GRANT NUMBER E229-ET

Financing Agreement

(Health Emergency Preparedness, Response and Resilience Program Using the Multiphase Programmatic Approach)

between

FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA

and

INTERNATIONAL DEVELOPMENT ASSOCIATION

GRANT NUMBER E229-ET

FINANCING AGREEMENT

AGREEMENT dated as of the Signature Date between FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA ("Recipient") and INTERNATIONAL DEVELOPMENT ASSOCIATION ("Association").

WHEREAS:

- A. The Participating Countries, including the Recipient, and the Regional Bodies have agreed to participate in the MPA Program;
- B. The Recipient, having satisfied itself as to the feasibility and priority of the Project, has requested the Association to assist in the financing of the project described in Schedule 1 to this Agreement ("Project");
- C. By a financing agreement to be entered into on or about the date hereof between the Republic of Kenya and the Association (the "Kenya Financing Agreement"), the Association will extend to the Republic of Kenya financing to assist the Republic of Kenya in financing part of the cost of activities related to the MPA Program on the terms and conditions set forth in the Kenya Financing Agreement;
- D. By a financing agreement to be entered into on or about the date hereof between the Democratic Republic of Sao Tome and Principe and the Association (the "STP Financing Agreement"), the Association will extend to the Democratic Republic of Sao Tome and Principe financing to assist the Democratic Republic of Sao Tome and Principe in financing part of the cost of activities related to the MPA Program on the terms and conditions set forth in the STP Financing Agreement;
- E. By a financing agreement to be entered into on or about the date hereof between the East, Central and Southern Africa-Health Community ("ECSA-HC") and the Association (the "ECSA-HC Financing Agreement"), the Association will extend to ECSA-HC financing to assist ECSA-HC in financing part of the cost of activities related to the MPA Program on the terms and conditions set forth in the ECSA-HC Financing Agreement;
- F. By a financing agreement to be entered into on or about the date hereof between the Intergovernmental Authority on Development (IGAD) and the Association (the "IGAD Financing Agreement"), the Association will extend to IGAD financing to assist IGAD in financing part of the cost of activities related to the MPA Program on the terms and conditions set forth in the IGAD Financing Agreement; and

WHEREAS the Association has also agreed, on the basis, *inter alia*, of the foregoing, to extend the financing provided for in Article II of this Agreement to the Recipient upon the terms and conditions set forth in this Agreement.

NOW THEREFORE the Association and the Recipient hereby agree as follows:

ARTICLE I — GENERAL CONDITIONS; DEFINITIONS

- 1.01. The General Conditions (as defined in the Appendix to this Agreement) apply to and form part of this Agreement.
- 1.02. Unless the context requires otherwise, the capitalized terms used in this Agreement have the meanings ascribed to them in the General Conditions or in the Appendix to this Agreement.

ARTICLE II — FINANCING

- 2.01. The Association agrees to extend to the Recipient a grant, which is deemed as Concessional Financing for purposes of the General Conditions, in an amount equivalent to one hundred and forty-five million three hundred thousand Special Drawing Rights (SDR 145,300,000) ("Financing"), to assist in financing the Project.
- 2.02. The Recipient may withdraw the proceeds of the Financing in accordance with Section III of Schedule 2 to this Agreement.
- 2.03. The Maximum Commitment Charge Rate is one-half of one percent (1/2 of 1%) per annum on the Unwithdrawn Financing Balance.
- 2.04. The Payment Dates are March 1 and September 1 in each year.
- 2.05. The Payment Currency is Dollar.

ARTICLE III — PROJECT

3.01. The Recipient declares its commitment to the objective of the Project and the MPA Program. To this end, the Recipient shall carry out the Project in accordance with the provisions of Article V of the General Conditions and Schedule 2 to this Agreement.

ARTICLE IV — EFFECTIVENESS; TERMINATION

4.01. The Additional Condition of Effectiveness consists of the following, namely, that the Recipient has adopted the Project Operations Manual in form and substance satisfactory to the Association.

- 4.02. The Effectiveness Deadline is the date ninety (90) days after the Signature Date.
- 4.03. For purposes of Section 10.05(b) of the General Conditions, the date on which the obligations of the Recipient under this Agreement (other than those providing for payment obligations) shall terminate is twenty (20) years after the Signature Date.

ARTICLE V — REPRESENTATIVE; ADDRESSES

- 5.01. The Recipient's Representative is its minister responsible for finance.
- 5.02. For purposes of Section 11.01 of the General Conditions:
 - (a) the Recipient's address is:

Ministry of Finance P. O. Box 1905 Addis Ababa Federal Democratic Republic of Ethiopia; and

(b) the Recipient's Electronic Address is:

Cable: Telex: Facsimile:

MINFIN 21147 (251-111) 551355

- 5.03. For purposes of Section 11.01 of the General Conditions:
 - (a) the Association's address is:

International Development Association 1818 H Street, N.W. Washington, D.C. 20433 United States of America; and

(b) the Association's Electronic Address is:

Telex: Facsimile:

248423 (MCI) 1-202-477-6391

AGREED as of the Signature Date.

FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA

By		Amp		
		Authorized Representative		
	Name:	HE Ato Ahmed Shide		
	Title:	Minister of Finance Ethiopia		
	Date:	12-Dec-2023		
INTERNATIO	NAL DEVELOR	PMENT ASSOCIATION		
Ву		Bouthuina Gurmazi		
		Authorized Representative		
	Name:	Boutheina Guermazi		
	Title:	Director, Regional Integration		
	Dotos	26-oct-2023		

SCHEDULE 1

Project Description

The objective of the Project is to strengthen health system resilience and multisectoral preparedness and response to Health Emergencies in Ethiopia.

The Project constitutes a phase of the MPA Program and consists of the following parts:

Part 1: Strengthening the Preparedness and Resilience of the Health System to manage Health Emergencies (HEs)

- 1.1. Supporting multisectoral and cross-border planning, financing, and governance for improved resilience to HEs by: (a) establishing a national One Health council to serve as a mechanism for collaboration among the relevant ministries and create accountability and political commitment; (b) in close collaboration with IGAD, strengthening framework of agreement between neighboring countries to enhance cross border collaboration and coordination mechanisms including human and animal health; (c) updating the national multisectoral strategic action plan for IHR, the health emergency preparedness plan, and as needed the national action plan for health security, with a focus on gender gaps; (d) developing a national multisectoral sexual exploitation, abuse and harassment action plan that includes activities to support gender-based violence prevention, access to services and referral process; (e) technical assistance for establishing a public health emergency response contingency and equity fund with matching funds from government, private sector, and other partners; (f) strengthening IPC initiatives that ensure appropriate guidance and measures at health facilities to better address the AMR burden.; and (g) providing technical assistance to strengthen the implementation of formal coordination and communication mechanisms between the human health/public health, animal health, and environmental health sectors at national and intermediate levels and to cross-border entities where appropriate, for multisectoral response to zoonotic events including clear definition of sectorspecific roles, responsibilities, and procedures with a One Health focus.
- 1.2. Supporting health workforce skill development by: (a) strengthening the undergraduate and post-graduate health workforce training curricula through mainstreaming concepts of HEs; (b) training of additional field epidemiologists, genomics, data scientists, and health informatics, and laboratory professionals, with a focus on gender equity in training as feasible; (c) establishing multidisciplinary surge teams at national, regional, district level and cross border areas with a clear training curriculum, standard operating procedures, reporting and accountability framework and equipped with necessary tools, backup rosters, a clear activation procedure and accredited to be deployed at national and regional level; (d) introducing and scaling up a national electronic health human resource

information management system; and (e) training of health and public health workers and administrators on climate and HE preparedness and response at national, decentralized, and community levels.

- 1.3. Supporting access to quality health commodities, including building capacity for local vaccine and pharmaceutical manufacturing through:
 - (a) technical assistance to conduct an in-depth legal analysis of relevant national laws and other applicable rules on: (i) manufacturing, storage, distribution, and products liability for human vaccines and pharmaceutical products; (ii) ownership, control, and autonomy of institutions responsible for manufacturing of human vaccines and pharmaceuticals, specifically, to determine the adequacy of the technical, legal and regulatory framework and its consistency with the good international practice; and identify any gaps, and recommend gap-filling measure, if any;
 - (b) technical assistance to strengthen the Ethiopian Food and Drug Authority's (EFDA) regulatory capacity to achieve Maturity Level 3 and associated improvements in the legal and/or regulatory ecosystem for pharmaceutical and vaccine production, risk management, and human resource development, including through benchmarking with other countries:
 - (c) strengthening national human resource capacity and learning through exchange programs, training of researchers including *inter alia* researchers of Armauer Hansen Research Institute (AHRI) in advanced clinical trials and commercialization of biomedical research, as well as in bulk antigen production, development of diagnostics, and production, specifically on molecular base assay and antigen/antibody base assay development;
 - (d) technical assistance to improve the enabling environment for local vaccine and pharmaceutical production, including the development of policies and action plans to incentivize private pharmaceutical investors and encourage participation of private companies along the entire pharmaceutical value chain; and
 - (e) subject to concluding Part 1.3(a) in form and substance satisfactory to the Association: technical assistance and capacity building through the Biopharma Project Management Unit (Biopharma PMU) for the establishment of a biopharma group and the development of a five-year roadmap, plans of action and strategy to guide the functioning of such biopharma group as an institution and lead the implementation of local vaccine and pharmaceutical production.

1.4. Supporting information systems for HEs and the digitalization of the health sector by: (a) establishing integrated and interoperable health information systems to monitor human and animal health risks, public health events, environmental emergencies, and their impacts on health systems and services, disaggregated by gender and other measures of vulnerability; (b) developing climate-informed health early warning systems vulnerability capacity and adaptation for projected climate shocks and associated hazards at community level; (c) integrated with DHIS-2 Platform, establishing district-based health risk registries and profiles and updating them on an annual basis; (d) establishing digitalized facility service availability and readiness of real-time monitoring systems to monitor the disruptions to essential health services through upgrading the existing master facility registry system; (e) improving the quality, reliability of data and geographic coverage of existing digital health information platforms; (f) integration of meteorological data with routine gender-disaggregated health data to better understand the relationship between health conditions and climactic conditions, identify high-risk populations, and assess climate shocks; and (g) exploring the role of digital health solutions and supporting the implementation of proven digital health solutions that improve health systems resilience and efficiency in service delivery.

