LOAN NUMBER 4147 - IND LOAN NUMBER 4151 - IND

LOAN AGREEMENT (Ordinary Operations)

(Responsive COVID-19 Vaccines for Recovery Project)

between

INDIA

and

ASIAN DEVELOPMENT BANK

DATED 31 December 2021

LOAN AGREEMENT (Ordinary Operations)

LOAN AGREEMENT dated 31 December 2021 between India acting by its President ("Borrower") and ASIAN DEVELOPMENT BANK ("ADB").

WHEREAS

- (A) ADB has received from the Borrower a governor's letter dated 05 November 2021 ("Governor's Letter"), confirming the Borrower's commitment to implement its Vaccination Allocation Plan (as defined hereinafter) and setting forth certain objectives, policies and actions of the Borrower designed to provide access within its territory to vaccines for the coronavirus disease ("COVID-19");
- (B) the Borrower has applied to ADB for Loans for the purposes of the Project described in Schedule 1 to this Loan Agreement;
- (C) the Borrower has also applied to the Asian Infrastructure Investment Bank ("AIIB") for a loan ("AIIB Loan") in an amount of five hundred million Dollars (\$500,000,000) to assist in financing a part of the Project, upon the terms and conditions set forth in a loan agreement between the Borrower and AIIB ("AIIB Loan Agreement");
- (D) the Project will be carried out by the Borrower acting through its Ministry of Health and Family Welfare ("MOHFW") (the Project Executing Agency or "EA"), and for this purpose the Borrower will make the proceeds of the Loans provided for herein available to the EA, upon terms and conditions mutually satisfactory to ADB and the Borrower; and
- (E) ADB has agreed to make the Loans to the Borrower from ADB's ordinary capital resources upon the terms and conditions set forth herein and in the Project Agreement of even date herewith between ADB and MOHFW;

NOW THEREFORE the parties hereto agree as follows:

ARTICLE I

Loan Regulations; Definitions

Section 1.01. All the provisions of ADB's Ordinary Operations Loan Regulations, dated 1 January 2017 ("Loan Regulations"), are hereby made applicable to this Loan Agreement with the same force and effect as if they were fully set forth herein, subject, however, to the following modifications:

(a) Section 2.01(kk) is deleted and the following is substituted therefor:

"Loan" means each of (a) Loan 1 and (b) Loan 2, (as defined in Section 1.02 of the Loan Agreement) collectively the "Loans";

(b) Section 2.01(II) is deleted and the following is substituted therefor:

"Loan Account" means:

- (i) in relation to Loan 1, the account opened or to be opened by ADB on its books in the name of the Borrower to which the amount of Loan 1 has been or will be credited; and
- (ii) in relation to Loan 2, the account opened or to be opened by ADB on its books in the name of the Borrower to which the amount of Loan 2 has been or will be credited.
- (c) Section 2.01 (Definitions) subsection (xx) shall be deleted and replaced in its entirety as follows:
 - (xx) "Reference Rate" means, (i) except as ADB has otherwise made a determination in accordance with Section 3.02(c), in respect of any Loan Currency other than Euro, LIBOR, and in respect of Euro, Euribor; and (ii) if a determination is made in accordance with Section 3.02(c), such other reference rate and any spread for the Loan Currency as ADB shall reasonably determine and promptly notify the Borrower and the Guarantor.
- (d) A new subsection 3.02(c) shall be inserted after subsection 3.02(b) as follows:

Section 3.02(c). If interest on any amount of the Loan is calculated based on LIBOR or Euribor, and ADB determines that (i) such Reference Rate has permanently ceased to be guoted for the relevant Loan Currency or a public statement or publication of information by the regulatory supervisor for the administrator of the Reference Rate announcing such Reference Rate is no longer representative has been made or (ii) ADB is no longer able, or it is no longer commercially acceptable for ADB, to continue to use such Reference Rate for purposes of its asset and liability management. ADB shall apply such other Reference Rate for the relevant Loan Currency, including any applicable spread, as it may reasonably determine. ADB shall promptly notify the Borrower and the Guarantor of such other reference rate and any spread, and of related amendments to the provisions of the Loan Agreement necessary to give effect to its application, which shall become effective as of the date of such notice.

