 2020. [WHO SAGE Roadmap for Prioritizing Uses of COVID-19 Vaccines in the Context of Limited Supply](#). Geneva.

^f The governor's letter with the attached National Deployment and Vaccination Plan is in Annex III of the Country National Vaccination Prioritization and Allocation Plan (accessible from the list of linked documents in Appendix 2).

Source: Asian Development Bank.

II. THE PROJECT

A. Rationale

1. The Pandemic

6. **Background.** Since the first case of COVID-19 was confirmed in India on 30 January 2020, 34,377,113 cases were confirmed and 461,389 people have died from the virus as of 10 November 2021.⁷ The pandemic resulted in very high costs to the country's overall health, well-being, and economy. India faced a devastating second wave starting March 2021, which peaked with a record high of 414,188 new COVID-19 cases on 7 May 2021.⁸ This was about 32% higher than the world's previous peak reported by the United States in 2020.⁹ The second wave in India overwhelmed hospitals and exhausted health workers, who were increasingly becoming infected. Despite the containment measures with localized lockdowns and social distancing, increased testing capacity (over 2.2 million samples a day) to detect cases, and a national vaccination drive, the possibility of a third wave looms large because of highly contagious variants.

7. Equitable access to safe and effective vaccines has proven to be lifesaving and is critical to ending the COVID-19 pandemic. Recognizing this need, the government started rolling out inoculations on 16 January 2021. More than 1.09 billion vaccine doses had been administered in more than 11.07 million sessions by 9 November 2021.¹⁰ India aims to inoculate 944.7 million people (68.9% of its total population). Given the devastating second wave and the threat of a third wave, the government allocated significant financing to strengthen health systems, which further strained its resource envelope.¹¹ The government requires immediate financing to inoculate the target population and limit the impacts of the pandemic.

2. Impact of the Pandemic

8. **Costs to the economy.** India's economy faced its worst contraction in fiscal year (FY) 2020 since World War II, contracting at 7.3%.¹² Its gross domestic product (GDP) will remain below the pre-pandemic trend in GDP despite projected growth of 10.0% in FY2021 and 7.5% in FY2022. The fiscal deficit widened significantly as the government confronted the pandemic and began supporting economic and social recovery. The fiscal deficit as a share of GDP increased to 9.2% in FY2021 amid falling revenue and higher expenditure, from 4.6% of GDP in FY2020.¹³ The ratio of public debt to GDP increased substantially in FY2021 and will continue to remain elevated in the medium term. As COVID-19 cases fell and lockdown measures eased, the economy started to recover, but the looming threat of a third wave remains. Extensive and accelerated vaccine deployment is key to India's economic recovery.

9. **Disproportionate impact on the vulnerable and women.** COVID-19 has had a significant impact on lives and livelihoods. During the first wave, unemployment as measured by the weekly status increased to 20.9% between April and June 2020, from 9.1% in the previous quarter.¹⁴ Although the unemployment rate fell in the next two quarters, earnings for those re-employed may not have recovered to pre-pandemic levels. The impact on women has been severe in terms of wage inequality and the burden of unpaid care. In the informal sector, women fared even worse. Between March and April 2021, rural Indian women in informal jobs accounted

⁷ Government of India, [Ministry of Health and Family Welfare](#). (accessed 10 November 2021).

⁸ Press Information Bureau. 2021. [PIB's Bulletin on COVID-19-Updated](#). Press Release. 7 May.

⁹ Outlook India. 2021. "[A Nightmare](#)": Healthcare Workers In Delhi Tell What It Meant To Face The Peak Of Second Wave Of Covid-19. 29 May.

¹⁰ Press Information Bureau. 2021. [PIB's Bulletin on COVID-19-Updated](#). Press Release. 9 November.

¹¹ Phase 2 of the COVID-19 emergency response and health system preparedness package was approved in July 2021 for \$3.17 billion.

¹² Government of India. 2021. [Provisional estimates of Annual National Income, 2020–21 and Quarterly estimates \(Q4\) of Gross Domestic Product, 2020–21](#). Press release. 31 May.

¹³ Government of India, Controller General of Accounts. 2021. [Monthly Accounts](#). Delhi.

¹⁴ Government of India, Ministry of Statistics and Program Implementation. 2021. [Quarterly Periodic Labour Force Survey October-December 2020](#). Delhi. Unemployment estimates are based on current weekly status.

for 80% of job losses.¹⁵ Women's share of unpaid care work grew by nearly 30% and India recorded 2.5 times increase in domestic violence between February and May 2020.¹⁶ India's pandemic response relies heavily on women frontline health workers, which puts them at a greater exposure to COVID-19 and increases vulnerability. In terms of access to vaccines, women's coverage was 46.8% as of 10 August 2021, which is lower than the proportionate population of women. Therefore, more efforts are needed to ensure equitable access for women. As economic activities resume, protecting the vulnerable, including informal workers and women, with vaccination should be prioritized, and access to free public vaccination is a key strategy for that.

10. **Impacts on the health system.** The pandemic has enormously strained health care delivery systems in India, exposing long-standing gaps and exacerbating inequities. With five hospital beds and nine physicians per 10,000 people,¹⁷ the country was not equipped for a crisis of this scale. The sudden unprecedented surge in cases during the second wave resulted in an acute shortage of medical oxygen—and several Indian states reported a crisis.¹⁸ Response efforts were further constrained by the lack of adequate health care staff such as specialists, doctors, nurses, and paramedics. The supply-side disruptions, and reduced health-seeking behavior for fear of contracting COVID-19 and mobility restrictions also hampered the delivery of essential and emergency health care services. Facility-based outpatient care declined by 33% and inpatient care fell by 21% compared with pre-pandemic levels.¹⁹ There was a staggering 22% decline in institutional deliveries, elevating the risk of infection and maternal complications from unsafe childbirth methods.

3. Government Response

11. **Measures introduced to control the pandemic.** The government adopted the whole-of-government approach and took proactive and preemptive measures to contain the pandemic since its onset in 2020. A stringent nationwide lockdown for 21 days was declared on 24 March 2020 and subsequently extended three times until 31 May 2020. India strengthened points of entry and public information and awareness campaigns, and quickly adopted digital solutions such as the *Aarogya Setu* application for contact tracing, hotspot mapping, and information dissemination. To fortify health systems, the government implemented a COVID-19 emergency response and health system preparedness package over two phases, totaling \$5.22 billion. Several development partners, including ADB, supported phase 1 of the package.²⁰ As a member of the South Asia Association of Regional Cooperation, India committed \$10 million to an emergency fund. It also donated 7.85 million doses of vaccines to its neighboring countries before April 2021.²¹ The government initiated the COVID-19 vaccination campaign on 16 January 2021.