Part 2: Improving early detection of and response to HEs through a multisectoral approach at national and sub-national levels

- 2.1. Supporting collaborative surveillance and laboratory diagnostics by: (a) establishing and improving integrated surveillance, including indicator-based, event-based, genomic, syndromic, and multisectoral threat and vulnerability surveillance; (b) ensuring timely verification, investigation, and risk assessment of alerts (feeding from the early warning and alert systems); (c) expanding laboratory and testing capacity for human, animal and environmental health threats, including rehabilitation of laboratories, international accreditation for institutions (as appropriate), adherence to quality standards, provision of reagents and commodities, and information management; (d) strengthening the capacity of selected points of entry for screening, isolation, and quarantine as well as expanding the capacities of existing centers to integrate the One Health approach; (e) ensuring laboratory quality assurance through the development of national quality standards at national and sub-national levels; (f) establishing interconnected multidisciplinary teams to advance research on analytical and modelling tools; (g) in collaboration with the Regional Bodies, developing frameworks for multisectoral and cross border data and public health asset sharing; and (h) reviewing the implementation of Ethiopian Public Health Institute's (EPHI) climate sensitive disease surveillance and early warning systems and support/scale-up the establishment sentinel sites at cross border areas.
- 2.2. Supporting emergency management, coordination, and essential service continuity by: (a) developing and institutionalizing multisectoral national simulation

exercises that test the health system's resilience to respond to HEs regularly and at all levels; (b) implementing and updating threat and vulnerability mapping and risk identification, with attention to reaching the most vulnerable, especially by gender; (c) revising the essential health service package and medicines and equipment list to include supplies needed to deal with HEs; (d) developing capacity to quickly reorganize and utilize alternative service-delivery platforms to prevent service disruption during emergencies; (e) assessing and expanding the capacity of the national emergency operating centers to be fit for non-traditional health sector related emergencies; and (f) conducting non-communicable disease risk factor assessments using WHO's STEPS Approach and providing training for community health extension workers to integrate non-communicable disease prevention activities to the routine community level essential health services packages.

2.3. Supporting risk communication and community engagement, empowerment, and social protection during HEs, with a focus on equitable reach to all populations, especially across gender dimensions by: (a) establishing platforms for proactive, appropriately audience-segmented risk communication to populations during HEs, including 'infoveillance" and "infodemic" management, two-way community engagement for empowering communities in the development of messaging and decision making during HEs, and proactive grievance redress to prevent mis/disinformation; (b) developing appropriate risk communication to reach women, girls, men and boys across gender divides in access to electronic, visual, and print media; (c) enhancing communities' readiness for and resilience to HEs and shocks through WASH infrastructure investments at community level; (d) technical assistance for the implementation of safety net programs to ensure continued access to health services for the most vulnerable groups on an ongoing basis and during HEs; (e) ensuring active participation and leadership of women's community groups and leaders in community engagement and readiness planning activities; and (f) developing mechanisms for engaging community health workers in climate emergency preparedness and response, including trainings, and designated roles and responsibilities.

Part 3: Project Management

- 3.1. Supporting monitoring and evaluation, including: (a) regular progressive review of the implementation of Project activities in conflict affected areas and security constrained areas; and (b) conducting national and regional Project implementation review based on the Project indicators.
- 3.2. Supporting the learning agenda through: (a) in collaboration with the Regional Bodies, establishment of national and cross-border learning platforms to exchange knowledge and experiences, facilitate peer coaching, and evidence generation including evidence on gender in PPR; and (b) engagement with academic institutions, civil society and think-tank groups to develop a research priority list

- and generating evidence on health threats including prioritized zoonotic diseases and other diseases at the animal-human-environment interface.
- 3.3. Supporting Project management through: (a) establishment of the Biopharma PMU including the development of terms of reference, recruitment of staff and developing work plans in accordance with section I.A.2 of Schedule 2 to this Agreement; and (b) supporting procurement, financial management, environmental and social aspects, monitoring and evaluation, and reporting under the Project through the provision of technical advisory services, training, operating costs, and acquisition of goods.

Part 4: Contingent Emergency Response

Provision of immediate response to an Eligible Crisis or Emergency, as needed.

