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Report No: PAD4929

INTERNATIONAL DEVELOPMENT ASSOCIATION

PROJECT PAPER

ON A

PROPOSED RESTRUCTURING AND ADDITIONAL CREDIT

IN THE AMOUNT OF SDR7.3 MILLION
(US\$10 MILLION EQUIVALENT)

TO THE
KINGDOM OF BHUTAN

FOR A

BHUTAN COVID-19 EMERGENCY RESPONSE AND HEALTH SYSTEMS PREPAREDNESS PROJECT

UNDER THE COVID-19 STRATEGIC PREPAREDNESS AND RESPONSE PROGRAM (SPRP)
USING THE MULTIPHASE PROGRAMMATIC APPROACH (MPA)

WITH A FINANCING ENVELOPE OF

UP TO US\$6 BILLION APPROVED BY THE BOARD ON APRIL 2, 2020 AND
UP TO US\$12 BILLION ADDITIONAL FINANCING APPROVED BY THE BOARD
ON OCTOBER 13, 2020

April 15, 2022

Health, Nutrition & Population Global Practice
South Asia Region

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CURRENCY EQUIVALENTS

(Exchange Rate Effective March 31, 2022)

Currency Unit = Bhutanese Ngultrum (BTN)

BTN 75.94 = US\$1

US\$1.38 = SDR 1

FISCAL YEAR

July 1 – June 30

Regional Vice President: Hartwig Schafer

Country Director: Mercy Miyang Tembon

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ABBREVIATIONS AND ACRONYMS

AF	Additional Financing
AEFI	Adverse Events Following Immunization
AFS	Annual Financial Statement
BVS	Bhutan Vaccine System
CERC	Contingent Emergency Response Component
CERHSP	COVID-19 Emergency Response and Health Systems Preparedness
COVAX	COVID-19 Vaccines Global Access Facility
COVID-19	Coronavirus Disease 2019
CPF	Country Partnership Framework
DRA	Drug Regulatory Authority
ESMF	Environment and Social Management Framework
EUL	Emergency Use Listing
FTCF	Fast Track COVID-19 Facility
GAVI	Global Alliance for Vaccines and Immunizations
GBV	Gender Based Violence
GRM	Grievance Redress Mechanism
GRS	Grievance Redress Service
HEIS	Hands-on Expanded Implementation Support
IBRD	International Bank for Reconstruction and Development
IDA	International Development Association
IFC	International Financial Corporation
IP	Implementation Progress
ISR	Implementation Status and Results Report
M&E	Monitoring and Evaluation
MOH	Ministry of Health
MPA	Multiphase Programmatic Approach
NITAG	National Immunization Technical Advisory Group
NVDP	National Vaccination and Deployment Plan
PDO	Project Development Objective
PP	Project Paper
PPE	Personal Protective equipment
RGOB	Royal Government of Bhutan
RITAG	Regional National Immunization Technical Advisory Group
RT-PCR	Reverse Transcription Polymerase Chain Reaction
SAGE	Strategic Advisory Group of Experts on Immunization
SARS-CoV-2	Novel Coronavirus
SEA	Sexual Exploitation and Abuse
SOP	Standard Operating Procedures



The World Bank

Additional Financing to Bhutan COVID-19 Emergency Response and Health Systems Preparedness Project
(P178656)

SPRP	Strategic Preparedness and Response Program
UN	United Nations
UNICEF	United Nations Children's Fund
VIRAT	Vaccine Introduction Readiness Assessment Tool
VRAF	Vaccine Readiness Assessment Framework
WB	World Bank
WBG	World Bank Group
WHO	World Health Organization

Bhutan COVID-19 Emergency Response and Health Systems Preparedness Project

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BASIC INFORMATION – PARENT (Bhutan: COVID-19 Emergency Response and Health Systems Preparedness Project - P173787)

Country	Product Line	Team Leader(s)		
Bhutan	IBRD/IDA	Manav Bhattarai		
Project ID	Financing Instrument	Resp CC	Req CC	Practice Area (Lead)
P173787	Investment Project Financing	HSAHP (9543)	SACBB (8702)	Health, Nutrition & Population