¹⁵ UN Women. 2021. [Your questions answered: Women and COVID-19 in India | UN Women – Headquarters](#). 27 July.

¹⁶ A. Madgavkar et al. 2020. [COVID-19 and gender equality: Countering the regressive effects](#). *Mckinsey Global Institute*. 15 July and Press Information Bureau release of Ministry of Women and Child Development. 2020. [Increased in Domestic Violence against Women](#). Press Release. 22 September.

¹⁷ The World Bank. [Data Indicator Hospital beds \(per 1,000 people\) - India](#), and [Data Indicator Physicians \(per 1,000 people\) - India](#). (accessed on 11 August 2021).

¹⁸ Press Information Bureau release of MOHFW. 2021. [Union Government takes Steps to boost supply of Oxygen to Hospitals](#). Press Release. 18 April.

¹⁹ National Health Mission data. The comparison is between April–June 2019 (pre-pandemic) and April–June 2021.

²⁰ ADB. 2020. [Report and Recommendation of the President to the Board of Directors: Proposed Countercyclical Support Facility Loans and Technical Assistance Grant to India for COVID-19 Active Response and Expenditure Support Program](#). Manila. More details are available in Development Coordination (accessible from the list of linked documents in Appendix 2).

²¹ This includes 3.3 million doses for Bangladesh, 1.7 million for Myanmar, 1.1 million for Nepal, 550,000 for Bhutan, 200,000 for Maldives, 500,000 for Sri Lanka, and 500,000 for Afghanistan. India also donated to 40 other countries globally apart from the seven neighboring countries.

12. **Main issues and gaps identified in the needs assessment.** India is leveraging the existing systems, infrastructure, and human resource capacity under its Universal Immunisation Programme (UIP) for the rollout and expansion of the COVID-19 vaccination campaign.²² The country has a high level of readiness to implement the COVID-19 vaccination program based on the World Health Organization (WHO) vaccine introduction readiness assessment tool and given the ongoing vaccine rollout. The systems are described in paras. 13–23. However, given the scale of the vaccination program, some improvements are needed, such as (i) increasing the involvement of the private sector in COVID-19 vaccination; (ii) strengthening the monitoring of biomedical waste management (BMWM); (iii) improving the monitoring of vaccination sites, including adverse events following immunization (AEFIs); and (iv) continuing efforts in risk communication and community engagement to ensure equitable access for all eligible population groups. ADB TA is helping the government fill these gaps.²³

13. **National vaccine road map, prioritization, and allocation plan.** The government formulated the National Deployment and Vaccination Plan (NDVP) for COVID-19 vaccines supported by WHO and the United Nations Children’s Fund (UNICEF).²⁴ The National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) has been guiding the government’s vaccine deployment efforts since August 2020, and the National Technical Advisory Group on Immunization has been providing guidance in technical areas such as vaccine selection and contradictions for vaccine administration. The NDVP, coupled with the COVID-19 vaccine operational guidelines and the COVID-19 vaccine communication strategy, presents a robust and comprehensive approach covering all key elements for vaccine deployment. The government also introduced various measures to ensure equitable vaccination for all. ADB’s Sustainable Development and Climate Change Department issued a memo on 20 April 2021 confirming that India’s NDVP meets the APVAX access criteria.

14. The government aims to inoculate 944.7 million individuals aged 18 years old and older, which is 68.9% of the population. It is estimated that more than 1,988 million doses of vaccines will be required for this purpose, based on the assumption of two vaccine doses per person and a 5% wastage rate. The vaccine prioritization plan was divided into three phases (Table 2). The project will support the vaccine needs for the eligible population in project states.²⁵

Table 2: Vaccine Prioritization Plan for India

Phase and Start Date	Priority Group	Eligible Population (million) ^a	% of Total Population	No. of Doses Required (million) ^b
1a 16 Jan 2021	Health care workers	10.00	0.73%	21.05
1b 2 Feb 2021	Frontline workers	20.00	1.46%	42.11
2a 1 Mar 2021	Senior citizens (≥ 60 years) and those aged 45–59 years with defined comorbidities	138.06	10.07%	290.65
2b 1 Apr 2021 ^c	Population aged 45–59 years	209.32	15.27%	440.67
3 1 May 2021	Population aged 18–44 years	597.33	43.57%	1,257.54
	Total	944.71	68.91%	1,988.86

^a The number of health care and frontline workers is counted in their respective age category, too.

²² In 2015, the government also launched Mission Indradhanush targeting pockets of low immunization coverage and hard-to-reach areas of which experience and established systems provided a solid foundation to India’s COVID-19 vaccine rollout efforts.

²³ Vaccine Needs Assessment (accessible from the list of linked documents in Appendix 2).

²⁴ NDVP in Annex III of National Vaccine Allocation Plan (accessible from the list of linked documents in Appendix 2)

²⁵ 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, which have over 10 million eligible population.

^b Assuming a two-dose regime and 5% wastage.

^c People aged 45–59 years with comorbidities became eligible for vaccine access on 1 March 2021, along with the priority group of senior citizens (60 years and older); followed by all citizens 45 years and older from 1 April 2021.

Source: Government of India, Ministry of Health and Family Welfare.

15. **Vaccine regulatory pathways.** All COVID-19 vaccines in India, either domestically manufactured or imported, must comply with the requirements and guidelines specified in the Drugs and Cosmetics Rules 1945, New Drugs and Clinical Trials Rules 2019, and other applicable guidelines published by the Central Drugs Standard Control Organization, the national regulatory authority. The government also issued special regulatory guidelines for the development of COVID-19 vaccines.²⁶ Further, regulatory requirements were eased for vaccines that were granted emergency approval for restricted use by the United States Food and Drug Administration, European Medicines Agency, Medicines and Healthcare Products Regulatory Agency of the United Kingdom, and Pharmaceuticals and Medical Devices Agency of Japan, or which are recognized under the WHO Emergency Use Listing Procedure. This will help facilitate the availability of imported vaccines, as well as the import of bulk drug material and optimal use of domestic fill-and-finish capacity.