Section 1.02. Wherever used in this Loan Agreement, the several terms defined in the Loan Regulations have the respective meanings therein set forth unless modified herein or the context otherwise requires. Additional terms used in this Loan Agreement have the following meanings:

(a) "Consulting Services" means consulting services as described in the Procurement Regulations and set out in the Procurement Plan, and to be financed out of the proceeds of the Loan;

- (b) "EA" or "Project Executing Agency" for the purposes of, and within the meaning of, the Loan Regulations means the Borrower acting through its MOHFW, or any successor thereto, which is responsible for the carrying out of the Project;
- (c) "Eligibility Criteria" means criteria, as described in paragraph 29 (including footnotes 28, 29 and 30) of ADB's policy on Support to Enhance COVID-19 Vaccine Access;
- (d) "Eligible Expenditures" means categories of expenditures agreed between ADB and the Borrower, to be financed out of the proceeds of the Loan, as set forth in the table to Schedule 3 to this Loan Agreement and as further detailed in the PAM;
- (e) "Eligible Vaccine" means a COVID-19 vaccine eligible for financing out of the proceeds of the Loan which, at all times during the Project implementation period, (i) satisfies the Eligibility Criteria, and (ii) has received all necessary authorizations of the Borrower for its distribution and administration within the territory of the Borrower, including authorization for use, and any other necessary authorizations for its manufacture, marketing or importation;
- "Financing Arrangements" means the arrangements between the Borrower and MOHFW as per current policy of the Borrower, and acceptable to ADB;
- (g) "FMAP" means the Financial Management Action Plan as included in the PAM:
- "GESI AP" means the Gender Equality and Social Inclusion action plan agreed between the ADB, Borrower and the EA;
- (i) "Goods" means equipment and materials as set out in the Procurement Plan and to be financed out of the proceeds of the Loan, including Eligible Vaccines and any related Nonconsulting Services such as transportation and insurance;
- (j) "Loan Disbursement Handbook" means ADB's Loan Disbursement Handbook (2017, as amended from time to time);
- (k) "Loans" means Loan 1 and Loan 2, as referred in Section 2.01(a) of this Loan Agreement and Loan means either or both Loan 1 and Loan 2 as the context may require;
- "Loan 1" means the Loan in an amount of \$500,000,000, as referred in Section 2.01(a) of this Loan Agreement;
- (m) "Loan 2" means the Loan in an amount of \$1,000,000,000, as referred in Section 2.01(a) of this Loan Agreement;
- (n) "MOHFW" means the Borrower's Ministry of Health and Family Welfare:

- (o) "Nonconsulting Services" means nonconsulting services as described in the Procurement Regulations and set out in the Procurement Plan, and to be financed out of the proceeds of the Loan;
- (p) "PAM" means the project administration manual for the Project dated November 2021 and agreed between the Borrower, the EA, and ADB, as updated from time to time in accordance with the respective administrative procedures of the Borrower, the EA and ADB;
- (q) "Procurement Plan" means the procurement plan for the Project dated 28 October 2021 and agreed between the Borrower, the EA, and ADB, as updated from time to time in accordance with the Procurement Policy, the Procurement Regulations, and other arrangements agreed with ADB;
- (r) "Procurement Policy" means ADB's Procurement Policy Goods, Works, Nonconsulting and Consulting Services (2017, as amended from time to time);
- (s) "Procurement Regulations" means ADB's Procurement Regulations for ADB Borrowers - Goods, Works, Nonconsulting and Consulting Services (2017, as amended from time to time);
- (t) "Project States" mean each of the States of the Borrower that comprise 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 and/or other States as may be agreed upon between ADB and the Borrower;
- (u) "Services" means Consulting Services and Nonconsulting Services;
- (v) "SPS" means ADB's Safeguard Policy Statement (2009);
- (w) "SRA" means entity designated by the World Health Organization as a stringent regulatory authority for purposes of assessment and approval of COVID-19 vaccines; and
- (x) "Vaccination Allocation Plan" means the National Deployment and Vaccination Plan for COVID-19 Vaccines adopted by the Borrower on 12 January 2021, including its addendum and subsequent policies, attached to and endorsed in the Governor's Letter, which, amongst other things, describes the Borrower's prioritization of COVID-19 vaccine access consistent with international norms and safeguards against exclusion of marginalized and vulnerable groups and sets out the national policy in relation to vaccine selection, acquisition, procurement, distribution, deployment and administration, as well as any related medical waste management, in the territory of the Borrower.

ARTICLE II

The Loan

Section 2.01. (a) ADB agrees to lend to the Borrower from its ordinary capital resources, Loans comprising (i) Loan 1 in an amount of five hundred million Dollars (\$500, 000,000); and (ii) Loan 2 in an amount of One billion dollars (\$1,000,000,000), as each such amount may be converted from time to time through a Currency Conversion in accordance with the provisions of Section 2.06 of this Loan Agreement.