SCHEDULE 2

Project Execution

Section I. Implementation Arrangements

A. Institutional Arrangements.

- 1. Grants Management Unit within the Ministry of Health
 - (a) The Recipient shall: (i) maintain, at all times during the implementation of the Project, the Grants Management Unit within the Ministry of Health, with composition, powers, functions, staffing, facilities and other resources satisfactory to the Association as further described in the Project Operations Manual; and (ii) designate the Grants Management Unit to be responsible for day-to-day management and implementation of the Project, including *inter alia*, preparation of work plans, environmental and social management, financial management, procurement, monitoring and evaluation, and reporting.
 - (b) Without limitation upon paragraph (a) above, the Recipient shall: (i) by no later than three (3) months after the Effective Date, recruit, assign, or appoint and thereafter maintain throughout Project implementation for the Grants Management Unit, *inter alia*: an accountant a procurement specialist, a contract administration officer; and (ii) recruit, assign or appoint any other staff needed to assist in the Project implementation and coordination including in accordance with the ESCP and the Project Operations Manual; all with terms of reference, qualifications and experience satisfactory to the Association.
 - (c) The Grants Management Unit shall closely coordinate and collaborate with other relevant ministries, departments and agencies and other institutions (MDAs) as further described in the Project Operations Manual, specifically: EPHI, EFDA, Ethiopia Pharmaceutical Supply Services (EPSS), Regional Health Bureaus and Zonal Health Offices, and Armauer Hansen Research Institute (AHRI); all of which shall be maintained throughout Project implementation with composition, powers, functions, staffing, facilities and other resources satisfactory to the Association including in accordance with the ESCP and the POM.

2. Biopharma Project Management Unit for Part 1.3 (e)

(a) For the purposes of carrying out Part 1.3(e), the Recipient shall establish a Biopharma Project Management Unit (Biopharma PMU) within the Ministry of Health with composition, powers, functions, staffing, facilities

and other resources satisfactory to the Association as further described in the Project Operations Manual. The Biopharma PMU shall be responsible for technical coordination of the activities under Part. 1.3(e) of the Project. The Biopharma PMU shall report to the office of the Minister and shall coordinate with the Grants Management Unit.

(b) Notwithstanding paragraph (a) above, the Recipient shall: (a) recruit or appoint, and thereafter maintain throughout Project implementation in the Biopharma PMU: (i) a senior Project coordinator, (ii) a good manufacturing practice (GMP) specialist, (iii) a senior industrial pharmacist, (iv) a regulatory affairs expert, and (v) a Project monitoring and evaluation specialist; all with terms of reference, qualifications and experience satisfactory to the Association; and (b) develop a work plan for the Biopharma PMU in form and substance satisfactory to the Association.

3. Regional Advisory Committee

The Recipient shall designate at all times during Project implementation a representative(s) to participate in the Regional Advisory Committee, under terms of reference and with qualified and experienced members in adequate number, all satisfactory to the Association and as further set out in the Project Operations Manual.

B. Project Operations Manual

1. The Recipient shall prepare and adopt an implementation manual acceptable to the Association ("Project Operations Manual" or "POM"), which shall contain detailed work flow, methods and procedures for the implementation of the Project, including but not limited to: (i) administration and coordination arrangements, including placement of necessary human resources for Project implementation; (ii) performance indicators of the Project; (iii) procurement arrangements including a manual to guide procurement; (iv) disbursement arrangements, reporting requirements, financial management procedures and audit procedures (v) monitoring and evaluation; (vi) composition, roles and responsibilities of the Biopharma PMU; (vii) corruption and fraud prevention measures; (viii) roles and responsibilities of the Grants Management Unit and MDAs in the implementation of the Project; (ix) Personal Data collection and processing requirements in accordance with applicable national law and good international practice; (x) environmental and social framework aspects, including a detailed description of the grievance redress mechanism process as well as any process for recording and reporting project-related accidents and incidents; (xi) details on the composition and working arrangements of the RAC; and (xii) such other arrangements and procedures as shall be required for the effective implementation of the Project.

- 2. The Recipient shall exchange views with the Association on the POM prior to its adoption, and thereafter ensure that the Project is carried out in accordance with the POM.
- 3. The Recipient shall ensure that the Project is carried out in accordance with the POM; provided, however, that in case of any conflict between the provisions of the POM and the provisions of this Agreement, the provisions of this Agreement shall prevail. Except as the Association shall otherwise agree, the Recipient shall not amend, abrogate or waive any provision of the POM.

C. Annual Work Plan and Budget

- 1. The Recipient shall not later than forty five (45) days after the Effective Date for the Fiscal Year in which this Agreement shall become effective, and not later than March 31st of each subsequent Fiscal Year, prepare and furnish to the Association for the Association's no objection, a draft consolidated annual program of activities proposed for implementation under the Project during the following Fiscal Year, together with a proposed budget which shall include the funds from the Financing for the implementation of the Project.
- 2. Without limitation to the provision of Section I.C.1 of this Schedule, each annual work plan and budget prepared under Section I.C.1 of this Schedule shall set forth:

 (i) a detailed description of the planned activities, including any proposed conferences and Training, under the Project for the period covered by the plan;

 (ii) the sources and proposed use of funds therefore; (iii) procurement and environmental and social management arrangements therefor, as applicable; and (iv) responsibility for the execution of said Project activities, budgets, start and completion dates, outputs and monitoring indicators to track progress of each activity.
- 3. The Recipient shall ensure that in preparing any training plan proposed for inclusion in an annual work plan and budget it shall identify in the training plan: (i) the objective and content of the Training envisaged; (ii) the selection method of the institutions or individuals conducting such Training, and said institutions if already known; (iii) the expected duration and an estimate of the cost of said Training; and (iv) the selection method of the personnel who will attend the Training, and number and names of such personnel if already known.
- 4. The Recipient shall exchange views with the Association on each such proposed consolidated annual work plan and budget and take into account any comments which the Association may have, before approval of the final annual work plan and budget not later than one (1) month after the date referred to in Section I.C.1 of this Schedule (once approved by the Association and finalized, an "Annual Work Plan and Budget").