16. **Vaccine options.** India's National Vaccine Policy 2011 outlines the criteria for the introduction of vaccines, such as (i) safety and efficacy; (ii) affordability and financial sustainability; (iii) program capacity, including cold chain capacity; and (iv) available vaccine production capacity. As per the recommendations of the National Technical Advisory Group on Immunization, India has been using the Covishield vaccine manufactured by the Serum Institute of India and the Covaxin vaccine manufactured by Bharat Biotech International Limited. In addition, Sputnik V, developed by Gamaleya Research Institute, is being imported by Dr. Reddy's Laboratories for deployment in private sector facilities. As of 12 September 2021, three additional vaccine candidates (Moderna, Janssen, and ZyCov-D) have emergency use authorization from the Central Drugs Standard Control Organization. Several other domestic vaccine candidates, such as Covovax, are in late-stage trials. However, the central government's current portfolio lists only five vaccines—Covishield, Covaxin, Sputnik V (domestic), ZyCov-D (being developed by Zydus Cadila), and Corbevax (being developed by Biological E). Covishield and Covaxin are being considered for APVAX support.²⁷

17. **Financing needs and funding sources.** Vaccination of India's eligible population is estimated to cost \$7,532 million (including \$1,260 million in operational costs).²⁸ Vaccine supplies are procured by the central government, the state governments, and the private sector, or received through donations. The central government launched the vaccination program with 76 million donated doses.²⁹ State governments supplied 45.6 million doses between 1 May and 21 June 2021. When several states faced difficulties in procuring vaccines and expressed fiscal distress, the central government decided to cover all public sector vaccine supplies, which drastically increased its financing requirements. As of 12 September 2021, it had ordered

²⁶ Government of India, Central Drugs Standard Control Organisation. 2020. [Draft Regulatory Guidelines for Development of Vaccines with Special Consideration for COVID-19 Vaccine](#). Delhi.

²⁷ Covishield and Covaxin have received WHO EUL meeting APVAX vaccine eligibility criterion 2.

²⁸ Operational costs are estimated at \$0.19 per beneficiary for the central government component, at about \$1.00 for the state component, and at \$2.05 for private sector use. The central component includes the cost of the Winning Over COVID-19 (Co-WIN) web portal (para. 21), SafeVac software for AEFI management, and associated call centers. The state component has seven programmatic areas: (i) enumeration and microplanning, (ii) capacity building, (iii) human resources, (iv) logistics and personal protective equipment, (v) cold chain and vaccine distribution, (vi) information education activities, and (vii) monitoring.

²⁹ Donated by the Prime Minister's Citizen Assistance and Relief in Emergency Situations (PM-CARES) Fund (66 million doses) and the COVID-19 Vaccines Global Access (COVAX) initiative (10 million doses).

1,245 million doses of Covishield and 355 million doses of Covaxin (covering 80.4% of the total vaccine doses needed). The order might further increase if private sector delivery continues to lag or if younger population groups are eventually included. The proposed project will help the central government meet its large and increasing financing requirements.

18. **Vaccine planning and coordination.** India uses a whole-of-government approach to support the vaccine rollout. It also has a robust cascading system of decentralized planning, coordination, and implementation arrangements (from central to state to district to block) with clearly defined roles and responsibilities. NEGVAC advises on all aspects of the COVID-19 vaccines, while the Ministry of Health and Family Welfare (MOHFW) supports the states in implementing the national vaccination program. State, district, and block task forces were set up under the guidance of state steering committees, and clear budget outlays are earmarked for each level. All levels run 24-7 operational control rooms. Overall AEFI management requires a high level of capacity to act upon emerging situations and possible trends. While the national AEFI committee has been reinforced, state and district AEFI committees require additional medical specialists since COVID-19 vaccines still only have emergency use authorization and cover a wider population with different comorbidity profiles, which increases the risk of adverse events. ADB TA through WHO is supporting this area.³⁰

19. **Cold chain and logistic capacity.** India has a fully operational cold chain system under the UIP with four centrally run medical depots, 37 state vaccine stores, 118 regional vaccine stores, 726 district vaccine stores, and 28,575 subdistrict cold chain points in community health centers, primary health centers (urban and rural), and subcenters. Based on the needs assessment conducted by UNICEF, cold chain gaps were bridged with domestic resources and support from Gavi, the Vaccine Alliance (Gavi), KfW, and the Government of Japan. Manufacturers supply vaccines via air, rail, or insulated vans based on MOHFW's periodic guidance (roughly every 2 weeks) to four regional depots and 56 consignee points for further delivery. Manufacturers also transfer vaccines to private providers. The national cold chain management information system and the electronic vaccine intelligence network system monitor real-time cold chain capacity, availability of vaccine stock, and storage temperatures.

20. **Service delivery.** India has 234,772 COVID-19 vaccination centers (CVCs), of which 215,927 are government-run and 18,845 are private. These are operated flexibly to also manage routine services. The system has sufficient human resource capacity³¹—with the option to engage additional human resources on a temporary basis by mobilizing retired auxiliary nurse midwives, retired staff nurses or nursing assistants, pharmacists, lab technicians, and nursing students. At least five people are required in each team to undertake verification and crowd management, ensure COVID-19-appropriate behavior, monitor vaccination procedures, and watch out for any potential AEFIs. A supervisor is responsible for three to five vaccination sites. All private facilities empaneled under various insurance schemes and any other private facilities that meet the operational requirements have been engaged. However, private sector delivery is lagging the planned contribution rate (7% instead of up to 25%). The World Bank and ADB TA are advising on how to improve private sector engagement and are supporting capacity building.³²

21. **Digital systems for vaccination.** Winning Over COVID-19 (Co-WIN) is an end-to-end, cloud-based electronic solution for the planning, implementation, monitoring, and evaluation of

³⁰ ADB. 2020. [Technical Assistance for Regional Support to Address the Outbreak of Coronavirus Disease 2019 and Potential Outbreaks of Other Communicable Diseases](#). Manila (TA 9550).

³¹ 260,000 vaccinators, 475,000 vaccination support team members, 90,000 data entry operators, 57,000 district officials, 2,360 national and state officials, and 30,000 cold chain handlers.

³² ADB. 2021. [Technical Assistance: Supporting Covid-19 Response and Vaccination Program](#). Manila (TA 6733).

COVID-19 vaccination, from nationwide web portal to individual mobile application. It is used in sync with the electronic vaccine intelligence network under the UIP. Registration on this platform is mandatory to record vaccination data and ensure transparency and accountability. The use of Co-WIN also ensures that (i) verifiable data is available on the number of persons vaccinated, (ii) a second dose of the same vaccine is provided, (iii) the prescribed time between doses is maintained, (iv) vaccine certificates are generated, (v) the vaccine is administered only after verification of the individual's identity, and (vi) the data is useful for future pandemic research and planning. Co-WIN also allows the program managers to (i) monitor real-time vaccination progress overall or for a specific state, district, or population group; (ii) monitor vaccine availability and utilization for improved planning; (iii) assess vaccine wastage and take measures to minimize it; and (iv) offer ease of reference for future interventions, such as administration of booster doses. Co-WIN is linked to other systems such as *Aarogya Setu* (mobile app), DigiLocker (digital wallet), and *Umang* (pan-Indian e-government services) for the download of vaccination certificates. The system is also integrated with the WHO-supported SafeVac for monitoring AEFIs. This allows for AEFI cases to be analyzed by using both automated data-mining and appropriate statistical methodologies to detect concerning trends. The Co-WIN system handles more than 1 billion visits daily and recorded 3.1 billion visits in one day to book vaccine slots. Since 2020, ADB TA has been supporting the data analytics-driven 'war room' that developed Co-WIN dashboards for better monitoring and evaluation (footnote 30). Co-WIN will be audited by the Comptroller and Auditor General of India to ensure system and data integrity and to identify areas for further improvement, lessons, and best practices.