- (b) Loan 1 has a principal repayment period of 7 years, and a grace period as defined in paragraph (c) of this Section.
- (c) The term "grace period" as used in paragraph (b) of this Section means the period prior to the first Principal Payment Date in accordance with the amortization schedule set forth in Paragraph 1 of Schedule 2 to this Loan Agreement as it applies to Loan 1.
- (d) Loan 2 has a principal repayment period of 2 years, and a grace period as defined in paragraph (e) of this Section.
- (e) The term "grace period" as used in paragraph (d) of this Section means the period prior to the first Principal Payment Date in accordance with the amortization schedule set forth in paragraph 2 of Schedule 2 to this Loan Agreement as it applies to Loan 2.

Section 2.02. The Borrower shall pay to ADB interest on the principal amount of the Loan 1 and Loan 2 respectively, withdrawn and outstanding from time to time at a rate for each Interest Period equal to the sum of

- (a) LIBOR; and
- (b) 0.60% as determined by Section 3.02 of the Loan Regulations; less a credit of 0.10% as provided by Section 3.03 of the Loan Regulations.

Section 2.03. The Borrower shall pay a commitment charge of 0.15% per annum on each of Loan 1 and Loan 2 respectively. Such charge shall accrue on the full amount of the Loan 1 and Loan 2, respectively (less amounts withdrawn in each case, from time to time), commencing 60 days after the date of this Loan Agreement.

Section 2.04. Interest and other charges on each of the Loans shall be payable semiannually on 01 May and 01 November in each year.

Section 2.05. The Borrower shall repay the principal amount of the Loan 1 and Loan 2, as applicable, withdrawn from the respective Loan Account in accordance with the provisions of Schedule 2 to this Loan Agreement.

Section 2.06. (a) The Borrower may at any time request any of the following Conversions of the terms of the Loan 1 or Loan 2, as the case may be, in order to facilitate prudent debt management, subject to relevant market opportunities being made available to ADB:

- a change of the Loan Currency of all or any portion of the principal amount of the Loan 1 or Loan 2, whether withdrawn and outstanding or unwithdrawn, to an Approved Currency;
- (ii) a change of the interest rate basis applicable to all or any portion of the principal amount of the Loan 1 or Loan 2, as the case may be, from a Floating Rate to a Fixed Rate, or vice versa; and
- (iii) the setting of limits on the Floating Rate applicable to all or any portion of the principal amount of the Loan 1 or Loan 2, as the case may be, withdrawn and outstanding by the establishment of an Interest Rate Cap or Interest Rate Collar on said Floating Rate.
- (b) Any conversion requested pursuant to paragraph (a) of this Section that is accepted by ADB shall be considered a "Conversion", as defined in Section 2.01(6) of the Loan Regulations, and shall be effected in accordance with the provisions of Article V of the Loan Regulations and the Conversion Guidelines.

ARTICLE III

Use of Proceeds of the Loan

Section 3.01. The Borrower shall make the proceeds of the Loan available to the EA and shall cause the EA to apply such proceeds to be applied exclusively to the financing of expenditures on the Project in accordance with the provisions of this Loan Agreement and the Project Agreement.

Section 3.02. The proceeds of the Loan shall be allocated and withdrawn in accordance with the provisions of Schedule 3 to this Loan Agreement, as such Schedule may be amended from time to time by agreement between the Borrower and ADB.

Section 3.03. Except as ADB may otherwise agree, the Borrower shall ensure, or cause the EA to ensure, that the items of expenditure to be financed out of the proceeds of the Loan are procured in accordance with the provisions of Schedule 4 to this Loan Agreement.

Section 3.04. The Loan Closing Date for the purposes of Section 9.02 of the Loan Regulations shall be 30 June 2025 or such other date as may from time to time be agreed between the Borrower and ADB.

ARTICLE IV

Particular Covenants

Section 4.01. In the carrying out of the Project and operation of the Project facilities, the Borrower shall perform, or cause to be performed by the EA, all obligations set forth in this Loan Agreement and the Project Agreement.

Section 4.02. The Borrower shall enable or cause the EA to enable, ADB's representatives to inspect the Project, the Goods and Services, and any relevant records and documents.

Section 4.03. ADB shall disclose the annual audited financial statements for the Project and the opinion of the auditors on the financial statements within 14 days of the date of ADB's confirmation of their acceptability by posting them on ADB's website.

