

08-Jun-2021

H.E. Lasha Khutsishvili
Minister of Finance
Ministry of Finance
16 Gorgasali Street
Tbilisi, Georgia

Re: GEORGIA; Loan No. 9113-GE
(Emergency COVID-19 Response Project)
Amendment No. 1 to the Loan Agreement

Dear Minister,

We refer to the Loan Agreement (“Loan Agreement”) for the above-referenced Loan between Georgia (“Borrower”) and the International Bank for Reconstruction and Development (“Bank”) for the Emergency COVID-19 Response Project (“Project”), dated May 1, 2020. We also refer to the negotiations related to, and agreed Minutes of Negotiations for the additional financing for the above project between the Borrower and the Bank, dated May 21, 2021, wherein the Bank and Georgia representatives discussed and agreed on the planned amendment of the Loan Agreement to bring it up to date and make it consistent with the additional financing Loan Agreement (“Additional Financing Loan Agreement”).

Based on these discussions, we propose to amend the Loan Agreement as follows (please note that the capitalized terms used in this letter (“Amendment Letter”) and not defined herein have the meaning ascribed to them in the Loan Agreement and the Additional Financing Loan Agreement).

1. The following new sub-parts are added to **Part 1 of Schedule 1** (Emergency COVID-19 Response):

“(c) supporting Georgia’s health sector in the acquisition and deployment of Project COVID-19 Vaccines;

(d) strengthening Georgia’s institutional framework to enable safe and effective vaccine deployment, including development of: (i) national policies surrounding prioritization of vaccine allocation; (ii) regulatory standards for vaccination; (iii) standards and protocols surrounding cold chain, supplies, storage, logistics, and training; and (iv) accountability, grievance, citizen and community engagement mechanisms; and

(e) supporting the development of Georgia’s vaccine-related infrastructure, immunization systems, and service delivery capacity, including, *inter alia*, cold chain facilities, vehicles and logistics infrastructure, assessment of vaccine management capacity and training of delivery workers.”

2. **Paragraph 1 of Section I.A of Schedule 2** is amended to read as follows:

“1. The Borrower shall vest responsibility for carrying out the overall Project with MoILHSA, with information and support from the Revenue Service, State Procurement Agency, *National Center for Disease Control and the Public Health, and the Interagency Coordination Commission.*”

3. **Paragraph 3 of Section I.B of Schedule 2** is amended to read as follows:

“3. The Borrower, *through MoILHSA* shall carry out the Project in accordance with this Agreement, the Project Operations Manual, the Global Budget and Reimbursements Manual, and *the Vaccine Delivery and Distribution Manual*. Except as the Bank shall otherwise agree, the Borrower shall not assign, amend, abrogate, or waive the provisions of the Project Operations Manual or the Global Budget and Reimbursements Manual without prior approval of the Bank. In the event of any conflict between the provisions of the Project Operations Manual or Global Budget and Reimbursements Manual *or the Vaccine Delivery and Distribution Manual* and this Agreement, the provisions of this Agreement shall prevail.”

4. **Paragraph 2(a) of Section I.D of Schedule 2** is amended to read as follows:

“2. Without limitation upon paragraph 1 above, the Borrower shall ensure that the Project is implemented in accordance with the Environmental and Social Commitment Plan (“ESCP”), in a manner acceptable to the Bank. To this end, the Borrower shall ensure that:

(a) the measures and actions specified in the ESCP are implemented with due diligence and efficiency, *as provided in the ESCP;*”

5. **A new Section I.E is added to Schedule 2** to read as follows:

“E. Standards for COVID-19 Vaccine Approval

1. All Project COVID-19 Vaccines shall satisfy the Vaccine Approval Criteria.”

6. **Paragraph 2 of Section III.B of Schedule 2** is deleted in its entirety and replaced with the following:

“The Closing Date is April 30, 2023.”

7. The following new Sections are added to the Appendix. The remaining sections are renumbered accordingly.

““Interagency Coordination Commission” means the commission established by the Government Resolution N2459 “On Establishment of an Interagency Coordination Commission for the Implementation COVID-19 Vaccination in Georgia”, dated December 15, 2020, or any successor thereto.