22. Immunization waste management. Any health care activities will generate biomedical waste (BMW), including immunization waste. India has 202 common biomedical waste treatment facilities (CBMWTFs) in operation, and 35 additional facilities are under construction. They can handle about 840 tons of BMW per day. The country currently generates about 619 tons per day of overall BMW, including COVID-19-related BMW. In addition to CBMWTFs, health care facilities also have captive BMW treatment systems. India has an extensive regulatory framework governing the management of BMW (BMWM): the BMWM Rules 2016 (and subsequent amendments) outline the overall compliance requirements in BMW generation, storage, transportation, disinfection, treatment, and disposal, while the BMWM guidelines under UIP 2021 focus on waste from the COVID-19 immunization program. Regular training sessions on BMWM are conducted for health care and frontline workers with WHO support, and the Central Pollution Control Board provides regular training on the maintenance and evaluation of CBMWTFs. In addition, the Supreme Court has made the use of a BMW tracking application (COVID19BWM) mandatory for all waste generators, transporters, and operators of treatment and disposal facilities. However, monitoring compliance at CVCs with the various guidelines for adequate and safe source segregation is a challenge, as are the varying levels of management capacity across different states. ADB TA is monitoring CVCs' compliance with guidelines and associated capacity building efforts (footnote 32).

23. Reaching all and overcoming vaccine hesitancy. India's COVID-19 communication strategy pays particular attention to equitable access to vaccines for all. For those without access to the internet or smartphones, registration on Co-WIN can be done onsite at CVCs or through the 1075 helpline call center, and in more than 267,000 common services centers. About 78% of doses are administered after onsite registration, 56% are administered in rural areas, and the vaccination ratio in tribal areas is higher than the national average. States also conducted more than 920,000 sessions in CVCs within easy reach of senior citizens, differently abled people, and rural residents by 12 September 2021. Some states or municipal corporations provide additional services such as beneficiary transportation. Special vaccination sessions are also conducted for

people without identification or with other restrictions.³³ Moreover, all the vaccination sites or outreach centers have at least one female health worker or volunteer to assist women's access.³⁴ MOHFW leads the vaccine communication hub with support from UNICEF, WHO, and other partners that help monitor media reporting and respond to misinformation. However, to achieve full vaccination coverage, including in hard-to-reach areas, and mitigate the risk of vaccine hesitancy, ADB TA is supporting dynamic data analysis as well as targeted risk communication and community engagement activities in rural and remote areas that help overcome demand-side barriers, especially among women and other vulnerable population segments.

4. Development Partner Coordination

24. A development partner coordination mechanism led by WHO has been very effective in coordinating ongoing and planned technical and financial support for the pandemic response. A subgroup specific to the COVID-19 vaccine rollout was formed and includes ADB, Gavi, the United Nations Development Programme, UNICEF, WHO, and the World Bank. ADB has coordinated loan and TA support to the government since the COVID-19 outbreak. In addition to vaccine finance from partners such as ADB and AIIB, technical support is being provided by WHO, UNICEF, United Nations Development Programme, United States Agency for International Development, Gavi, the Bill and Melinda Gates Foundation, KfW, Japan International Cooperation Agency, the Government of Japan, and the Global Fund.³⁵

B. Project Description

1. Impact and Outcome

25. 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 population safely vaccinated against COVID-19 in project states (footnote 25); the aim is to cover at least 317 million beneficiaries, 47.5% of them women.³⁶

2. Outputs

26. **Output: Safe and effective COVID-19 vaccines supplied for eligible population in project states.** The project will support the procurement of safe and effective vaccines against COVID-19 through APVAX's RRC. It will procure at least 667 million doses of vaccines, which will be administered to a target population by 2024 in accordance with the current NDVP for COVID-19 vaccines and any subsequent guidelines. The eligible vaccines will be procured through bilateral arrangements with vaccine manufacturers or distributors.

27. **Value addition.** Ongoing ADB TA (footnote 32) is supporting the national COVID-19 vaccination program implementation by (i) augmenting the project management capacity of its Immunization Division with consultants on the monitoring, reporting, and evaluation of the vaccine rollout; (ii) assisting the vaccination site monitoring; (iii) carrying out dynamic analysis of data

³³ Nomads, prison inmates, patients in mental health institutions, citizens in old-age homes, roadside beggars, people residing in rehabilitation centers or camps, and any other individuals found eligible. More than 821,000 individuals have received vaccines without identification as of 12 September 2021.

³⁴ Vaccination sites are supported by community mobilizers and outreach workers, including more than 1 million women accredited social health activists, 1.4 million *Anganwadi* workers (*Anganwadi* is a type of rural childcare center), 1.28 million *Anganwadi* helpers, and 100,000 nongovernment and civil society organizations.

³⁵ Development Coordination (accessible from the list of linked documents in Appendix 2).

³⁶ The design and monitoring framework is in Appendix 1.

segregated by gender, rural and urban, and priority groups to aid decision-making; (iv) assisting private providers (both workplace and independent vaccine providers) with capacity building and monitoring their compliance with guidelines; (v) supporting vaccination-related BMWM and disposal monitoring; (vi) increasing awareness of and willingness for vaccination among vulnerable people, especially women; and (vii) strengthening the capacity for monitoring and managing AEFIs. All TA activities are designed to underpin national and state government efforts, ensure equitable access, and build the capacity of stakeholders, including women, while creating synergy with the proposed vaccine financing as well as other health sector interventions of ADB. The TA activities are supported by WHO and UNICEF through their respective administrative arrangements with ADB, under the overall coordination of the Immunization Division of MOHFW.

3. Summary Cost Estimates and Financing Plan

28. **Project proposal.** The project is estimated to cost \$2,057.77 million, including vaccine costs, taxes, contingencies, interest, commitment charges during implementation, and other financial charges. The summary cost estimates are in Table 3. The project will finance expenditures in relation to the procurement of COVID-19 vaccines that meet the APVAX eligibility criteria. The project will be guided by the Indicative Master List of Eligible Items and Agreed List of Acceptable Expenditure Items ('Positive List') for ADB financing under the RRC.³⁷

Table 3: Summary Cost Estimates

Item	Description	Amount (\$ million)	Share of Total (%)
A.	Base Cost^a		
	Safe and effective COVID-19 vaccines supplied ^b	1,930.15	93.80
B.	Contingencies^c	69.85	3.39
C.	Financial charges during Implementation^d	57.77	2.81
	Total (A+B+C)	2,057.77	100.00

COVID-19 = coronavirus disease.

