Loan Agreement

(Additional Financing for the Panama COVID-19 Emergency Response Project)

between

REPUBLIC OF PANAMA

and

INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT

LOAN AGREEMENT

AGREEMENT dated as of the Signature Date between REPUBLIC OF PANAMA ("Borrower") and INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT ("Bank") for the purpose of providing additional financing for the Original Project) (as defined in the Appendix to this Agreement).

The Borrower and the Bank 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 — LOAN

- 2.01. The Bank agrees to lend to the Borrower the amount of one hundred million Dollars, (\$100,000,000), as such amount may be converted from time to time through a Currency Conversion ("Loan"), to assist in financing the project described in Schedule 1 to this Agreement ("Project").
- 2.02. The Borrower may withdraw the proceeds of the Loan in accordance with Section III of Schedule 2 to this Agreement.
- 2.03. The Front-end Fee is one quarter of one percent (0.25%) of the Loan amount.
- 2.04. The Commitment Charge is one quarter of one percent (0.25%) per annum on the Unwithdrawn Loan Balance, provided that the Commitment Charge for the period beginning on the date of accrual of the Commitment Charge and ending on September 28, 2023 shall be zero percent (0%).
- 2.05. The interest rate is the Reference Rate plus the Variable Spread or such rate as may apply following a Conversion; subject to Section 3.02(e) of the General Conditions.
- 2.06. The Payment Dates are April 15 and October 15 in each year.
- 2.07. The principal amount of the Loan shall be repaid in accordance with Schedule 3 to this Agreement.

ARTICLE III — PROJECT

3.01. The Borrower declares its commitment to the objective of the Project and the MPA Program. To this end, the Borrower shall carry out the Project through MINSA 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 consist of the following, namely that two environmental specialists and two social specialists have been appointed as part of the PIU, with experience, qualifications, terms of reference and in a manner acceptable to the Bank.
- 4.02. The Effectiveness Deadline is the date ninety (90) days after the Signature Date.

ARTICLE V — REPRESENTATIVE; ADDRESSES

- 5.01. Except as provided in the ESCP, the Borrower's Representative is its Minister of Economy and Finance, its Vice-minister of Finance, or its Vice-minister of Economy.
- 5.02. For purposes of Section 10.01 of the General Conditions: (a) the Borrower's address is:

Ministry of Economy and Finance Vice-ministry of Economy Directorate of Public Finance Edificio Ogawa, Vía España y Calle 52E Corregimiento de Bella Vista 0816-02886 Panama City Republic of Panama; and

(b) the Borrower's Electronic Address is:

E-mail: ridcp@mef.gob.pa

5.03. For purposes of Section 10.01 of the General Conditions: (a) the Bank's address is:

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

(b) the Bank's Electronic Address is:

Telex: Facsimile: E-mail:

248423(MCI) or 1-202-477-6391 <u>mkerf@worldbank.org</u>

REPUBLIC OF PANAMA

	Authorized Representative
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SCHEDULE 1

Project Description

The objective of the Project is to prevent, detect and respond to the threat posed by COVID-19 and strengthen national systems for public health preparedness in the Republic of Panama.

The Project constitutes a phase of the MPA Program, and consists of the Original Project and the following parts 1.2(b) and 1.3:

<u>Part 1: Strengthening the Response to COVID-19 and National Systems for Public Health Preparedness</u>

1.1. Support Measures to Prevent the Spread of COVID-19.

Provision of support for safeguarding the environment for frontline workers providing care under protocols critical to the COVID-19 response, for the application of health protocols for preventing transmission among the overall population, and for the immunization campaign, through the financing of, *inter alia*:

- (a) basic cleaning and sanitation supplies;
- (b) essential equipment for disinfection and sterilization procedures, including, *inter alia*, medical supplies and supplies to ensure safe hospital waste management practices; and
- (c) communication campaigns related to COVID-19, including for general awareness raising of risks related to COVID-19, for vaccination including pediatric vaccination, for health prevention and promotion, and for raising awareness on climate-induced diseases and with culturally appropriate messages (including in indigenous languages).