Implementing Agency: Ministry of Health, Royal Government of Bhutan

Is this a regionally tagged project?	
No	

Bank/IFC Collaboration	
No	

Approval Date	Closing Date	Expected Guarantee Expiration Date	Environmental and Social Risk Classification
17-Apr-2020	31-Dec-2022		Substantial

Financing & Implementation Modalities

<input checked="" type="checkbox"/> Multiphase Programmatic Approach [MPA]	<input checked="" type="checkbox"/> Contingent Emergency Response Component (CERC)
<input type="checkbox"/> Series of Projects (SOP)	<input type="checkbox"/> Fragile State(s)
<input type="checkbox"/> Performance-Based Conditions (PBCs)	<input type="checkbox"/> Small State(s)
<input type="checkbox"/> Financial Intermediaries (FI)	<input type="checkbox"/> Fragile within a Non-fragile Country
<input type="checkbox"/> Project-Based Guarantee	<input type="checkbox"/> Conflict
<input type="checkbox"/> Deferred Drawdown	<input checked="" type="checkbox"/> Responding to Natural or Man-made disaster
<input type="checkbox"/> Alternate Procurement Arrangements (APA)	<input type="checkbox"/> Hands-on Expanded Implementation Support (HEIS)

Development Objective(s)



MPA Program Development Objective (PrDO)

The Program Development Objective is to prevent, detect and respond to the threat posed by COVID-19 and strengthen national systems for public health preparedness

Project Development Objectives (Phase 094)

To prevent, detect and respond to the threat posed by COVID-19 and to strengthen national systems for public health preparedness in Bhutan

Ratings (from Parent ISR)

	Implementation			Latest ISR
	11-Sep-2020	14-Dec-2020	16-Jun-2021	21-Dec-2021
Progress towards achievement of PDO	S	S	S	S
Overall Implementation Progress (IP)	S	S	S	S
Overall ESS Performance	S	S	S	S
Overall Risk	S	S	M	S
Financial Management	S	S	S	S
Project Management	S	S	S	S
Procurement	MS	MS	MS	MS
Monitoring and Evaluation	S	S	S	S

BASIC INFORMATION – ADDITIONAL FINANCING (Additional Financing to Bhutan COVID-19 Emergency Response and Health Systems Preparedness Project - P178656)

Project ID	Project Name	Additional Financing Type	Urgent Need or Capacity Constraints
P178656	Additional Financing to Bhutan COVID-19 Emergency Response and Health Systems Preparedness Project	Scale Up	No



Financing instrument	Product line	Approval Date	
Investment Project Financing	IBRD/IDA	22-Apr-2022	
Projected Date of Full Disbursement	Bank/IFC Collaboration		
30-Apr-2024	No		
Is this a regionally tagged project?			
No			

Financing & Implementation Modalities

<input checked="" type="checkbox"/> Multiphase Programmatic Approach (MPA)	<input type="checkbox"/> Series of Projects (SOP)
<input type="checkbox"/> Fragile State(s)	<input type="checkbox"/> Performance-Based Conditions (PBCs)
<input type="checkbox"/> Small State(s)	<input type="checkbox"/> Financial Intermediaries (FI)
<input type="checkbox"/> Fragile within a Non-fragile Country	<input type="checkbox"/> Project-Based Guarantee
<input type="checkbox"/> Conflict	<input type="checkbox"/> Responding to Natural or Man-made disaster
<input type="checkbox"/> Alternate Procurement Arrangements (APA)	<input checked="" type="checkbox"/> Hands-on, Enhanced Implementation Support (HEIS)
<input checked="" type="checkbox"/> Contingent Emergency Response Component (CERC)	

Disbursement Summary (from Parent ISR)

Source of Funds	Net Commitments	Total Disbursed	Remaining Balance	Disbursed	
IBRD				<div style="width: 0%; height: 10px; background-color: #ccc;"></div>	%
IDA	5.00	5.15	0.00	<div style="width: 100%; height: 10px; background-color: #28a745;"></div>	100 %
Grants				<div style="width: 0%; height: 10px; background-color: #ccc;"></div>	%