5. The Recipient shall carry out the activities included in each of the Annual Work Plan and Budget during the Fiscal Year to which they related. The Annual Work Plan and Budget may be revised during the Fiscal Year to which it relates, with the prior written agreement of the Association.

D. Environmental and Social Standards

- 1. The Recipient shall ensure that the Project is carried out in accordance with the Environmental and Social Standards, in a manner acceptable to the Association.
- 2. Without limitation upon paragraph 1 above, the Recipient shall ensure that the Project is implemented in accordance with the Environmental and Social Commitment Plan ("ESCP"), in a manner acceptable to the Association. To this end, the Recipient shall ensure that:
 - (a) the measures and actions specified in the ESCP are implemented with due diligence and efficiency, as provided in the ESCP;
 - (b) sufficient funds are available to cover the costs of implementing the ESCP;
 - (c) policies and procedures are maintained, and qualified and experienced staff in adequate numbers are retained to implement the ESCP, as provided in the ESCP; and
 - (d) the ESCP, or any provision thereof, is not amended, repealed, suspended or waived, except as the Association shall otherwise agree in writing, as specified in the ESCP, and ensure that the revised ESCP is disclosed promptly thereafter.
- 3. Without limitation upon the provisions of paragraph 2 above, if sixty (60) days prior to the Closing Date, the Association determines that there are measures and actions specified in the ESCP which will not be completed by the Closing Date, the Recipient shall: (a) not later than thirty (30) days before the Closing Date, prepare and present to the Association, an action plan satisfactory to the Association on the outstanding measures and actions, including a timetable and budget allocation for such measures and actions (which action plan shall be deemed to be considered an amendment of the ESCP); and (b) thereafter, carry out said action plan in accordance with its terms and in a manner acceptable to the Association.
- 4. In case of any inconsistencies between the ESCP and the provisions of this Agreement, the provisions of this Agreement shall prevail.

5. The Recipient shall ensure that:

- (a) all measures necessary are taken to collect, compile, and furnish to the Association through regular reports, with the frequency specified in the ESCP, and promptly in a separate report or reports, if so requested by the Association, information on the status of compliance with the ESCP and the environmental and social instruments referred to therein, all such reports in form and substance acceptable to the Association, setting out, *inter alia*: (i) the status of implementation of the ESCP; (ii) conditions, if any, which interfere or threaten to interfere with the implementation of the ESCP; and (iii) corrective and preventive measures taken or required to be taken to address such conditions; and
- (b) the Association is promptly notified of any incident or accident related to or having an impact on the Project which has, or is likely to have, a significant adverse effect on the environment, the affected communities, the public or workers in accordance with the ESCP, the environmental and social instruments referenced therein and the Environmental and Social Standards.
- 6. The Recipient shall establish, publicize, maintain and operate an accessible grievance mechanism, to receive and facilitate resolution of concerns and grievances of Project-affected people, and take all measures necessary and appropriate to resolve, or facilitate the resolution of, such concerns and grievances, in a manner acceptable to the Association.
- 7. The Recipient shall ensure that all bidding documents and contracts for civil works under the Project include the obligation of contractors, and subcontractors and supervising entities to: (a) comply with the relevant aspects of ESCP and the environmental and social instruments referred to therein; and (b) adopt and enforce codes of conduct that should be provided to and signed by all workers, detailing measures to address environmental, social, health and safety risks, and the risks of sexual exploitation and abuse, sexual harassment and violence against children, all as applicable to such civil works commissioned or carried out pursuant to said contracts.

E. Contingent Emergency Response

- 1. In order to ensure the proper implementation of contingent emergency response activities under Part 4 of the Project ("Contingent Emergency Response Part"), the Recipient shall ensure that:
 - (a) a manual ("CERC Manual") is prepared and adopted in form and substance acceptable to the Association, which shall set forth detailed implementation arrangements for the Contingent Emergency Response

Part, including: (i) any structures or institutional arrangements for coordinating and implementing the Contingent Emergency Response Part; (ii) specific activities which may be included in the Contingent Emergency Response Part, Eligible Expenditures required therefor ("Emergency Expenditures"), and any procedures for such inclusion; (iii) financial management arrangements for the Contingent Emergency Response Part; (iv) procurement methods and procedures for the Contingent Emergency Response Part; (v) documentation required for withdrawals of Financing amounts to finance Emergency Expenditures; (vi) a description of the environmental and social assessment and management arrangements for the Contingent Emergency Response Part; and (vii) a template Emergency Action Plan:

- (b) the Emergency Action Plan is prepared and adopted in form and substance acceptable to the Association;
- (c) the Emergency Response Part is carried out in accordance with the CERC Manual and the Emergency Action Plan; provided, however, that in the event of any inconsistency between the provisions of the CERC Manual or the Emergency Action Plan and this Agreement, the provisions of this Agreement shall prevail; and
- (d) neither the CERC Manual or the Emergency Action Plan is amended, suspended, abrogated, repealed or waived without the prior written approval by the Association.
- 2. The Recipient shall ensure that the structures and arrangements referred to in the CERC Manual are maintained throughout the implementation of the Contingent Emergency Response Part, with adequate staff and resources satisfactory to Association.
- 3. The Recipient shall ensure that:
 - (a) the environmental and social instruments required for the Contingent Emergency Response Part are prepared, disclosed and adopted in accordance with the CERC Manual and the ESCP, and in form and substance acceptable to the Association; and
 - (b) the Contingent Emergency Response Part is carried out in accordance with the environmental and social instruments in a manner acceptable to the Association.
- 4. Activities under the Contingency Emergency Response Part shall be undertaken only after an Eligible Crisis or Emergency has occurred.