1.2. Strengthen Case Detection Capacity and Support Critical Aspects of Health Service Provision.

Provision of support for:

- (a) case detection, tracing and proper care provision to ensure the identification of potential COVID-19 cases, the appropriate referral to treatment and the rapid investigation of suspected cases and potential contacts with proper testing and follow up to prevent further spread of the disease, all through the financing of, *inter alia*:
 - (i) key case detection inputs and supplies, including laboratory supplies for COVID-19 diagnostics and testing booths to protect health workers during COVID-19 testing;

- (ii) key health service delivery inputs, including equipment for hospitals and intensive care units, personal protective equipment and medical supplies (including, *inter alia*, medications, for treatment of COVID-19 and non-COVID-19 patients), ensuring the use of climate-smart technologies while addressing the immediate health system needs for medical supplies and medical devices to treat severe cases affected by COVID-19;
- (iii) surge staffing due to increased patient load, including expert support on clinical care of COVID-19 patients; and
- (iv) relevant training activities; and
- (b) the delivery of basic services during the COVID-19 pandemic, for COVID-19 and non-COVID-19 patients, and for addressing expected climate change impacts to improve the resilience of the health system in the event of future emergencies and climate related disasters, all through the financing of:
 - (i) the continuity of essential services during the COVID-19 pandemic and other emergencies, including the financing of the expansion and upgrading of current telemedicine services, equipment and supplies, hardware and software for video-consultations, training and supervision, minor works to accommodate for the installation of equipment, including antennas, and ambulance services; and
 - (ii) waste management, including integrated management of hospital waste, and the financing of waste management or storage equipment for vaccines or related waste; minor works to adapt the space and infrastructure to accommodate for said equipment; personal protective equipment; vehicles for transporting waste to treatment plants; containers for the proper segregation of hospital solid waste; information technology systems; updating of the waste management plans of health facilities to ensure compliance with environmental and social standards; strengthening institutional capacity in technical, economic, administrative, regulatory, operational and human resources aspects for the development of the adequate regulatory framework and protocols and for the improvement of hospital waste management in health facilities and within the relevant authorities at the national level.

1.3. Vaccine Acquisition. Purchase of Project COVID-19 Vaccines.

Part 2: Project Management and Monitoring

Provision of support to the PIU, including, *inter alia*, for the:

- (a) financial management, procurement, environmental and social requirements, and audits of the Project; and
- (b) for the monitoring and evaluation of the Project.

SCHEDULE 2

Project Execution

Section I. <u>Implementation Arrangements</u>

A. Institutional Arrangements.

1. COVID-19 Action Plan and National Strategic Vaccination Plan

Without limiting any other provision of this Agreement, the Borrower, through MINSA, shall: (a) ensure that the Project is carried out in accordance with the COVID-19 Action Plan and the NSVP; and (b) maintain, at all times during the implementation of the Project, adequate public health emergency coordination and management arrangements, all in a manner acceptable to the Bank.

2. Project Implementation and Management

The Borrower, through MINSA, shall: (a) operate and maintain, throughout Project implementation a unit within UGSAF (the "PIU") and CODIPRO, both with functions, responsibilities, resources and composition satisfactory to the Bank, as set forth in the Project Operational Manual; and (b) ensure that the PIU coordinates with other relevant departments within MINSA, including, *inter alia*, with the General Sub-Directorate of Environmental Health for the environmental aspects, with the Directorate of Indigenous Health Affairs for the social aspects and with the Expanded Program for Immunization ("PAI") for activities related with vaccination.