Section 4.04. The Borrower shall take all actions which shall be necessary to enable the EA to perform its obligations under the Project Agreement and shall not take or permit any action which would interfere with the performance of such obligations.

Section 4.05. (a) The Borrower shall exercise its rights under the Financing Arrangements in such a manner as to protect the interests of the Borrower and ADB and to accomplish the purposes of the Loan.

(b) No rights or obligations under the Financing Arrangements shall be assigned, amended, abrogated or waived without the prior notice to ADB.

ARTICLE V

Effectiveness

Section 5.01. A date 90 days after the date of this Loan Agreement is specified for the effectiveness of this Loan Agreement for the purposes of Section 10.04 of the Loan Regulations.

ARTICLE VI

Miscellaneous

Section 6.01. The Secretary, Additional Secretary, Joint Secretary, Director, or Deputy Secretary, in the Department of Economic Affairs of the Ministry of Finance of the Borrower is designated as representative of the Borrower for the purposes of Section 12.02 of the Loan Regulations.

Section 6.02. The following addresses are specified for the purposes of Section 12.01 of the Loan Regulations:

For the Borrower

The Secretary to the Government of India Ministry of Finance Department of Economic Affairs North Block New Delhi – 110001 India

Facsimile Number:

91-11-23094075

For ADB

Asian Development Bank 6 ADB Avenue Mandaluyong City 1550 Metro Manila Philippines

Facsimile Numbers:

(632) 8636-2444 (632) 8636-2449.

IN WITNESS WHEREOF the parties hereto, acting through their representatives thereunto duly authorized, have caused this Loan Agreement to be signed in their respective names as of the day and year first above written and to be delivered at the principal office of ADB.

INDIA

By Rajat Kumar Mishra

Additional Secretary (MBC)
Department of Economic Affairs

ASIAN DEVELOPMENT BANK

Officer-in-Charge India Resident Mission

Description of the Project

- The objective of the Project is to vaccinate priority populations against COVID-19.
 The Project is described in more detail in the Governor's Letter.
- The Project shall comprise supporting, together with AIIB Loan financing, the procurement of approximately 667 million doses of the Eligible Vaccines through bilateral arrangements with vaccine manufacturers or distributors.
- The Project is expected to be completed by 31 December 2024.

Amortization Schedule

1. (a) Loan 1: The following table sets forth the Principal Payment Dates of Loan 1 and the percentage of the total principal amount of Loan 1 payable on each Principal Payment Date (Installment Share). If the proceeds of Loan 1 shall have been fully withdrawn as of the first Principal Payment Date, the principal amount of Loan 1 repayable by the Borrower on each Principal Payment Date shall be determined by ADB by multiplying (a) the total principal amount of Loan 1 withdrawn and outstanding as of the first Principal Payment Date; by (b) the Installment Share for each Principal Payment Date, such repayment amount to be adjusted, as necessary, to deduct any amounts referred to in paragraph 4 of this Schedule, to which a Currency Conversion applies.

Sequence	Date Payment Due	Installment Share (Expressed as a % based on 30% annuity)	
1	1 May 2025	2.468849	
2	1 November 2025	1 November 2025 2.839176	
3	1 May 2026	3.265053	
4	1 November 2026	3.754811	
5	1 May 2027	4.318032	
6	1 November 2027	4.965737	
7	1 May 2028	5.710598	
8	1 November 2028	6.567187	
9	1 May 2029	7.552266	
10	1 November 2029	8.685105	
11	1 May 2030	9.987871	
12	1 November 2030	11.486052	
13	1 May 2031	13.208960	
14	1 November 2031	15.190303	
	Total	100.000000	

(b) Loan 2: The following table sets forth the Principal Payment Dates of Loan 2 and the percentage of the total principal amount of Loan 2 payable on each Principal Payment Date (Installment Share). If the proceeds of Loan 2 shall have been fully withdrawn as of the first Principal Payment Date, the principal amount of Loan 2 repayable by the Borrower on each Principal Payment Date shall be determined by ADB by multiplying (a) the total principal amount of Loan 2 withdrawn and outstanding as of the first Principal Payment Date; by (b) the Installment Share for each Principal Payment Date, such repayment amount to be adjusted, as necessary, to deduct any amounts referred to in paragraph 4 of this Schedule, to which a Currency Conversion applies.