F. Memoranda of Understanding with ECSA-HC

- 1. In order to maximize the benefits of regional harmonization for purposes of the Project, the Recipient shall not later than three (3) months after the Effective Date, enter into a separate memorandum of understanding with ECSA-HC (the "MOU"), in form and substance satisfactory to the Association, as such MOU shall include provisions to the effect of ensuring that the Recipient shall participate in any activity carried out by ECSA-HC under the MPA, including *inter alia* training events, workshops, data collection and analysis or knowledge-sharing.
- 2. The Recipient shall exercise its rights and obligations under the MOU in such manner as to protect the interests of the Recipient and the Association and to accomplish the purposes of the Financing. Except as the Association shall otherwise agree, the Recipient shall not assign, amend, abrogate or waive the MOU or any provision contained therein (whether in whole or in part).
- 3. In the event of any conflict between the provisions of the MOU and those of this Agreement the provisions of this Agreement shall prevail.

Section II. Project Monitoring, Reporting and Evaluation

- 1. The Recipient shall furnish to the Association each Project Report not later than forty five (45) days after the end of each calendar semester, covering the calendar semester.
- 2. Except as may otherwise be explicitly required or permitted under this Agreement or as may be explicitly requested by the Association, in sharing any information, report or document related to the activities described in Schedule 1 of this Agreement, the Recipient shall ensure that such information, report or document does not include Personal Data.

Section III. Withdrawal of the Proceeds of the Financing

A. General

Without limitation upon the provisions of Article II of the General Conditions and in accordance with the Disbursement and Financial Information Letter, the Recipient may withdraw the proceeds of the Financing to finance Eligible Expenditures in the amount allocated and, if applicable, up to the percentage set forth against each Category of the following table:

Category	Amount of the Financing Allocated (expressed in SDR)	Percentage of Expenditures to be Financed (inclusive of Taxes)
(1) Goods, works, non- consulting services, consulting services, Training, and Operating Costs for the Project (except for Parts 1.3(e) and 4 of the Project)	135,985,000	100%
(2) Goods, non-consulting services, consulting services, Training and Operating Costs for Part 1.3(e) of the Project	9,315,000	100%
(3) Emergency Expenditures under Part 4 of the Project	0	100%
TOTAL AMOUNT	145,300,000	

B. Withdrawal Conditions; Withdrawal Period

- 1. Notwithstanding the provisions of Part A of this Section, no withdrawal shall be made:
 - (a) for payments made prior to the Signature Date; or
 - (b) under Category 2, unless and until:
 - (i) the Biopharma PMU has been established in form and substance satisfactory to the Association and in particular: (A) terms of reference satisfactory to the Association have been adopted; (B) a senior Project coordinator, a good manufacturing practice (GMP) specialist, a senior industrial pharmacist, a regulatory affairs expert, and a Project monitoring and evaluation specialist have been hired or appointed with terms of reference, qualifications and experience satisfactory to the Association; and (C) an annual work plan has been adopted in form and substance satisfactory to the Association; and

- (ii) the Recipient has conducted the legal due diligence referred to in Part. 1.3(a) of the Project, in form and substance satisfactory to the Association; or
- (c) for Emergency Expenditures under Category (3), unless and until all of the following conditions have been met in respect of said expenditures:
 - (i) (A) the Recipient has determined that an Eligible Crisis or Emergency has occurred, and has furnished to the Association a request to withdraw Financing amounts under Category (3); and (B) the Association has agreed with such determination, accepted said request and notified the Recipient thereof; and
 - (ii) the Recipient has adopted the CERC Manual and Emergency Action Plan, in form and substance acceptable to the Association.
- 2. The Closing Date is March 31, 2030.