B. Project Implementation Manual.

- 1. The Borrower, through MINSA, shall by no later than one (1) month after the Effective Date, update and adopt a Project implementation manual ("Project Implementation Manual") containing detailed guidelines and procedures for the implementation of the Project, including, *inter alia*, with respect to: (a) administration and coordination; (b) monitoring and evaluation; (c) financial management; (d) procurement; (e) accounting procedures; (f) environmental and social standards; (g) corruption and fraud mitigation measures; (h) a grievance redress mechanism; (i) Personal Data collection and processing in accordance with good international practice; and (j) roles and responsibilities for 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.
- 2. The Borrower, through MINSA, shall carry out the Project in accordance with the Project Implementation Manual.
- 3. The Borrower, through MINSA, shall ensure that the Project Implementation Manual is not amended, suspended, repealed or abrogated without the prior written approval of the Bank.

4. In the event of any conflict between the provisions of the Project Implementation Manual and this Agreement, the provisions of this Agreement shall prevail.

C. Vaccine Delivery and Distribution Manual.

- 1. Without limitation on Section I.B above, in order to ensure adequate implementation of Part 1.3 of the Project, the Borrower, through MINSA, shall by no later than one (1) month after the Effective Date, prepare and adopt, a manual for Project COVID-19 Vaccine delivery and distribution ("Vaccine Delivery and Distribution Manual"), in form and substance satisfactory to the Bank, which shall include:
 - (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, as said plan may be amended from time to time, as the vaccination campaign progresses, in a manner acceptable to the Bank;
 - (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;
 - rules and procedures for processing and collection of Personal Data in accordance with good international practice; and
 - (d) vaccine distribution plan, including action plan setting out timeline and steps for immunization.
- 2. The Borrower, through MINSA, shall carry out the Project in accordance with this Agreement and the Vaccine Delivery and Distribution Manual.
- 3. Except as the Bank shall otherwise agree, the Borrower, through MINSA, shall not assign, amend, abrogate, or waive the provisions of the Vaccine Delivery and Distribution Manual without prior approval of the Bank.
- 4. In the event of any conflict between the provisions of the Vaccine Delivery and Distribution Manual and this Agreement, the provisions of this Agreement shall prevail.

D. Standards for COVID-19 Vaccine Approval.

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

E. Environmental and Social Standards.

- 1. The Borrower, through MINSA, shall ensure that the Project is carried out in accordance with the Environmental and Social Standards, in a manner acceptable to the Bank.
- 2. Without limitation upon paragraph 1 above, the Borrower, through MINSA, 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;
- (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 Bank shall otherwise agree in writing, as specified in the ESCP, and ensure that the revised ESCP is disclosed promptly thereafter.
- 3. In case of any inconsistencies between the ESCP and the provisions of this Agreement, the provisions of this Agreement shall prevail.
- 4. The Borrower, through MINSA, shall ensure that:
 - (a) all measures necessary are taken to collect, compile, and furnish to the Bank through regular reports, with the frequency specified in the ESCP, and promptly in a separate report or reports, if so requested by the Bank, 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 Bank, 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 Bank 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.
- 5. The Borrower, through MINSA, 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 Bank.
- 6. The Borrower, through MINSA, 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.

7. In case the Borrower's police personnel are used for the provision of security to Project workers, sites and/or assets, the Borrower shall, through MINSA, in coordination with other government authorities, ensure that such personnel are deployed in accordance with the relevant requirements of ESSs and the ESCP.

Section II. Project Monitoring Reporting and Evaluation

The Borrower, through MINSA, shall furnish to the Bank each Project Report not later than one month after the end of each calendar semester, covering the calendar semester. Except as may otherwise be explicitly required or permitted under this Agreement or as may be explicitly requested by the Bank, in sharing any information, report or document related to the activities described in Schedule 1 of this Agreement, the Borrower shall ensure that such information, report or document does not include Personal Data.