^a In September 2021 prices, at an exchange rate of \$1 = ₹73.00.

^b Including 5% tax on vaccines procured.

^c Includes physical and price contingencies, and a provision for exchange rate fluctuation.

^d Includes interest, commitment charges and front fee, which will be borne by the Borrower.

Source: Asian Development Bank estimates.

29. **Loan financing from ADB and Asian Infrastructure Investment Bank.** The government requested a loan of \$500 million and a loan of \$1 billion, both from ADB's ordinary capital resources, to help finance the vaccine procurement. The first loan will have a 10-year term, including a grace period of 3 years; the 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 agreements. The government has also requested a loan of \$500 million from AIIB to help finance the vaccine procurement.³⁸ Its terms and conditions will be described in a loan agreement between the government and AIIB. ADB will partially administer the AIIB loan as per a co-lenders' agreement between ADB and AIIB.

30. **Government contributions.** The government will provide in-kind contributions in the form of counterpart staff, logistics, cold chain infrastructure, and other facilities. A separate budget

³⁷ Indicative Master List of Eligible Items and Agreed List of Acceptable Expenditure Items ('Positive List'), for ADB financing under the Rapid Response Component (accessible from the list of linked documents in Appendix 2).

³⁸ ADB's partial administration will entail oversight of procurement, compliance with safeguards, financial management, and disbursement.

code will be provided to procure the vaccines under the project. The government has provided adequate resources to cover the operational costs. The project financing plan is in Table 4.

Table 4: Summary Project Financing Plan

Source	Project		National Vaccination Program ^a	
	Amount (\$ million)	Share of Total (%)	Amount (\$ million)	Share of Total (%)
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 ^b	2.81	4,542.51 ^c	60.31
Other sources ^d	-	-	989.77	13.14
Total	2,057.77	100.00	7,532.28	100.00

^a The national coronavirus-related vaccination program is financed through the government's own resources, development partners, and other donors. The total program cost was estimated assuming a 5% vaccine wastage. Total vaccine costs are estimated at \$6.27 billion and total operational costs at \$1.26 billion.

^b The government will finance the interest, commitment charges, and front fee.

^c Includes central and state government contributions, vaccines, ancillary supplies, and operational costs.

^d Contributions from the private sector and donations.

Source: Asian Development Bank estimates.

31. **Key findings from debt sustainability analysis.** The fiscal deficit widened to 9.2% of GDP in FY2021 as the government focused on mitigating the effects of the pandemic and supporting economic recovery. This widening and the contraction of the economy contributed to an increase in the ratio of public debt to GDP from 72.2% in FY2020 to 89.1% in FY2021. The ratio is expected to remain elevated (above 80%) in the medium term, but with risks broadly contained. GDP growth is expected to be 10% in FY2022, 7.5% in FY2023, and 6.5% in the medium term. The fiscal deficit is budgeted at 6.8% for FY2022, and the government plans to reduce it gradually to below 4.5% of GDP by FY2026. Further, India's public debt is predominantly held by domestic residents and is denominated largely in domestic currency, which helps reduce external financing risks. Nevertheless, improving the fiscal conditions and domestic resource mobilization should remain a priority for the government beyond the pandemic. This assessment on debt sustainability is consistent with the recent International Monetary Fund analysis.³⁹

4. Implementation Arrangements

32. MOHFW will be the executing agency, and its Immunization Division will be the implementing agency. The division will coordinate all aspects of project implementation with other MOHFW divisions and units, other agencies, and the project states, which will strengthen project-specific planning, monitoring and evaluation, reporting, and coordination requirements, and satisfy ADB's project administration requirements.

33. Procurement will be undertaken following simplified and expedient procedures permitted under the ADB Procurement Policy (2017, as amended from time to time) and Procurement Regulations for ADB Borrowers (2017, as amended from time to time).⁴⁰ As per APVAX policy, ADB member country eligibility restrictions will be waived. Since the vaccine supply has been limited to a few vaccine manufacturers globally and given the urgent need to vaccinate a large population, MOHFW has procured and will procure the vaccines through direct contracting by

³⁹ International Monetary Fund Assessment Letter. August 2021.

⁴⁰ ADB. 2017. [ADB Procurement Policy](#). Manila; and ADB. 2017. [Procurement Regulations for ADB Borrowers](#). Manila.

negotiating bilateral contracts with manufacturers. The project will finance a portion of these contracts for APVAX-eligible vaccines. MOHFW has engaged a procurement agent funded by the government to support procurement, contract management, and delivery of the vaccines (para. 38). Before confirming eligible expenditure under the project, ADB will review all relevant vaccine agreements. Value for money in procurement will be achieved by (i) selecting vaccines that are best suited to the domestic supply chain; (ii) identifying vaccines that will efficiently meet the project disbursement conditions; (iii) engaging with manufacturers that have advantageous vaccine delivery timelines; and (iv) entering into agreements on terms and conditions that are reasonable, noting the currently constrained vaccine market globally. ADB's Anticorruption Policy⁴¹ (1998, as amended to date) will apply to all contracts to be financed under the project.

34. The implementation arrangements are summarized in Table 5 and described in detail in the project administration manual (PAM).⁴²

Table 5: Implementation Arrangements

Aspects	Arrangements		
Implementation period	November 2021– December 2024		
Estimated completion date	31 December 2024		
Estimated loan closing date	30 June 2025		
(i) Oversight body	National Expert Group on Vaccine Administration for COVID-19		
(ii) Executing agency	Ministry of Health and Family Welfare		
(iii) Implementing agency	Immunization Division		
Procurement	Direct contracting	Multiple contracts	\$2,000 billion
Retroactive financing	Withdrawals from the loan account for eligible expenditures in relation to vaccine procurement incurred before loan effectiveness, but not more than 12 months before signing of the loan agreement, provided that (i) the expenditure does not exceed 30% of the RRC financing amount, and (ii) the disbursement conditions are met. The executing and implementing agencies have been advised that approval of retroactive financing does not commit ADB to finance advance payment to vaccine suppliers and/or any vaccine-related procurement costs. Retroactive Financing under AIIB loan will be set out in the financing agreement to be signed between India and AIIB. ^a Any retroactive financing will be subject to the APVAX eligibility criteria and other requirements.		
Disbursement	The loan proceeds of ADB will be disbursed following ADB's <i>Loan Disbursement Handbook</i> (2017, as amended from time to time) ^b		

ADB = Asian Development Bank, APVAX = Asia Pacific Vaccine Access Facility, RRC = rapid response component.