Sequence	Date Payment Due	Installment Share (Expressed as a % based on 30% annuity)
1	1 May 2025	20.026535
2	1 November 2025	23.030515
3	1 May 2026	26.485093
4	1 November 2026	30.457857
	Total	100.000000

- 2. If the proceeds of Loan 1 or Loan 2 respectively, shall not have been fully withdrawn as of the first Principal Payment Date, the principal amount of Loan 1 or Loan 2 respectively, repayable by the Borrower on each Principal Payment Date shall be determined as follows:
 - (a) to the extent that any proceeds of Loan 1 or Loan 2 respectively, shall have been withdrawn as of the first Principal Payment Date, the Borrower shall repay the amount withdrawn and outstanding as of such date in accordance with paragraph 1 of this Schedule; and
 - (b) any withdrawal made after the first Principal Payment Date shall be repaid on each Principal Payment Date falling after the date of such withdrawal in amounts determined by ADB by multiplying the amount of each such withdrawal by a fraction, the numerator of which shall be the original Installment Share specified in the table in paragraph 1 of this Schedule for said Principal Payment Date (the Original Installment Share) and the denominator of which shall be the sum of all remaining Original Installment Shares for Principal Payment Dates falling on or after such date, such repayment amounts to be adjusted, as necessary, to deduct any amounts referred to in paragraph 4 of this Schedule, to which a Currency Conversion applies.
- 3. Withdrawals made within 2 calendar months prior to any Principal Payment Date shall, for the purposes solely of calculating the principal amounts payable on any Principal Payment Date, be treated as withdrawn and outstanding on the second Principal Payment Date following the date of withdrawal and shall be repayable on each Principal Payment Date commencing with the second Principal Payment Date following the date of withdrawal.
- 4. Notwithstanding the provisions of paragraphs 1 and 2 of this Schedule, upon a Currency Conversion of all or any portion of the withdrawn principal amount of Loan 1 or Loan 2 respectively, to an Approved Currency, the amount so converted in said Approved Currency that shall be repayable on any Principal Payment Date occurring during the Conversion Period, shall be determined by ADB by multiplying such amount in its currency of denomination immediately prior to said Conversion by either (a) the exchange rate that reflects the amounts of principal in said Approved Currency payable by ADB under the Currency Hedge Transaction relating to said Conversion; or (b) if ADB so determines in accordance with the Conversion Guidelines, the exchange rate component of the Screen Rate.

Schedule 2

5. If the principal amount of the Loan 1 or Loan 2 respectively, withdrawn and outstanding from time to time shall be denominated in more than one Loan Currency, the provisions of this Schedule shall apply separately to the amount denominated in each Loan Currency, so as to produce a separate amortization schedule for each such amount.

Allocation and Withdrawal of Loan Proceeds

General

1. The table attached to this Schedule sets forth the Categories of items of Eligible Expenditures to be financed out of the proceeds of Loan 1 or Loan 2 respectively, and the allocation of Loan 1 or Loan 2 respectively, proceeds to each such Category ("Table"). (Reference to "Category" in this Schedule is to a Category of the Table.)

Basis for Withdrawal from the Loan Account

- Except as ADB may otherwise agree, the proceeds of Loan 1 or Loan 2 respectively, shall be allocated to items of Eligible Expenditures, and disbursed on the basis of the withdrawal percentage for each item of expenditure set forth in the Table.
- With respect to any COVID-19 vaccine, ADB shall only finance those that continue to qualify as an Eligible Vaccine at the time a withdrawal request is made from the respective Loan Account of Loan 1 or Loan 2 respectively.

Reallocation

- Notwithstanding the allocation of Loan proceeds and the withdrawal percentages set forth in the Table.
- (a) if the amount of Loan 1 or Loan 2 respectively, allocated to any Category appears to be insufficient to finance all agreed expenditures in that Category, ADB may, by notice to and in consultation with the Borrower and the EA, (i) reallocate to such Category, to the extent required to meet the estimated shortfall, amounts of the Loan which have been allocated to another Category but, in the opinion of ADB, are not needed to meet other expenditures; and (ii) if such reallocation cannot fully meet the estimated shortfall, reduce the withdrawal percentage applicable to such expenditures in order that further withdrawals under such Category may continue until all expenditures thereunder shall have been made; and
- (b) if the amount of the Loan allocated to any Category appears to exceed all agreed expenditures in that Category, ADB may, by notice to and in consultation with the Borrower and the EA, reallocate such excess amount to any other Category.

Disbursement Procedures

Except as ADB may otherwise agree, the Loan proceeds shall be disbursed in accordance with the Loan Disbursement Handbook.