“National Center for Disease Control and Public Health” means the Legal Entity of Public Law National Center for Disease Control and Public Health established by the Law of Georgia on the Legal Entity of the Public Law and Resolution No. 122 of the Government of Georgia of February 6, 2014, or any successor thereto.

“Project COVID-19 Vaccine” means a vaccine for the prevention of COVID-19, authorized by the Borrower’s national regulatory authority for distribution, marketing, and administration within the

territory of the Borrower, and purchased, acquired or deployed under the Project; “Project COVID-19 Vaccines” means the plural thereof.

“Project Implementing Unit” or “PIU” means the unit established within MoILHSA and referred to in Section I.A (1) of Schedule 2 to this Agreement and Section I.A (2) of Schedule 2 to the Original Loan Agreement.

“Project Operations Manual” means the manual acceptable to the Bank, referred to in Section I.B.1 to Schedule 2 of the Original Loan Agreement, and Section I.B.1 to Schedule 2 of this Agreement, containing: detailed guidelines and procedures for the implementation of the Project, including with respect to: administration and coordination, monitoring and evaluation, financial management, procurement and accounting procedures, environmental and social safeguards, anti-corruption and fraud mitigation measures, a grievance redress mechanism, provisions on Personal Data collection and processing in accordance with Law of Georgia on Personal Data Protection and good international practice, roles and responsibilities for Project implementation, including the specific roles and responsibilities of the agencies and units involved in Project implementation, and such other arrangements and procedures as shall be required for the effective implementation of the Project, in form and substance satisfactory to the Bank.

“Stringent Regulatory Authority” means a National Regulatory Authority (“NRA”) that is classified by WHO as a Stringent Regulatory Authority.

“Vaccine Approval Criteria” means that the Project COVID-19 Vaccine: (a) has received regular or emergency licensure or authorization from at least one of the Stringent Regulatory Authorities identified by WHO for vaccines procured and/or supplied under the COVAX Facility, as may be amended from time to time by WHO; (b) has received the WHO Prequalification or WHO Emergency Use Listing; or (c) has met such other criteria as may be agreed in writing between the Borrower and the Bank.

“Vaccine Delivery and Distribution Manual” means the Borrower’s manual which forms a part of the Project Operations Manual, referred to in Article 4.01 to this Agreement, as the same may be amended from time to time with the Bank’s prior written approval, and which includes the following:

- (a) rules and procedures for prioritizing intra-country vaccine allocation following principles established in the WHO Fair Allocation Framework, including an action plan setting out the timeline and steps for implementing such rules;
- (b) rules and procedures establishing minimum standards for vaccine management and monitoring, including medical and technical criteria, communications and outreach plan, cold chain infrastructure, and other related logistics infrastructure;
- (c) rules and procedures for processing and collection of Personal Data in accordance with Law of Georgia on Personal Data Protection and good international practice; and
- (d) vaccine distribution plan, including action plan setting out timeline and steps for immunization.

“WHO” means the World Health Organization.

“WHO Emergency Use Listing” means a risk-based procedure for assessing and listing by WHO of unlicensed vaccines, therapeutics, and in vitro diagnostics with the aim of expediting the availability of these products to people affected by a declared public health emergency.

“WHO Fair Allocation Framework” means the rules which govern the allocation of vaccines to participants in the COVAX Facility, as developed by WHO, subject to periodic review by the COVAX Facility.

“WHO Prequalification” means a service provided by WHO to assess the quality, safety, and efficacy of medical products for priority diseases, and which are intended for United Nations and international procurement to developing countries.””

Except as specifically amended in this Amendment Letter, all other provisions of the Loan Agreement remain in full force and effect. Please confirm your agreement to the amendments set out above by countersigning this Amendment Letter. This Amendment Letter shall become effective upon: (i) receipt by the Bank of the countersigned and validated copy of this Amendment Letter through DocuSign; (ii) receipt by the Bank of the Borrower’s confirmation of completion of ratification procedures under the laws of Georgia and confirmation that no other internal steps under the laws of Georgia are pending; and (iii) notification by the Bank of the effectiveness of this Amendment Letter.

Very truly yours,

INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT



Sebastian Molineus
Regional Director for the South Caucasus

AGREED:

GEORGIA

By:  _____

Name: Lasha Khutsishvili

Title: Minister

Date: 09-Jun-2021