^a Cofinancing Framework Agreement for Sovereign Operations, dated 21 March 2019, between AIIB and ADB. Section 3.06 (a) (i) provides that AIIB will notify ADB of any particular details pertaining to cofinancing, such as lending terms, disbursement parameters such as advance funding or retroactive financing, or other relevant details.

^b ADB. 2017. *Loan Disbursement Handbook*. Manila.

Source: Asian Development Bank.

III. DUE DILIGENCE

A. Economic Viability

35. The COVID-19 pandemic is a health, economic, and social crisis resulting in loss of lives, an increase in morbidity, loss of livelihood, a slowdown of the economy, and disruptions to education and human capital development for long-term economic growth. In the absence of vaccinations, the costs of the pandemic could be prolonged and exacerbated. The potential contribution toward herd immunity against COVID-19 through vaccinations will substantially reduce mortality and morbidity and help resume economic activities and thus restore livelihoods.

⁴¹ ADB. 1998. *Anticorruption Policy*. Manila.

⁴² Project Administration Manual (accessible from the list of linked documents in Appendix 2).

B. Governance

36. The national COVID-19 vaccination program has well-structured and functioning governance arrangements despite the complex federal setting. The program systems, supported by strong digital platforms, are adequate to ensure that the resources are used for equitable and priority-based allocation of vaccines and can transparently track vaccine doses and beneficiaries. Given the importance, the national COVID-19 vaccination program is subject to intensive oversights by NEGVAC, the Prime Minister's office, the Parliament as well as the Supreme Court, in addition to the usual oversight mechanisms. Various oversight and independent assurance activities will prevent and detect key integrity risks. Various mechanisms for grievance redressal are in place to deal with beneficiary concerns. The Comptroller and Auditor General will carry out a performance audit of the national vaccination program to provide additional assurance of sound governance, effectiveness, efficiency, and economy of the program.

37. ADB's Anticorruption Policy (1998, as amended to date) was explained to and discussed with the government. The specific policy requirements and supplementary measures are described in the PAM (footnote 42).

38. Strategic procurement planning was carried out, including a capacity assessment of the executing, and implementing agencies. Under the guidance of NEGVAC, MOHFW has directly procured COVID-19 vaccines from manufacturers, and engaged HLL Lifecare Limited (HLL), a government-owned enterprise under MOHFW, as a procurement agent to support procurement and contract management. HLL has the knowledge, capacity, experience, and track record to provide the required services. Based on the overall assessment, the project's procurement risk is rated *substantial*, mainly because of the unprecedented scale and complexity of vaccine deployment that may strain MOHFW capacity. To mitigate this risk, MOHFW will continue using the services of HLL, financed by the government, to manage the vaccine supply contracts.

39. ADB conducted a financial management assessment for the project. The pre-mitigation financial management risk is *substantial* primarily because of the unprecedented scale and complexity of vaccine deployment. The project will follow the existing country systems and leverage the existing financial management capacity of MOHFW. The ongoing ADB TA will assist MOHFW in meeting ADB-specific financial management requirements. The key financial management risks identified are (i) the lack of a 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, which may result in funds or vaccines being misused; and (iii) delay in submitting audited project financial statements to ADB. These risks will be mitigated by (i) establishing a sub-budget head for the project, (ii) including the project in the annual internal audit workplan, (iii) ensuring timely submission of project financial statements to the Comptroller and Auditor General for timely audit, and (iv) monitoring quarterly progress reports, including audit observations and the status of implementation of audit recommendations.

C. Poverty, Social, and Gender

40. **Poverty and social considerations.** The COVID-19 pandemic has reversed many gains made by India in poverty alleviation and health outcomes, and exacerbated inequality. Affordable vaccines and equitable access are critical. While the government offers free vaccination in public facilities, demand-side constraints such as lack of awareness, hesitancy, and other barriers should be removed to ensure that all eligible individuals benefit. The government is implementing the COVID-19 vaccination communication strategy with support from various partners; introduced several flexible delivery modes such as near-to-home vaccination, workplace vaccination, and

community outreach; and has been guiding the states on how to handle different types of barriers (e.g., lack of a recognized identity card). The states also provide additional support to those faced with access barriers.

41. **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 MOHFW. The project aims to achieve the vaccination of about 317 million people, at least 47.5% of them women. Vaccination will allow women to reestablish their income-earning activities and access health care services and will lessen their burden of care work. The project will also build women's capacity for vaccination-supporting activities. The GESI action plan targets include (i) a 50% increase in knowledge about COVID-19 prevention and management, and COVID-19 vaccines among vulnerable population groups—e.g., the poor, aged, disabled, those from rural and remote areas, and disadvantaged minorities—with a special focus on women, in 10 out of 19 project states; (ii) at least 20 partner institutions or networks working with disadvantaged communities, especially women, trained as master trainers to facilitate the country-wide promotion of COVID-19-appropriate behaviors, and the dissemination of COVID-19-related information and vaccine communication; (iii) at least 2,000 staff involved in BMW generation, management, and disposal (at least 40% of them women) trained; and at least 200 civil society and nongovernment organizations trained in amplifying the message of environmentally sound BMW; and (iv) dynamic analyses of Co-WIN data (disaggregated by location, gender, priority vulnerable groups) to support timely policymaking. The Immunization Division, AIIB, and ADB will jointly monitor progress in implementing the GESI action plan.

D. Environment and Social Safeguards

42. In compliance with ADB's Safeguard Policy Statement (2009),⁴³ the project's safeguard categories are as follows.⁴⁴

43. **Environment (category C).** The project supports the procurement and delivery of COVID-19 vaccines and does not entail activities with potentially adverse environmental impacts. However, the administration of vaccines will generate BMW, which will require safe treatment and disposal. ADB carried out due diligence on the current regulatory framework governing BMW, and the capacity for adequate management and disposal of BMW generated by the vaccination program.⁴⁵ The incremental increase in BMW from the vaccination program is estimated at 50 tons per day, or 4.2% of total BMW generation in the country. Project states have adequate existing and planned capacity to handle the incremental waste. In addition, ADB TA has been supporting (i) the monitoring of CVCs' compliance with BMW and source segregation standards, (ii) training of more than 2,000 staff involved in BMW, (iii) the formulation of guidelines for safe deep burial or incineration, and (iv) training of nongovernment and civil society organizations in raising awareness of safe BMW and advocating sustained public interest in this issue.

44. **Involuntary resettlement (category C).** The project does not involve civil works and will not require any land acquisition. It will not result in any involuntary resettlement impacts.