APPENDIX

Definitions

- 1. "AMR" means antimicrobial resistance.
- 2. "Anti-Corruption Guidelines" means, for purposes of paragraph 5 of the Appendix to the General Conditions, the "Guidelines on Preventing and Combating Fraud and Corruption in Projects Financed by IBRD Loans and IDA Credits and Grants", dated October 15, 2006, and revised in January 2011 and as of July 1, 2016.
- 3. "Annual Work Plan and Budget" means the work plan and budget prepared annually by the Recipient in accordance with the provisions of Section I.C. of Schedule 2 to this Agreement.
- 4. "Armauer Hansen Research Institute" or "AHRI" means the research institute established and operating pursuant to 'The Armauer Hansen Research Institute Establishment Regulation No, 530/2023' published in the Recipient's Federal Negarit Gazette 29th Year No. 14, of February 14, 2023.
- 5. "Biopharma Project Management Unit" or "Biopharma PMU" means the unit to be established by the Recipient for the purposes of carrying out Part 1.3 of the Project, in accordance with section I.A.2 of Schedule 2 to this Agreement.
- 6. "Category" means a category set forth in the table in Section III.A of Schedule 2 to this Agreement.
- 7. "CERC Manual" means the manual referred to in Section I.E of Schedule 2 to this Agreement, as such manual may be updated from time to time with the agreement of the Association, and which is an integral part of the Project Operations Manual.
- 8. "Contingent Emergency Response Part" means any activity or activities to be carried out under Part 4 of the Project to respond to an Eligible Crisis or Emergency.
- 9. "DHIS-2 Platform" means open-source health information management system.
- 10. "ECSA-HC" means East, Central and Southern Africa Health Community, a regional organization established and operating under the ECSA Convention.
- 11. "ECSA Convention" means the Convention of the East, Central and Southern Africa Health Community dated November 22, 2002, which entered into force and effect as of July 1, 1980, in accordance with Article 17 of the Convention, pursuant to which ECSA-HC was established and is operating.

- 12. "Emergency Action Plan" means the plan referred to in Section I.E. of Schedule 2 to this Agreement, detailing the activities, budget, implementation plan, and monitoring and evaluation arrangements, to respond to the Eligible Crisis or Emergency.
- 13. "Emergency Expenditures" means any of the eligible expenditures set forth in the CERC Manual referred to in Section I.E. of Schedule 2 to this Agreement and required for the Contingent Emergency Response Part.
- 14. "Eligible Crisis or Emergency" means an event that has caused, or is likely to imminently cause, a major adverse economic and/or social impact to the Recipient, associated with a natural or man-made crisis or disaster.
- 15. "Environmental and Social Commitment Plan" or "ESCP" means the environmental and social commitment plan for the Project, dated August 8, 2023, as the same may be amended from time to time in accordance with the provisions thereof, which sets out the material measures and actions that the Recipient shall carry out or cause to be carried out to address the potential environmental and social risks and impacts of the Project, including the timeframes of the actions and measures, institutional, staffing, training, monitoring and reporting arrangements, and any environmental and social instruments to be prepared thereunder.
- 16. "Environmental and Social Management Framework" means the environmental and social management framework in accordance with the ESCP.
- "Environmental and Social Standards" or "ESSs" means, collectively: 17. (i) "Environmental and Social Standard 1: Assessment and Management of Environmental and Social Risks and Impacts"; (ii) "Environmental and Social Standard 2: Labor and Working Conditions"; (iii) "Environmental and Social Standard 3: Resource Efficiency and Pollution Prevention and Management"; (iv) "Environmental and Social Standard 4: Community Health and Safety"; (v) "Environmental and Social Standard 5: Land Acquisition, Restrictions on Land Use and Involuntary Resettlement"; (vi) "Environmental and Social Standard 6: Biodiversity Conservation and Sustainable Management of Living Natural Resources"; (vii) "Environmental and Social Standard 7: Indigenous Peoples/Sub-Saharan African Historically Underserved Traditional Local Communities"; "Environmental and Social Standard 8: Cultural (ix) "Environmental and Social Standard 9: Financial Intermediaries"; (x) "Environmental and Social Standard 10: Stakeholder Engagement and Information Disclosure"; effective on October 1, 2018, as published by the Association.
- 18. "Ethiopian Food and Drug Authority" or "EFDA" means the authority established and operating pursuant to the Food and Medicine Administration Proclamation No.1112/2019 published in the Recipient's Federal Negarit Gazette 25th Year No.

- 39, of February 28, 2019 and the "Definition of Organization, Powers and Duties of the Ethiopian Food and Drug Authority Council of Ministers Regulation No. 531/2023" published in the Recipient's Federal Negarit Gazette 29th Year No. 15, of March 3, 2023; or any successor thereto acceptable to the Association.
- 19. "Ethiopia Pharmaceutical Supply Services" or "EPSS" means the institution of the Recipient in charge of enabling public health institutions to supply quality assured essential pharmaceuticals at affordable prices in a sustainable manner to the public, established and operating pursuant to Drug Fund and Pharmaceuticals Supply Agency Establishment Proclamation no. 553/2007 (as amended); or any successor thereto acceptable to the Association.
- 20. "Ethiopian Public Health Institute" or "EPHI" means the institute established and operating pursuant to the Ethiopian Public Health Institute Establishment Council of Ministers Regulation No. 301/2013, or any successor thereto acceptable to the Association.
- 21. "Fiscal Year" means the twelve (12) month period corresponding to any of the Recipient's fiscal years, which period commences on July 8 and ends on July 7 in each calendar year.
- 22. "General Conditions" means the "International Development Association General Conditions for IDA Financing, Investment Project Financing", dated December 14, 2018 (Last revised on July 15, 2023).
- 23. "Grants Management Unit" means the grants management unit under the Strategic Affairs Chief Executive Office within the Ministry of Health or any successor thereto.
- 24. "Health Emergencies" or "HEs" means any acute or chronic shocks to health systems that by virtue of scale, timing, or unpredictability overwhelm routine capabilities and hinder the provision of essential health services.
- 25. "IGAD" means Intergovernmental Authority on Development, a regional economic community set up through IGAD Constitutive Agreement, responsible for carrying out the Project.
- 26. "IGAD Constitutive Agreement" means the agreement establishing the Inter-Governmental Authority on Development of March 21, 1996.
- 27. "IHR" means the World Health Organization's International Health Regulations (2005).
- 28. "IPC" means infection prevention and control.