Retroactive Financing

6. Withdrawals from the Loan Account for Loan 1 or Loan 2 may be made for Eligible Expenditures incurred under the Project before the Effective Date in connection with items to be retroactively financed, subject to a maximum amount equivalent to 30% of the Loan amount; provided that the expenditures have been incurred after the allocation by the Borrower of resources to respond to the COVID-19 pandemic, but not earlier than 12 months before the date of this Loan Agreement.

Condition for Withdrawals from Loan Account

- Notwithstanding any other provision of this Loan Agreement, no withdrawals shall be made from the Loan Account for Loan 1 or Loan 2, for financing vaccines until
- (a) ADB has received a letter from the Borrower confirming (i) which COVID-19 vaccine(s) has/have been selected to be procured using the proceeds of the Loan; (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 of the Borrower, and have been authorized by the Drugs Controller General of India heading the Central Drugs Standard Control Organization, and any other relevant regulatory authorities for distribution and administration within the territory of the Borrower;
- (b) ADB has, based on the information provided in the aforementioned letter, notified the Borrower that the COVID-19 vaccine(s) to be procured are designated as Eligible Vaccines; and
- (c) ADB shall have been provided by the EA, through the Borrower, with evidence that the concerned contracts for procurement of Eligible Vaccines contain provisions requiring the concerned COVID-19 vaccine manufacturer or supplier to comply with ADB's Anticorruption Policy (1998, as amended to date) and its Integrity Principles and Guidelines (2015, as amended from time to time), where such provisions may be included in the concerned contracts or supplemented through a Side Letter or otherwise (in each case, in form and substance satisfactory to ADB).

Attachment to Schedule 3

TABLE

	ALLOCATIO	ON AND WITHDRAWAL OF LO	AN PROCEEDS
Number	Item	Total Amount Allocated for ADB Financing (\$) Category	Basis for Withdrawal from the Loan Account
		LOAN 1	
1	Eligible Vaccines**	482,540,000	25.0% of total expenditure claimed*
2	Unallocated	17,460,000	
	Total	500,000,000	
		LOANS	
		LOAN 2	
1	Eligible Vaccines**	965,070,000	50.0% of total expenditure claimed*
2	Unallocated	34,930,000	
	Total	1,000,000,000	

Inclusive of taxes and duties imposed within the territory of the Borrower. Subject to the condition for withdrawal described in paragraph 7 of Schedule 3.

Execution of Project

Implementation Arrangements

- (a) The Borrower shall ensure and cause the EA to ensure, that the Project is implemented in accordance with the detailed arrangements set forth in the PAM. Any subsequent change to the PAM shall become effective only after approval of such change by the Borrower, the EA and ADB. In the event of any discrepancy between the PAM and this Loan Agreement, the provisions of this Loan Agreement shall prevail.
- (b) The Borrower shall ensure or cause the EA to ensure that the EA's Immunization Division, as the implementing agency, shall be responsible to work under the supervision of the EA and coordinate with other EA divisions/units, other agencies, and Project States for all aspects of Project implementation.

Procurement

- 2. The Borrower shall ensure, or cause the EA to ensure, that:
 - unless otherwise approved by ADB, the procurement of Goods and Services is carried out in accordance with the Procurement Policy and the Procurement Regulations;
 - (b) Goods and Services shall be procured based on the detailed arrangements set forth in the Procurement Plan, including the procurement and selection methods, the type of bidding documents, and ADB's review requirements. The Borrower may modify the detailed arrangements set forth in the Procurement Plan only with the prior agreement of ADB, and such modifications must be set out in updates to the Procurement Plan;
 - Goods and Services may also be procured under the Project from non-member countries of ADB; and
 - (d) (i) all Goods procured and Services obtained (including all computer hardware, software and systems, whether separately procured or incorporated within other goods and services procured) do not violate or infringe any industrial property or intellectual property right or claim of any third party; and (ii) all contracts for the procurement of Goods and Services contain appropriate representations, warranties and, if appropriate, indemnities from the contractor, supplier, consultant or service provider with respect to the matters referred to in this subparagraph.
- The Borrower may appoint a procurement agent to carry out the procurement in accordance with the terms and conditions set forth in the Procurement Plan. The Borrower shall ensure that such procurement agent follows all of the requirements of the Loan Agreement and the Procurement Plan.