45. **Indigenous peoples (category C).** While indigenous 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 applicable safeguard policies, but they may benefit as individual indigenous

⁴³ ADB. 2009. [Safeguard Policy Statement](#). Manila.

⁴⁴ ADB. [Safeguard Categories](#). Manila.

⁴⁵ Due Diligence Report on the India COVID-19 Immunization Waste Management Plan (accessible from the list of linked documents in Appendix 2).

people. The project will ensure that members of indigenous groups will not be excluded and will not suffer any disadvantages in targeting because they belong to an indigenous people 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.

E. Summary of Risk Assessment and Risk Management Plan

46. Significant risks and mitigating measures are summarized in Table 6 and described in detail in the risk assessment and risk management plan.⁴⁶

Table 6: Summary of Risks and Mitigating Measures

Risks	Mitigation Measures
Limited domestic vaccine supplies to inoculate a large eligible population	(i) Mission Suraksha (COVID-19 Vaccine Development Mission) supports indigenous research and development of COVID-19 vaccines. (ii) Bilateral discussions to make raw material available for vaccine production. (iii) Eased regulatory pathways for vaccines that were granted emergency approval by selected SRAs or have WHO EUL status. (iv) Domestic manufacturers increased production in response to increased demand, both domestic and international.
Uncertainties about emerging variants and duration of effective protection from vaccination will require deployment adjustments.	(i) NEGVAC and the National Technical Advisory Group on Immunization continuously monitor vaccine efficacy against variants, and the Empowered Groups (high-level oversight bodies) advise on disease surveillance and vaccination. (ii) India's SARS-CoV-2 Genomics Consortium undertakes continuous genomic surveillance linked to epidemiological surveillance and clinical correlation.
Private sector participation in the national vaccination program is limited but imported vaccines will be delivered by private service providers.	(i) The government liberalized its vaccine procurement policy to allow private providers to purchase vaccines from manufacturers for up to 25% of supplies and introduced a vaccine demand aggregation module to facilitate vaccine purchasing, especially for smaller private providers. (ii) ADB TA through WHO will strengthen private providers' capacity (especially for different vaccine regimes) and monitor their compliance with applicable guidelines and advise MOHFW on ways to improve private sector involvement.
Vaccine hesitancy and access constraints undermine the aim of reaching herd immunity.	(i) MOHFW has been implementing a risk communication and community engagement strategy through mass media, social media, and community networks, with the support of many partners. (ii) ADB TA through UNICEF targets vulnerable groups for vaccine awareness and community support, especially in rural and remote areas.
Vaccine procurement and deployment on an unprecedented adult vaccination scale may significantly strain MOHFW's capacity.	(i) Selection of vaccines, price, and supply amounts are decided by MOHFW, on advice from NEGVAC. (ii) MOHFW engaged a procurement agent to manage vaccine supply agreements and deployment logistics and will continue using these arrangements.
Internal audit plan does not include the project, and external audit may be delayed.	(i) MOHFW will include the project in the internal audit plan and assign adequately experienced internal audit staff to conduct the audit. (ii) MOHFW will submit the project financial statements to CAG in a timely manner, and CAG will audit the project financial statements in line with ADB-agreed terms of reference.
BMW may increase beyond treatment capacity	(i) A tracking application (COVID19BWM) was developed to track COVID-19-related BMW at the time of generation, collection, and disposal, and the Supreme Court made its use mandatory for all health facilities. (ii) ADB TA through WHO will provide capacity building on BMW management.

ADB = Asian Development Bank, BMW = biomedical waste, CAG = Comptroller and Auditor General, COVID-19 = coronavirus disease, EUL = Emergency Use Listing, MOHFW = Ministry of Health and Family Welfare, NEGVAC = National Expert Group on Vaccine Administration for COVID-19, SRA = stringent regulatory authority, TA = technical assistance, UNICEF = United Nations Children's Fund, WHO = World Health Organization.

Source: Asian Development Bank.

⁴⁶ Risk Assessment and Risk Management Plan (accessible from the list of linked documents in Appendix 2).

IV. ASSURANCES AND CONDITIONS

47. The government has assured ADB that the project implementation shall conform to all applicable ADB requirements, including those concerning anticorruption measures, safeguards, gender, procurement, consulting services, financial management, and disbursement as described in detail in the PAM (footnote 42) and loan documents. The government has agreed with ADB on certain covenants for the project set forth in the draft loan agreements.

48. No withdrawals shall be made from the loan account for (i) financing an advance payment for a contract to supply eligible vaccines until ADB has received a letter from the government confirming (a) which COVID-19 vaccine(s) have been selected to be procured using the proceeds of the loans; and (b) which of the eligibility criteria in the definition of eligible vaccine have been satisfied in respect of the COVID-19 vaccine(s) to be procured, and based on the information provided in the aforementioned letter, ADB has notified the government that the COVID-19 vaccine to be procured meets ADB's eligibility criteria; and (ii) financing a contract to supply eligible vaccines until ADB has received a letter from the government confirming that in addition to (i)(a) and (i)(b), the eligible vaccines have received all necessary authorizations of the government, 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 the country; and based on the information provided in the aforementioned letter, ADB has notified the government that the COVID-19 vaccines to be procured are designated as eligible vaccines.

V. RECOMMENDATION

49. I am satisfied that the proposed loans would comply with the Articles of Agreement of the Asian Development Bank (ADB) and recommend that the Board approve:

- (i) the loan of \$500,000,000 to India for the Responsive COVID-19 Vaccines for Recovery Project under the Asia Pacific Vaccine Access Facility, from ADB's ordinary capital resources, in regular terms, with interest to be determined in accordance with ADB's LIBOR-based lending facility for a term of 10 years, including a grace period of 3 years; and such other terms and conditions as are substantially set forth in the draft loan agreement and project agreement presented to the Board; and
- (ii) the loan of \$1,000,000,000 to India for the Responsive COVID-19 Vaccines for Recovery Project under the Asia Pacific Vaccine Access Facility, from ADB's ordinary capital resources, in regular terms, with interest to be determined in accordance with ADB's LIBOR-based lending facility for a term of 5 years, including a grace period of 3 years; and such other terms and conditions as are substantially set forth in the draft loan agreement and project agreement presented to the Board.