MPA Financing Data (US\$, Millions)

MPA Program Financing Envelope	18,000,000,000.00
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MPA FINANCING DETAILS (US\$, Millions)

Board Approved MPA Financing Envelope:	18,000,000,000.00
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MPA Program Financing Envelope:	18,000,000,000.00
of which Bank Financing (IBRD):	9,900,000,000.00
of which Bank Financing (IDA):	8,100,000,000.00
of which other financing sources:	0.00

PROJECT FINANCING DATA – ADDITIONAL FINANCING (Additional Financing to Bhutan COVID-19 Emergency Response and Health Systems Preparedness Project - P178656)

FINANCING DATA (US\$, Millions)

SUMMARY (Total Financing)

	Current Financing	Proposed Additional Financing	Total Proposed Financing
Total Project Cost	5.00	10.00	15.00
Total Financing	5.00	10.00	15.00
of which IBRD/IDA	5.00	10.00	15.00
Financing Gap	0.00	0.00	0.00

DETAILS - Additional Financing

World Bank Group Financing

International Development Association (IDA)	10.00
IDA Credit	10.00

IDA Resources (in US\$, Millions)

	Credit Amount	Grant Amount	Guarantee Amount	Total Amount
Bhutan	10.00	0.00	0.00	10.00
National PBA	10.00	0.00	0.00	10.00
Total	10.00	0.00	0.00	10.00



COMPLIANCE

Policy

Does the project depart from the CPF in content or in other significant respects?

Yes No

Does the project require any other Policy waiver(s)?

Yes No

Environmental and Social Standards Relevance Given its Context at the Time of Appraisal

E & S Standards	Relevance
Assessment and Management of Environmental and Social Risks and Impacts	Relevant
Stakeholder Engagement and Information Disclosure	Relevant
Labor and Working Conditions	Relevant
Resource Efficiency and Pollution Prevention and Management	Relevant
Community Health and Safety	Relevant
Land Acquisition, Restrictions on Land Use and Involuntary Resettlement	Not Currently Relevant
Biodiversity Conservation and Sustainable Management of Living Natural Resources	Not Currently Relevant
Indigenous Peoples/Sub-Saharan African Historically Underserved Traditional Local Communities	Relevant
Cultural Heritage	Not Currently Relevant
Financial Intermediaries	Not Currently Relevant

NOTE: For further information regarding the World Bank’s due diligence assessment of the Project’s potential environmental and social risks and impacts, please refer to the Project’s Appraisal Environmental and Social Review Summary (ESRS).

INSTITUTIONAL DATA

Practice Area (Lead)

Health, Nutrition & Population

**Contributing Practice Areas****Climate Change and Disaster Screening**

This operation has been screened for short and long-term climate change and disaster risks

PROJECT TEAM**Bank Staff**

Name	Role	Specialization	Unit
Sangeeta Carol Pinto	Team Leader (ADM Responsible)	Operations	HSAHP
Md Kamruzzaman	Procurement Specialist (ADM Responsible)	Procurement	ESARU
Sangeeta Patel	Procurement Specialist	Procurement	ESARU
Rinzin Dorji	Financial Management Specialist (ADM Responsible)	Financial Management	ESAG2
Iqbal Ahmed	Environmental Specialist (ADM Responsible)	Environment Safeguards	SSAEN
Jun Zeng	Social Specialist (ADM Responsible)	Social Safeguards	SSAS2
Ajay Ram Dass	Team Member	Program Assistant	HSAHP
Dorji Drakpa	Team Member	Team Assistant	SACBT
E. Gail Richardson	Program Manager	Practice Manager	LCC3C
Junko Funahashi	Counsel	Lead Counsel	LEGAS
Keiko Inoue	Team Member	Practice Leader	HSADR
Rekha Shreesh	Social Specialist	Social Safeguards	SSAS1
Satish Kumar Shivakumar	Team Member	Loans	WFACS
Srivathsan Sridharan	Team Member	Loans	WFACS
Vidya Venugopal	Counsel	Counsel	LEGAS