Safeguards

4. The Borrower shall ensure, or cause the EA to ensure, that the Project does not have any environmental, indigenous peoples or involuntary resettlement impacts, all within the meaning of the SPS. In the event that the Project does have any such impact, the Borrower shall or shall cause the EA to take all steps required to ensure that the Project complies with the applicable laws and regulations of the Borrower and with the SPS.

Prohibited List of Investments

The Borrower shall ensure, or cause the EA to ensure, that no proceeds of the Loans are used to finance any activity included in the list of prohibited investment activities provided in Appendix 5 of the SPS.

Vaccine Selection; Vaccination Allocation Plan

The Borrower:

- represents on its and on behalf of the EA, that it has conducted its own due diligence, and made its own independent determination of, the quality, safety, and efficacy of the Eligible Vaccines to be procured under the Project;
- (b) shall ensure and cause the EA to ensure, that Loans' proceeds allocated for financing of vaccines shall only be used for the procurement, distribution or administration of a vaccine which has been confirmed by ADB to be an Eligible Vaccine:
- (c) assumes sole responsibility and causes EA to assume sole responsibility, for the selection, importation, procurement, distribution, marketing or administration, of any Eligible Vaccine under the Project, and agrees that ADB shall have no responsibility or liability in respect thereof;
- (d) shall ensure and cause the EA to ensure that the deployment, distribution and administration of Eligible Vaccines are implemented in accordance with the Vaccination Allocation Plan; and
- (e) shall and shall cause the EA to (i) inform and exchange views with ADB on any changes to the Vaccination Allocation Plan and any sector, legal, regulatory or policy reform discussions that may be held with other bilateral or multilateral agencies that may have implications on the implementation of the deployment, distribution and administration of the Eligible Vaccines; and (ii) provide ADB a reasonable opportunity to comment on any resulting policy proposal.
- 7. In instances where any COVID-19 vaccine which ADB has not confirmed as an Eligible Vaccine is proposed for procurement under the Project subsequent to the initial withdrawal from each of the Loan Account for any Eligible Vaccine, the Borrower shall ensure that no withdrawal request is made from the respective Loan Account in relation to such vaccine until:

Schedule 4

- (a) ADB has received a letter from the Borrower confirming (i) which of the Eligibility Criteria has been satisfied in respect of such vaccine; and (ii) that such vaccine has received all necessary authorizations of the Borrower, and has been authorized by the Drugs Controller General of India heading the Central Drugs Standard Control Organization, and any other relevant regulatory authorities for distribution and administration within the territory of the Borrower; and
- (b) based on the information provided in the aforementioned letter, ADB has notified the Borrower that such vaccine is designated as an Eligible Vaccine.

Compliance with Local Laws

- The Borrower shall ensure and cause the EA to ensure that the selection, importation, procurement, deployment, distribution, marketing, administration and disposal of any Eligible Vaccine is conducted in accordance with the applicable laws and regulations of the Borrower.
- 9. The Borrower, through the Drugs Controller General of India heading the Central Drugs Standard Control Organization, and any other relevant regulatory authorities, shall promptly take all such steps and cause the EA to promptly take all such steps as may be necessary to facilitate the continuing authorization of Eligible Vaccines for distribution and administration within the territory of the Borrower, including through the prompt issuance or renewal of all the necessary authorizations, provided that the requisite quality, safety, efficacy and other legal requirements for authorization continue to be met. The Borrower shall and shall cause the EA to promptly inform ADB of any event or circumstance which may arise that may prevent, hinder, delay or place conditions on such continuing authorization.

Vaccine Storage, Transportation and Waste Management

- The Borrower shall ensure and cause the EA to ensure that:
 - (a) Eligible Vaccines are properly stored, handled and transported within the territory of the Borrower to preserve their quality, efficacy and safety in accordance with, the relevant vaccine manufacturer's requirements, applicable laws and regulations of the Borrower and international good practice, including the effective vaccine management framework of the World Health Organization and the United Nations Children's Fund; and
 - (b) any medical or other waste generated in connection with the storage, transportation, distribution or administration of Eligible Vaccines and associated medical equipment is properly treated, disposed of and managed in accordance with the Bio-medical Waste Management (BMWM) rules (2016, including as amended from time to time) and guidelines on BMWM under Universal Immunization Program (2021) of the Borrower.