Section III. Withdrawal of Loan Proceeds

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 Borrower may withdraw the proceeds of the Loan 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 Loan Allocated (expressed in USD)	Percentage of Expenditures to be financed (inclusive of Taxes)
(1) Goods, works, non-consulting services, consulting services, Training and Operating Costs under Parts 1.1 and 1.2 of the Project.	39,000,000	100%
(2) Goods under Parts 1.3 of the Project.	60,000,000	100%
(3) Goods, non-consulting services, consulting services, Training and Operating Costs under Part 2 of the Project.	1,000,000	100%
TOTAL AMOUNT	100,000,000	

B. Withdrawal Conditions; Withdrawal Period.

1. Notwithstanding the provisions of Part A above, no withdrawal shall be made:

- (a) for payments made prior to the Signature Date, except that withdrawals up to an aggregate amount not to exceed \$90,000,000 may be made for payments made prior to this date but on or after December 17, 2020, for Eligible Expenditures under Categories (1) and (2), *provided*, *however*, that no such withdrawal shall be made under this paragraph for Eligible Expenditures under Category (2) consisting of purchases of goods (Project COVID-19 Vaccines) the deployment of which occurred before the ESMF has been updated in accordance with the ESCP, until a Rapid E&S Assessment has been carried out and finalized in accordance with the ESCP and in form and substance acceptable to the Bank; or
- (b) for payments under Category (1) or (2) only after the Bank has received satisfactory evidence that the Environmental and Social Instruments have been prepared or updated (as applicable), consulted upon, disclosed and adopted in form and substance satisfactory to the Bank.
- 2. The Closing Date is December 29, 2023.

SCHEDULE 3

Commitment-Linked Amortization Repayment Schedule

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").

Level Principal Repayments

	1 1 0
Principal Payment Date	Installment Share
On each April15 and October 15	
Beginning April 15, 2025	
through April 15, 2041	2.94%
On October 15, 2041	2.98%

APPENDIX

Definitions

- 1. "Anti-Corruption Guidelines" means, for purposes of paragraph 6 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.
- 2. "Category" means a category set forth in the table in Section III.A of Schedule 2 to this Agreement.
- 3. "CODIPRO" means *Consejo Directivo de Proyectos*, a steering committee established in the UGSAF, or any of its successor or successors thereto, acceptable to the Bank.
- 4. "COVAX Facility" means the COVID-19 Vaccine Global Access Facility, a mechanism through which demand and resources are pooled to support the availability of, and equitable access to, COVID-19 vaccines for all economies, and which is coordinated by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI), and the WHO.
- 5. "COVID-19" means the coronavirus disease caused by the 2019 novel coronavirus (SARS-CoV-2).
- 6. "COVID-19 Action Plan" means the Borrower's action plan for COVID-19, dated April 15, 2020, and acceptable to the Bank, as said document may be modified from time to time during the COVID-19 outbreak, and such term includes all schedules and annexes to said document.
- 7. "Environmental and Social Commitment Plan" or "ESCP" means the environmental and social commitment plan for the Project, dated March 15, 2022, 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 Borrower 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.
- 8. "Environmental and Social Instruments" means: (i) the Environmental and Social Management Framework; (ii) the Labor Management Procedure; (iii) the Indigenous Peoples Plan; and (iv) the Stakeholder Engagement Plan, to be prepared or updated by MINSA, as relevant, and to be disclosed, consulted upon and adopted for the Project, as set out in the ESCP, in accordance with the Environmental and Social Standards.
- 9. "Environmental and Social Management Framework" or "ESMF" means the Borrower's framework to be prepared, disclosed, consulted upon, and adopted for the Project, as set out in the ESCP, in accordance with the Environmental and Social Standards, as such framework may be amended from time to time with the agreement of the Bank.