Extended Team

Name	Title	Organization	Location
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I. BACKGROUND AND RATIONALE FOR ADDITIONAL FINANCING

A. Introduction

1. **This Project Paper seeks approval to provide an IDA credit in the amount of SDR7.3 million (US\$10 million equivalent) for an Additional Financing (AF) to the Bhutan COVID-19 Emergency Response and Health Systems Preparedness Project (CERHSP; P173787).** The proposed AF would scale-up support to the Project for vaccine procurement under the COVID-19 Strategic Preparedness and Response Program (SPRP) using the Multiphase Programmatic Approach (MPA) approved by the Board on April 2, 2020, and the vaccines AF to the SPRP approved on October 13, 2020.¹ The primary objective of this AF is to enable the Royal Government of Bhutan (RGOB) to provide free and equitable access to COVID-19 vaccines to the eligible population in response to the evolving vaccination guidance, beyond what was achieved through the parent project, and to further enhance testing and response capacity in light of repeated COVID-19 waves. This Project Paper also seeks approval to restructure the CERHSP to (a) reflect the increased allocations to Sub-component 1.1 for case detection, confirmation, contact tracing, recording and reporting, Sub-component 1.2 for health systems strengthening for longer term pandemic preparedness, Sub-component 1.3 for vaccine financing, and Component 3 for implementation management and monitoring and evaluation; (b) introduce modifications to the Results Framework; and (c) extend the closing date of the original Credit and the AF to December 31, 2023.

2. **Bhutan has gone through four significant outbreaks of COVID-19 since March 2020.** The first outbreak occurred in August 2020 (35th epi week), the second in December 2020 (52nd epi week), the third in May 2021 (21st epi week, attributable to the Delta variant), and the ongoing wave since December 2021 on account of the Omicron variant. Over 17,620 persons have tested positive since the start of the pandemic, with 4,086 active cases and 13,527 recoveries as of March 13, 2022. Further, the data indicates that test positivity is highest amongst productive, mobile age-groups of 15-24 years, with 57.5 percent of tested positive being males. The most recent outbreak is linked to community transmission in nine districts. As of this date, Bhutan has registered seven COVID-19 related deaths through the pandemic.

3. **Bhutan has been an exemplar nation in the South-Asia Region in launching a strong health sector emergency response to COVID-19.** Surveillance activities were immediately strengthened in all 20 districts with addition of district-based Case Investigation and Contact Tracing (CICT) teams. District health authorities were provisioned with personal protective equipment (PPE) and necessary COVID-19 commodities, including rapid diagnostic tests. Laboratories were capacitated and accredited to undertake Reverse Transcription Polymerase Chain Reaction (RT-PCR) tests, while Antigen-Rapid Diagnostic Test (Ag-RDT) tests were deployed in the community. Isolation, triage, and treatment centers were established in designated hospitals and public health centers.

¹ The World Bank Group approved a US\$12 billion Fast Track COVID-19 Facility (FTCF or “the Facility”) to assist IBRD and IDA countries in addressing the global pandemic and its impacts. Of this amount, US\$6 billion came from IBRD/IDA (“the Bank”) and US\$6 billion from the International Finance Corporation (IFC). The IFC subsequently increased its contribution to US\$8 billion, bringing the FTCF total to US\$14 billion. The AF of US\$12 billion was approved to support the purchase and deployment of vaccines as well as strengthening the related immunization and health care delivery system.



4. **With the availability of safe and effective COVID-19 vaccines in early 2021, Bhutan quickly acquired vaccines with the World Health Organization (WHO) Emergency Use Listing (EUL) from bilateral donations, COVAX and through direct contracts with vaccine suppliers.** COVID-19 vaccinations were conducted in campaign mode for a prioritized population of 533,558 persons above 18 years of age. Within 16 days, nearly 93 percent of the eligible population was administered their first dose of vaccine. By end July 2021, Bhutan had vaccinated 90.2 percent of its eligible population with a two-dose regimen. By October 2021, Bhutan expanded its eligibility criteria to population above 12 years of age and as of December 2021, it further expanded the eligibility criteria to children 5-11 years of age. As of March 1, 2022, a total of 98.4 percent of population above 12 years of age has been administered the first dose of vaccine and 94.5 percent the second dose. Bhutan has also initiated booster doses for prioritized groups and boosted 89.1 percent of the population above 18 years old. Additionally, as of March 11, 2022, Bhutan vaccinated over 96.1 percent of its children 5-11 years of age with the first dose of a COVID-19 vaccine.

