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LOAN NUMBER 4116-GEO

LOAN AGREEMENT  
(Ordinary Operations)

(COVID-19 Vaccine Support Project under the Asia Pacific Vaccine Access Facility – Rapid  
Response Component)

between

GEORGIA

and

ASIAN DEVELOPMENT BANK

DATED 28 October 2021

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GEO 55195

**LOAN AGREEMENT  
(Ordinary Operations)**

LOAN AGREEMENT dated 28 October 2021 between GEORGIA ("Borrower") and ASIAN DEVELOPMENT BANK ("ADB").

**WHEREAS**

(A) ADB has received from the Borrower a governor's letter dated 11 August 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 a loan for the purposes of the Project described in Schedule 1 to this Loan Agreement;

(C) by a loan agreement of even date herewith between the Borrower and ADB ("ADB Project Investment Component Loan Agreement"), ADB has agreed to make a loan to the Borrower from ADB's ordinary capital resources in an amount of four hundred sixty-four thousand Euro (€464,000) for the purpose of strengthening the capacity of the Project Executing Agency to effectively and efficiently manage the procurement and delivery of the COVID-19 vaccines and the development and conduct of vaccination program management and monitoring; and

(D) ADB has agreed to make a loan to the Borrower from ADB's ordinary capital resources upon the terms and conditions set forth herein;

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 (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.

- (b) 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 quoted 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) "ARMPA" means the Agency for Regulation of Medical and Pharmaceutical Activities of the Borrower;
- (b) "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;
- (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;

- (f) "GAP" means the gender action plan prepared for the Project, including any update thereto, and agreed between the Borrower and ADB;
- (g) "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;
- (h) "Loan Disbursement Handbook" means ADB's Loan Disbursement Handbook (2017, as amended from time to time);
- (i) "MoLHSA" means the Borrower's Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs;
- (j) "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;
- (k) "PAM" means the project administration manual for the Project dated 11 August 2021 and agreed between the Borrower and ADB, as updated from time to time in accordance with the respective administrative procedures of the Borrower and ADB;
- (l) "Procurement Plan" means the procurement plan for the Project dated 11 August 2021 and agreed between the Borrower and ADB, as updated from time to time in accordance with the Procurement Policy, the Procurement Regulations, and other arrangements agreed with ADB;
- (m) "Procurement Policy" means ADB's Procurement Policy – Goods, Works, Nonconsulting and Consulting Services (2017, as amended from time to time);
- (n) "Procurement Regulations" means ADB's Procurement Regulations for ADB Borrowers - Goods, Works, Nonconsulting and Consulting Services (2017, as amended from time to time);
- (o) "Project Executing Agency" for the purposes of, and within the meaning of, the Loan Regulations means MoLHSA or any successor thereto acceptable to ADB, which is responsible for the carrying out of the Project;
- (p) "Services" means Consulting Services and Nonconsulting Services;
- (q) "SPS" means ADB's Safeguard Policy Statement (2009);
- (r) "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

- (s) "Vaccination Allocation Plan" means the National Vaccine Deployment Plan adopted by the Borrower on 21 January 2021 and amended on 8 April 2021, 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 in the territory of the Borrower.

## ARTICLE II

### The Loan

Section 2.01. (a) ADB agrees to lend to the Borrower from ADB's ordinary capital resources an amount of twelve million one hundred seventy-nine thousand Euros (€12,179,000), as 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) The Loan has a principal repayment period of 7 years, and a grace period as defined in subsection (c) hereinafter.

(c) The term "grace period" as used in subsection (b) hereinabove means the period prior to the first Principal Payment Date in accordance with the amortization schedule set forth in Schedule 2 to this Loan Agreement.

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

(a) EURIBOR; and

(b) 0.60% as provided 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. Such charge shall accrue on the full amount of the Loan (less amounts withdrawn from time to time), commencing 60 days after the date of this Loan Agreement.

Section 2.04. Interest and other charges on the Loan shall be payable semiannually on 15 February and 15 August in each year.

Section 2.05. The Borrower shall repay the principal amount of the Loan withdrawn from the 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 in order to facilitate prudent debt management:

- (i) a change of the Loan Currency of all or any portion of the principal amount of the Loan, 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 withdrawn and outstanding 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 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 subsection (a) hereinabove that is accepted by ADB shall be considered a "Conversion", as defined in Section 2.01(f) 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 cause the proceeds of the Loan to be applied exclusively to the financing of Eligible Expenditures on the Project in accordance with the provisions of this Loan 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 procure, or cause to be procured, the items of Eligible Expenditures to be financed out of the proceeds of the Loan 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 31 October 2023 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, the Borrower shall perform, or cause to be performed, all obligations set forth in Schedule 4 to this Loan Agreement.