Masatsugu Asakawa
President

15 November 2021

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) ^a			
Results Chain	Performance Indicators	Data Sources and Reporting Mechanisms	Risks and Critical Assumptions
Outcome Eligible population safely vaccinated against COVID-19 in project states	By 2024: At least 317 million targeted people (at least 47.5% women) vaccinated with at least two doses against COVID-19 in project states ^{b,c} (Baseline as of 16 August 2021: male: 52.6%, female: 46.8%, others: 0.6%) (OP 1.1)	Co-WIN dashboard and MOHFW project progress reports	A: Sufficient resources to cover operational costs made available on time by the government and development partners. A: Adequate and effective awareness-raising campaigns ensure that priority population groups are willing to get vaccinated.
Output Safe and effective COVID-19 vaccines supplied for eligible population in project states	a. By 2024, at least 667 million doses of COVID-19 vaccine procured and delivered to the project states ^d (2021 baseline: 0) (OP 1.1.2) (Under TA support) b. Co-WIN dashboard-generated reports disaggregated by rural, urban, women, men, others, and age made available throughout project implementation. (2021 baseline: Co-WIN dashboard operational) c. By 2022, lessons and best practices from COVID-19 vaccination, especially in relation to gender equality and social inclusion aspects, compiled and disseminated for system strengthening and future pandemic response (2021 baseline: N/A) d. By 2023, share of vulnerable people ^e reporting improved knowledge of the prevention and management of COVID-19, and of COVID-19 vaccines in 10 states ^g increased by 50% (out of which at least 20% are women) ^f (2021 baseline to be established by December 2021) ^h (OP 2.5.1) e. By 2023, at least 2,000 medical and paramedical, auxiliary, and treatment and	a. MOHFW project progress report and Co-WIN dashboard b. Co-WIN dashboard and TA monitoring reports c–e. MOHFW project progress reports, and TA monitoring reports	A: Adequate supply of vaccines that meet APVAX eligibility criteria. R: Changing priorities of the implementing agency.

	disposal facility staff (of which 40% are women) have acquired knowledge of BMWM (2020 baseline: 0) (OP 3.3.2)		
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<p>Key Activities with Milestones</p> <p>Safe and effective COVID-19 vaccines supplied for eligible population in project states</p> <p>a. Procure the required number of vaccine doses for ADB financing (Q1 2021–Q2 2024) and monitor distribution of vaccine doses to project states (Q3 2021–Q3 2024)</p> <p>b. & c. Support MOHFW, through project management consultants, in implementing the vaccination program and meeting the project requirements (Q3 2021–Q3 2024)</p> <p>d. Engage at least 20 partner institutions or networks working with disadvantaged communities, especially women, to facilitate the country-wide promotion of COVID-19-appropriate behaviors, and the dissemination of COVID-19-related information and vaccine communication (Q3 2021–Q3 2024)</p> <p>e. Develop guidelines on safe deep burial of BMW (Q4 2021), conduct 10 sessions of training of trainers (Q1 2022), conduct training on management and safe disposal of BMW for relevant staff (from Q1 2022 to Q2 2023), and train NGOs and CSOs on BMWM awareness (Q1 2022–Q2 2023).</p> <p>Project Management Activities</p> <p>Prepare and submit quarterly progress reports (Q1 2022 onward).</p> <p>Plan and agree on the performance audit of the national vaccination program with CAG (Q1 2022).</p> <p>Submit annual audited project financial statements (Q2 2022 onward) and program performance audit reports (by Q3 2024 or within 1 month from the completion of the report, whichever is earlier).</p> <p>Submit project completion report (by Q1 2025).</p> <p>Inputs</p> <p>ADB: \$1,500 million (loan)</p> <p>AIIB: \$500 million (loan)</p> <p>ADB: \$4,000,000 (TA grant)ⁱ</p>

A = assumption, ADB = Asian Development Bank, AIIB = Asia Infrastructure Investment Bank, APVAX = Asia Pacific Vaccine Access Facility, BMW = biomedical waste, BMWM = biomedical waste management, CAG = Comptroller and Auditor General, COVID-19 = coronavirus disease, Co-WIN = Winning over Covid-19, CSO = civil society organization, MOHFW = Ministry of Health and Family Welfare, NDVP = National Deployment and Vaccination Plan, NGO = nongovernment organization, OP = operational priority, Q = quarter, R = risk, TA = technical assistance, UNICEF = United Nations Children’s Fund.

- a The NDVP is in Annex III of the National Deployment and Vaccine Allocation Plan (accessible from the list of linked documents in Appendix 2).
- b The number of beneficiaries will depend on the price of the vaccine, number of doses required under the vaccine regime, and wastage rate. ADB assumed 5% wastage based on national trends and a two-dose regime at a cost of \$3 per dose.
- c 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.
- d The number of doses will depend on the actual price of the vaccine and vaccine dose regime (one dose, two doses, or three doses). ADB assumed \$3 per dose with two doses per eligible beneficiary and 5% wastage.
- e Vulnerable people are women, income-poor individuals, older people, people with disabilities, residents in rural and remote areas, and disadvantaged minority groups. Women-specific targets will include poor women, older women, women with disabilities, women residing in rural and remote areas, and women from disadvantaged minority groups.
- f Out of 50% people with increased knowledge of COVID-19 prevention, 20% are women, which means that of those reporting improved knowledge, 40% are women.
- g 10 selected states from the 19 project states where UNICEF has established partnerships with CSOs/NGOs in rural areas or with marginalized groups.
- h Tools and indicators to establish a baseline for visible messaging would be developed by UNICEF with inputs from ADB and biannual survey would be carried out to assess against the same indicators established.
- i Support will be covered by ongoing TA from ADB, 2021. [Technical Assistance to India for Supporting COVID-19 Response and Vaccination Program](#). Manila (TA 6733) funded by Japan Fund for Poverty Reduction (\$2 million for vaccination support) and Technical Assistance Special Fund (\$2 million).

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 to a reduction in transmission of COVID-19 in South Asia and beyond.
 Source: Asian Development Bank.

LIST OF LINKED DOCUMENTS

<http://www.adb.org/Documents/RRPs/?id=55082-001-3>

1. Loan Agreement
2. Project Agreement
3. Vaccine Needs Assessment
4. Project Administration Manual
5. Contribution to Strategy 2030 Operational Priorities
6. Development Partner Coordination
7. Country Economic Indicators
8. Debt Sustainability Analysis
9. National Deployment and Vaccine Allocation Plan
10. Summary Poverty Reduction and Social Strategy
11. Gender Equality and Social Inclusion Action Plan
12. Risk Assessment and Risk Management Plan
13. Indicative Master List of Eligible Items, and Agreed List of Acceptable Expenditure Items ('Positive List'), for ADB-financing under the Rapid Response Component
14. Eligibility Criteria for the Use of Funds under the Rapid Response Component

Supplementary Documents

15. Due Diligence on India's COVID-19 Immunization Waste Management Plan
16. Financial Management Assessment Report
17. Summary of Procurement Strategy
18. Sector Assessment (Summary): Vaccines
19. Program Monitoring and Evaluation System Assessment