B. Consistency with the Country Partnership Framework (CPF)

5. **The proposed AF is consistent with the World Bank Group’s (WBG) Country Partnership Framework for FY21-24 for Bhutan discussed by the Board of Executive Directors on December 18, 2020 (Report # 154927-BT).** Specifically, the AF contributes to Focus Area 1 – ‘Human Capital’ and Focus Area 2 – ‘Resilience’. The proposed AF is expected to contribute to improvements in human capital accumulation through investments for capacitating Bhutan’s health system to manage the COVID-19 pandemic.

C. Project Design and Scope

6. **The design, scope, and implementation arrangements of the parent Project will be maintained in the proposed AF.** The parent project is structured into four components: Component 1, *Emergency COVID-19 Response*, provides immediate support to limit transmission of COVID-19 through containment strategies. Component 2, *Community Engagement and Risk Communication*, supports information and communication activities to raise awareness, knowledge, and understanding among the general population about the risks and potential impact of the COVID-19 pandemic as well as on Project COVID-19 Vaccine deployment and to address vaccine hesitancy. Component 3, *Implementation Management and Monitoring and Evaluation*, supports efforts to strengthen the Ministry of Health’s capacity. The Project also includes a *Contingency Emergency Response Component (CERC)* which could support an immediate response to an eligible crisis or emergency. Annex 2 details each of the components. The AF will increase IDA allocation to Sub-component 1.1 to purchase COVID-19 diagnostic test kits, Sub-component 1.2 for health systems strengthening for longer term pandemic preparedness, Sub-component 1.3 to finance the purchase of additional COVID-19 vaccines for eligible population, and Component 3 to finance consultant costs associated with implementing the project over an extended timeframe. Additionally, a level II restructuring is proposed to (a) reflect these increased allocations, (b) introduce a new outcome indicator to track booster dose coverage (by gender), (c) revise end line targets for three intermediate results indicators, (d) extend the date of end line targets for all indicators in the results framework to the new project closing date of December 31, 2023; and (e) extend the closing date of the original Credit and the AF to December 31, 2023.



D. Project Performance

7. Progress towards achievement of Project Development Objectives (PDO) as well as Implementation Progress (IP) are assessed as satisfactory, and the Project is in compliance with all legal covenants as documented in the Implementation Status and Results Report (ISR) of December 21, 2021.

The CERHSP, financed by a credit in the amount of US\$5 million equivalent, was approved by the WBG's Board of Executive Directors on April 17, 2020, with the PDO *to prevent, detect and respond to the threat posed by COVID-19 and to strengthen national systems for public health preparedness in Bhutan*. A Level 2 restructuring was approved by the Regional Vice President on December 15, 2021, to redeploy unspent Credit balance of US\$2 million for the procurement of vaccines meeting the World Bank's Vaccine Approval Criteria.

8. The Project has financed Bhutan's efforts to prevent, test, trace, treat and manage the COVID-19 pandemic. Specifically, the Project supported strengthening surveillance capacities with mobilization and deployment of case investigation and contact tracing teams in all 20 districts. Fifty hospitals and 184 primary health centers were provided with testing equipment, RT-PCR and Antigen Test Kits, consumables, hygiene products and PPE. Intensive Care Units were prepared in four COVID centers (total of 54 beds) to manage COVID-19 patients needing critical care. Capacities of five laboratories for COVID-19 testing were strengthened. Approximately 45,000 people above 12 years old (6 percent of the population) received the primary series Moderna vaccines and another 135,000 population above 18 years old (18 percent of the population) received their booster dose of Moderna vaccine, also financed by IDA. Mass-, mid- and print-media were leveraged to create awareness of public health measures to manage COVID-19 as well as promote demand for testing, treatment, and vaccination services. Over 4,756 awareness campaigns were launched, including a COVID-19 dashboard, video and radio spots, posters, pamphlets, travel advisories and social media campaigns. Hotlines were set up: Hotline 1010 was set up for public service-related information dissemination, Hotline 112 for sharing health related information and advice, and Hotline 1414 to address grievances related to health and COVID-19 related services. Trainings of health administrators and workers were conducted in COVID-19 prevention and treatment measures, social and behavior change communication, and to ensure compliance with social and environment safeguards requirements. Supervision visits were conducted to monitor and strengthen the health response to COVID-19, including progress with the minor civil works financed by the Project.