- 29. "MDA" means ministries, departments and agencies and other institutions (MDAs) as further elaborated in the Project Operations Manual, specifically: EPHI, EFDA, EPSS, Regional Health Bureaus and Zonal Health Offices and Armauer Hansen Research Institute (AHRI); all of which shall be maintained throughout Project implementation with composition, powers, functions, staffing, facilities and other resources satisfactory to the Association.
- 30. "Maturity Level 3" means the maturity level 3 in accordance with the WHO Global Benchmarking Tool.
- 31. "MOU" means the memorandum of understanding in accordance with section I.F of Schedule 2 to this Agreement.
- 32. "MPA Program" means the multiphase programmatic approach program designed to strengthen health system resilience and multisectoral preparedness and response to health emergencies in Eastern and Southern Africa.
- 33. "NAPHS" means national action plan for health security.
- 34. "One Health" means an approach that recognizes that the health of people is closely connected to the health of animals and our shared environment and demands collaboration across three interdependent sectors—animal health (agriculture sector), human health (health sector) and ecosystems (environmental sector)—to prevent, detect and respond to disease threats.
- 35. "Operating Costs" means the reasonable incremental expenses incurred by the Recipient in connection with Project implementation, including consumable materials and supplies, communications, mass media and printing services, vehicle insurance, rental, operation and maintenance, utilities, office rental and maintenance, charges for the opening and operation of bank accounts required for the Project, travel, lodging and *per diems*, and salaries of contractual staff working on the Project (other than consulting services), but excluding salaries of officials of the Recipient and of the MDAs.
- 36. "Participating Countries" means the countries participating in [Phase I] of the MPA Program, namely Federal Democratic Republic of Ethiopia, Republic of Kenya, and Democratic Republic of Sao Tome and Principe. "Participating Country" means any one of the Participating Countries.
- 37. "Personal Data" means any information relating to an identified or identifiable individual. An identifiable individual is one who can be identified by reasonable means, directly or indirectly, by reference to an attribute or combination of attributes within the data, or combination of the data with other available information. Attributes that can be used to identify an identifiable individual include, but are not limited to, name, identification, number, location data, online

- identifier, metadata and factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of an individual.
- 38. "PPR" means prevention, preparedness and response.
- 39. "Procurement Regulations" means, for purposes of paragraph 85 of the Appendix to the General Conditions, the "World Bank Procurement Regulations for IPF Borrowers", dated November 2020.
- 40. "Project Operations Manual" or "POM" means the Project's implementation manual referred to in Section I.B of Schedule 2 to this Agreement.
- 41. "Regional Advisory Committee" or "RAC" means the committee to be coconvened by the Regional Bodies that shall: (a) be responsible for interregionallevel coordination of Project implementation among the Participating Countries
 and the Regional Bodies including, *inter alia*: (i) providing strategic guidance and
 oversight; (ii) act as the main mechanism for interregional knowledge exchange
 and planning, and exploring opportunities for partnerships; and (iii) monitoring
 and evaluation of Project implementation, and reporting and record keeping;
 (b) meet semi-annually in the first year of Project implementation and annually
 thereafter; and (c) include representatives of all Participating Countries and
 Regional Bodies, as well as representatives of the Association and other entities as
 further described in the POM.
- 42. "Regional Bodies" means the regional and sub-regional organizations participating in this MPA Program, namely IGAD and ECSA-HC. "Regional Body" means any one of the Regional Bodies.
- 43. "Regional Health Bureaus and Zonal Health Offices" means regional government administrative structures that are mandated to plan, execute and monitor the health sector priorities and interventions in their respective regional governments and zonal administrations.
- 44. "Signature Date" means the later of the two dates on which the Recipient and the Association signed this Agreement and such definition applies to all references to "the date of the Financing Agreement" in the General Conditions.
- 45. "Training" means the training of persons involved in Project-supported activities, based on the Annual Work Plan and Budget approved by the Association, such as tuitions, seminars, workshops, and study tours both national and international, and costs associated with such activities including travel and subsistence costs for training participants, costs associated with securing the services of trainers, rental of training facilities, preparation and reproduction of training materials, and other costs directly related to training preparation and implementation.

- 46. "WASH" means water, sanitation and hygiene.
- 47. "WHO" means the World Health Organization.
- 48. "WHO Global Benchmarking Tool" means "WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of medical products, revision VI. Geneva: World Health Organization; 2021. License: CC BY-NC-SA 3.0 IGO, as this may be adjusted from time to time.
- 49. "WHO's STEPS Approach" means the WHO STEPwise approach to non-communicable disease risk factor surveillance (STEPS), consisting of a simple, standardized method for collecting, analyzing and disseminating data on key non-communicable disease risk factors in countries.