Section 4.02. (a) The Borrower shall, through the Project Executing Agency, (i) maintain separate accounts and records for the Project; (ii) prepare annual financial statements for the Project in accordance with financial reporting standards acceptable to ADB; (iii) have such financial statements audited annually by independent auditors whose qualifications, experience and terms of reference are acceptable to ADB, in accordance with auditing standards acceptable to ADB; (iv) as part of each such audit, have the auditors prepare a report, which includes the auditors' opinion(s) on the financial statements and the use of the Loan proceeds, and a management letter (which sets out the deficiencies in the internal control of the Project that were identified in the course of the audit, if any); and (v) furnish to ADB, no later than 6 months after the end of each related fiscal year, copies of such audited financial statements, audit report and management letter, all in the English language, and such other information concerning these documents and the audit thereof as ADB shall from time to time reasonably request.

(b) 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.

(c) The Borrower shall, through the Project Executing Agency, enable ADB, upon ADB's request, to discuss the financial statements for the Project and the Borrower's financial affairs where they relate to the Project with the auditors appointed pursuant to subsection (a)(iii) hereinabove, and shall authorize and require any representative of such auditors to participate in any such discussions requested by ADB. This is provided that such discussions shall be conducted only in the presence of an authorized officer of the Borrower, unless the Borrower shall otherwise agree.

Section 4.03. The Borrower shall, through the Project Executing Agency, enable ADB's representatives to inspect the Project, the Goods and Services, and any relevant records and documents.

## **ARTICLE V**

### **Effectiveness**

Section 5.01. The following are specified as additional conditions to the effectiveness of this Loan Agreement for the purposes of Section 10.01(f) of the Loan Regulations: the ADB Project Investment Component Loan Agreement shall have been duly executed and delivered on behalf of the Borrower, and all conditions precedent to its effectiveness (other than a condition requiring the effectiveness of this Loan Agreement) shall have been fulfilled.

Section 5.02. 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 Minister 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**

Ministry of Finance  
16 V. Gorgasali Street, 0114  
Tbilisi, Georgia

Email: publicdebt@mof.ge

**For ADB**

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

Facsimile Numbers:

(632) 8636-2444  
(632) 8636-2338.

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.

GEORGIA

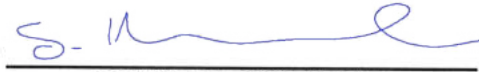
By



LASHA KHUTSISHVILI  
Minister of Finance

ASIAN DEVELOPMENT BANK

By



SHANE J. ROSENTHAL  
Country Director  
Georgia Resident Mission

## **SCHEDULE 1**

### **Description of the Project**

1. The objective of the Project is: to vaccinate target populations against COVID-19. The Project is described in more detail in the Governor's Letter.
2. The Project shall comprise procurement of: (a) vaccines that meet the Eligibility Criteria; (b) safety boxes, syringes, and other items required for the administration of the vaccines; and (c) international and national logistics and related services required for the transportation of vaccines from the place of purchase to designated delivery points in Georgia.
3. The Project is expected to be completed by 30 April 2023.

## SCHEDULE 2

### Amortization Schedule

1. The following table sets forth the Principal Payment Dates of the Loan and the percentage of the total principal amount of the Loan payable on each Principal Payment Date (Installment Share). If the proceeds of the Loan shall have been fully withdrawn as of the first Principal Payment Date, the principal amount of the Loan repayable by the Borrower on each Principal Payment Date shall be determined by ADB by multiplying (a) the total principal amount of the Loan 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.

<u>Payment Due</u>	<u>Installment Share</u> (Expressed as a %)
15 February 2025	7.142857
15 August 2025	7.142857
15 February 2026	7.142857
15 August 2026	7.142857
15 February 2027	7.142857
15 August 2027	7.142857
15 February 2028	7.142857
15 August 2028	7.142857
15 February 2029	7.142857
15 August 2029	7.142857
15 February 2030	7.142857
15 August 2030	7.142857
15 February 2031	7.142857
15 August 2031	7.142859
<b>Total</b>	<b>100.000000</b>

2. If the proceeds of the Loan shall not have been fully withdrawn as of the first Principal Payment Date, the principal amount of the Loan repayable by the Borrower on each Principal Payment Date shall be determined as follows:

- (a) to the extent that any proceeds of the Loan 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 the Loan 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.

5. If the principal amount of the Loan 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.

**SCHEDULE 3****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 the Loan and the allocation of the Loan 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

2. Except as ADB may otherwise agree, the proceeds of the Loan 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.

3. 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 Loan Account.

Interest and Commitment Charges

4. The amount allocated to Category "Interest and Commitment Charges" is for financing interest and commitment charges on the Loan during the implementation period of the Project. ADB shall be entitled to withdraw from the Loan Account and pay to itself, on behalf of the Borrower, the amounts required to meet payments, when due, of such interest and commitment charges.