- 10. "Environmental and Social Standards" or "ESSs" means, collectively: (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 Historically Underserved Traditional Local Communities"; (viii) "Environmental and Social Standard 8: Cultural Heritage"; (ix) "Environmental and Social Standard 10: Stakeholder Engagement and Information Disclosure"; effective on October 1, 2018, as published by the Bank.
- 11. "General Conditions" means the "International Bank for Reconstruction and Development General Conditions for IBRD Financing, Investment Project Financing", dated December 14, 2018 (revised on August 1, 2020, December 21, 2020, April 1, 2021 and January 1, 2022).
- 12. "MINSA" means *Ministerio de Salud*, the Borrower's Ministry of Health, or any successor thereto acceptable to the Bank.
- 13. "MPA Program" means the global emergency multiphase programmatic approach program designed to assist countries to prevent, detect and respond to the threat posed by COVID-19 and strengthen national systems for public health preparedness.
- 14. "National Strategic Vaccination Plan" or "NSVP"" means the Borrower's immunization plan for COVID-19, originally developed by MINSA in September 2020, containing the rules and procedures for vaccine allocation, management, monitoring, and distribution of vaccines, acceptable to the Bank, as said document may be modified from time to time, and such term includes all schedules and annexes to said document.
- 15. "Operating Costs" means reasonable and necessary incremental expenses incurred on account of Project implementation, including, *inter alia*, office supplies, vehicle rental, operation and maintenance, insurance costs, bank charges, office administration, maintenance and rental costs, communication costs, equipment maintenance, utilities, document duplication/printing, consumables, travel, accommodation, *per diem*, supervision costs, and salaries of additional staff needed to cover the increased demand for health services as a result of COVID-19 (surge staffing) that were not foreseen or included in the Borrower's budget (excluding regular salaries of the Borrower's civil service staff).
- 16. "Original Loan Agreement" means the Loan Agreement for the Original Project between the Borrower and the Bank, dated July 13, 2020 (Loan No. 9150-PA).
- 17. "Original Project" means the Panama COVID-19 Emergency Response Project financed through the Original Loan Agreement.

- 18. "PAI" means *Programa Ampliado de Inmunización*, the Expanded Program for Immunization of MINSA.
- 19. "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.
- 20. "PIU" means the Project Implementation Unit referred to in Section I.A.2 of Schedule 2 to this Agreement.
- 21. "Procurement Regulations" means, for purposes of paragraph 87 of the Appendix to the General Conditions, the "World Bank Procurement Regulations for IPF Borrowers", dated November 2020.
- 22. "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 acquired or deployed under the Project; "Project COVID-19 Vaccines" means the plural thereof.
- 23. "Project Implementation Manual" means the manual referred to in Section I.B of Schedule 2 to this Agreement, as such manual may be amended by the Borrower from time to time, with the approval of the Bank.
- 24. "Rapid E&S Assessment" means a rapid environmental and social assessment to assess whether any relevant activities carried out prior to the adoption of the ESMF were implemented in accordance with ESSs requirements, as further described in the ESCP.
- 25. "Signature Date" means the later of the two dates on which the Borrower and the Bank signed this Agreement and such definition applies to all references to "the date of the Loan Agreement" in the General Conditions.
- 26. "Stringent Regulatory Authority" means a National Regulatory Authority ("NRA") that is classified by WHO as a Stringent Regulatory Authority.
- 27. "Training" means expenditures (other than those for consultants' services) incurred by MINSA to finance, *inter alia*, reasonable transportation costs and per-diem of trainees and trainers (if applicable), training fees, and rental of training facilities, materials and equipment under the Project.
- 28. "UGSAF" means *Unidad de Gestión de Salud, Administrativa y Financiera*, the Health, Administrative and Financial Management Unit of MINSA, or any of its successor or successors thereto, acceptable to the Bank.

- 29. "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.
- 30. "Vaccine Delivery and Distribution Manual" means the Borrower's manual referred to in Section I.C of Schedule 2 to this Agreement, as the same may be amended from time to time with the Bank's prior written approval.
- 31. "WHO" means the World Health Organization.
- 32. "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.
- 33. "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.
- 34. "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.