Limitation of Liability

- 11. The Borrower acknowledges and causes the EA to acknowledge and agree that:
 - (a) the confirmation by ADB of any vaccine as an Eligible Vaccine does not constitute an endorsement, or warranty of the fitness, by ADB of such vaccine for any particular purpose, including with regard to its quality, safety or efficacy, and the Borrower is exclusively responsible for authorizing the use of any Eligible Vaccines, for distribution and administration within the territory of the Borrower, including but not limited to quality monitoring throughout the supply chain, compliance with applicable treatment guidelines and application of measures to monitor and address adverse reactions; and
 - (b) ADB disclaims any and all financial or other liability and responsibility for any injury, death, loss, damage or other prejudice of any kind whatsoever that may arise as a result of or in connection with the selection, procurement, importation, manufacturing, fill and finish, distribution, marketing, administration or use of any vaccine under the Project or the treatment, disposal, or management of any medical or other waste generated in connection with the storage, handling, transportation, distribution or administration of any such vaccine.

Communications and Participation

12. The Borrower shall ensure or cause the EA to ensure that the Project is undertaken in conformity with the stakeholder communication strategy as agreed between ADB, the Borrower and the EA and referred in the PAM.

Gender and Development

13. The Borrower shall or shall cause the EA to ensure that (a) the GESI AP is implemented in accordance with its terms; (b) the bidding documents and contracts include relevant provisions for contractors to comply with the measures set forth in the GESI AP; (c) adequate resources are allocated for implementation of the GESI AP; and (d) progress on implementation of the GESI AP, including progress toward achieving key gender outcome and output targets, are regularly monitored and reported to ADB.

Counterpart Support

14. The Borrower shall ensure or cause the EA to ensure to make available the loan proceeds under the Project under appropriate arrangements acceptable to ADB, and ensure sufficient counterpart funds from its budget for each fiscal year, in a timely manner, for the efficient implementation of the Project. In addition to the above, the Borrower shall ensure that the EA has sufficient funds to satisfy its liabilities arising from any Goods and/or Services contract.

Financial Management Action Plan

16. The Borrower shall ensure or cause the EA to implement the FMAP as set out in the PAM, within the stipulated time frames, and the progress toward achieving the targets is monitored and reported to ADB on regular basis.

Governance and Anticorruption

17. The Borrower shall, and cause the EA to, comply with ADB's Anticorruption Policy (1998, as amended to date) and (a) shall ensure that the anticorruption provisions acceptable to ADB, the Borrower, and the EA are included in all bidding documents and contracts financed by ADB in connection with the Project, including provisions specifying the right of ADB to review and examine the records and accounts of the EA and all contractors, suppliers, consultants, and other service providers as they relate to the Project, and as included in the PAM; (b) shall allow and assist ADB's representatives to carry out random spot checks on the work in progress and utilization of funds for the Project; (c) acknowledge that ADB reserves the right to investigate directly or through its agents any alleged corrupt, fraudulent, collusive or coercive practice, or other integrity violations relating to the Project; and (d) cooperate with any such investigation and extend all necessary assistance for satisfactory completion of such investigation, and as included in the PAM. Firms or individuals who are debarred or temporarily suspended by ADB are ineligible to participate in ADB financed, administered or supported activities.

Accounting, Auditing and Reporting

18. Notwithstanding the generality of Section 2.09 of the Project Agreement, the Borrower shall ensure or cause the EA to ensure that the audit report for the Project financial statements shall include a management letter, if any, and auditor's opinions, which cover (i) whether the financial statements present an accurate and fair view or are presented fairly, in all material respects, in accordance with the applicable financial reporting standards; (ii) whether the proceeds of each Loan and co-financed loan if any, were used only for the purpose(s) of the Project; and (iii) whether the EA was in compliance with the financial covenants (where applicable) contained in this Loan Agreement. Similar requirements if any from the Co-Financiers shall also be adhered to by the EA on a timely basis.

Project Performance Monitoring and Evaluation

19. The Borrower shall ensure or cause the EA to ensure that within 3 months from the effective date of the Loans, it will develop a Project Performance Monitoring System (PPMS) for the Project. The PPMS will monitor and evaluate the impacts, outcomes, outputs and activities in relation to the targets and milestones set for the Project.

Schedule 4

Project Review

20. ADB, the Borrower and the EA shall meet regularly as required, to discuss the progress of the Project and any changes to implementation arrangements or remedial measures required to be undertaken towards achieving the objectives of the Project. ADB, the Borrower and the EA shall undertake an inception mission soon after the Project is declared effective, and thereafter, regular reviews shall follow at least annually. As necessary, special loan administration missions shall be fielded, under which any changes in scope or implementation arrangements may be required to ensure achievement of the Project objectives shall be addressed.