Reallocation

5. Notwithstanding the allocation of Loan proceeds and the withdrawal percentages set forth in the Table,

- (a) if the amount of the Loan allocated to any Category appears to be insufficient to finance all agreed expenditures in that Category, ADB may, by notice to the Borrower, (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 the Borrower, reallocate such excess amount to any other Category.

Disbursement Procedures

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

Advance Financing and Retroactive Financing

7. Withdrawals from the Loan Account may be made for advance financing for up to 6 months of estimated Eligible Expenditures or 50% of the total Loan amount, whichever is lower, in accordance with the advance fund procedures described in the Loan Disbursement Handbook.

8. Withdrawals from the Loan Account 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 declaration of the COVID-19 emergency, but not earlier than 12 months before the date of this Loan Agreement.

9. The aggregate of the outstanding balance of the advance financing amount and the percentage approved for retroactive financing shall not, at any time, exceed 60% of the Loan amount.

Condition for Withdrawals from Loan Account

10. Notwithstanding any other provision of this Loan Agreement, no withdrawals shall be made from the Loan Account for financing Eligible Vaccines until:

- (a) ADB has received a letter from the Project Executing Agency, on behalf of 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 Drug Regulatory Authority of Georgia 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 the COVID-19 vaccine(s) to be procured are designated as Eligible Vaccines.

TABLE

ALLOCATION AND WITHDRAWAL OF LOAN PROCEEDS			
Number	Item	Total Amount Allocated for ADB Financing €	Basis for Withdrawal from the Loan Account
		Category	
1	Eligible Vaccines (Goods and Services)**	10,775,000	100% of total expenditure claimed*
2	Interest and Commitment Charges	205,000	100% of amounts due
3	Unallocated	1,199,000	
	<b>TOTAL</b>	<b>12,179,000</b>	

\* Exclusive of taxes and duties imposed within the territory of the Borrower.

\*\* Subject to the condition for withdrawal described in paragraph 10 of Schedule 3.

## SCHEDULE 4

### Execution of Project; Financial Matters

#### Implementation Arrangements

1. The Borrower shall ensure, or cause the Project Executing Agency 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 and ADB. In the event of any discrepancy between the PAM and this Loan Agreement, the provisions of this Loan Agreement shall prevail.

#### Procurement

2. The Borrower shall ensure, or cause the Project Executing Agency, to ensure that:

- (a) 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;
- (c) 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.

#### Safeguards

3. The Borrower shall ensure, or cause the Project Executing Agency 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 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

4. The Borrower shall ensure, or cause the Project Executing Agency to ensure, that no proceeds of the Loan 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

5. The Borrower:

- (a) represents 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 Project Executing Agency to ensure, that Loan 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 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 Project Executing Agency to ensure, that the deployment, distribution and administration of Eligible Vaccines are implemented in accordance with the Vaccination Allocation Plan; and
- (e) shall (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.

6. 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 the Loan Account for any Eligible Vaccine, the Borrower shall ensure, or cause the Project Executing Agency to ensure, that no withdrawal request is made from the Loan Account in relation to such vaccine until:

- (a) ADB has received a letter from the Project Executing Agency, on behalf of 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 ARMPA 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

7. The Borrower shall ensure, or cause the Project Executing Agency 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.

8. The Borrower, through the Project Executing Agency, ARMPA, and any other relevant regulatory authorities, shall 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 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

9. The Borrower shall ensure, or cause the Project Executing Agency 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 Vaccination Allocation Plan and the Borrower's regulations on medical waste management.

#### Limitation of Liability

10. The Borrower acknowledges and agrees 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.

#### Financial Management

11. The Borrower shall ensure, or cause the Project Executing Agency to ensure, that the financial management action plan, which sets out specific time-bound actions, as summarized in the PAM, is implemented in accordance with its terms.

#### Gender and Development

12. The Borrower shall ensure, or cause the Project Executing Agency to ensure, that (a) the GAP 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 GAP; (c) adequate resources are allocated for implementation of the GAP; and (d) progress on implementation of the GAP, including progress toward achieving key gender outcome and output targets, are regularly monitored and reported to ADB.

#### Counterpart Support

13. The Borrower shall ensure that the Project Executing Agency has sufficient funds to promptly satisfy its liabilities arising from any Goods and/or Services contract.

#### Governance and Anticorruption

14. The Borrower and the Project Executing Agency shall (a) comply with ADB's Anticorruption Policy (1998, as amended to date) and 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 (b) cooperate with any such investigation and extend all necessary assistance for satisfactory completion of such investigation.

15. The Borrower and the Project Executing Agency shall ensure that the anticorruption provisions acceptable to ADB are included in all bidding documents and contracts, including provisions specifying the right of ADB to audit and examine the records and accounts of the executing and implementing agencies and all contractors, suppliers, consultants, and other service providers as they relate to the Project. Firms or individuals who are debarred or temporarily suspended by ADB are ineligible to participate in ADB financed, administered or supported activities.