9. Procurement performance is rated as Moderately Satisfactory on account of ad-hoc planning and implementation of procurement activities. The Project has financed 64 contracts for goods comprising medical equipment, pharmaceuticals, hygiene products, medical consumables, and PPEs following request for quotations and direct contracting procedures. Additionally, five works contracts and two non-consulting contracts have been financed by the project and successfully completed. Further one goods, one works and three consultancy contracts are currently under implementation. Bhutan has strategically used domestic resources for emergency procurement as and when the need arises and thereafter, considered other sources of financing, as and when available. This has resulted in most of the above procurements being either retrospectively financed or constituting advance contracting. The Bank is providing Hands on Expanded Implementation Support (HEIS) for procurement to support better procurement planning and compliance with its Procurement Regulations.

10. Financial Management is rated as Satisfactory. All quarterly Interim Unaudited Financial Reports (IUFs) submitted to date have been found acceptable. The annual audited financial statement (AFS) of



the fiscal year 2019-20 with unqualified opinion by the Royal Audit Authority was submitted in a timely manner and has been found acceptable to the Bank. There are no overdue audit reports. As of March 31, 2022, the Credit is fully disbursed.

11. The Project's Environment and Social Standards compliance has been Satisfactory. Approximately 421.6 tons of general waste and 241.7 tons of COVID-19 waste was generated by health facilities in 2021. The waste was collected, segregated, disinfected, stored and disposed off following the National Guidelines on Infection Control and Medical Waste Management. While all hospitals have autoclaves for disinfection and disposal of waste, all primary health facilities are equipped with deep burial pits for treatment and disposal of healthcare waste generated through project activities. The risks related to medical waste management and the exposure to COVID-19 are being mitigated through the implementation of the updated Environment and Social Management Framework (ESMF), the occupational health and safety standards and specific infectious-control strategies, guidelines and requirements as recommended by WHO and Centers for Disease Control and Prevention. The Environment and Social Management Plan (ESMP) and Labor Management Plan (LMP) were developed for minor civil works and followed and monitored for compliance. Activities described in the Stakeholder Engagement Plan (SEP) continue to be implemented. A hotline 1414 was established for redressing grievances associated with COVID-19 health response. While fully operational, no grievances were registered as of December 2021. The workers engaged in minor civil works financed by the Project are complying with Occupational Health Safety (OHS) measures. There are no child workers and forced laborers employed at any sites. From a vulnerability perspective, 99.6 percent of frontline health workers have been fully vaccinated. Sixty percent of the health workers (approximately 3,600 health workers) are engaged in COVID-19 vaccination and comprise male and female health workers in a 1:1 ratio. To ensure a gender sensitive COVID-19 response, separate male and female isolation wards were established, measures undertaken to ensure menstrual hygiene of females in isolation as well as mothers and children placed together in quarantine facilities. All contractors and engineers were trained to identify and report on gender-based violence (GBV). Additionally, Information, Education and Communications campaigns deployed during the pandemic emphasize inclusiveness of COVID-19 health response and vaccination plans, particularly for the most vulnerable, including pregnant and lactating women.

E. Rationale for Additional Financing

12. On January 19, 2022, the RGOB requested an AF to support primary vaccination and single dose boosters for eligible population with safe and effective COVID-19 vaccines, procure diagnostic test kits, and strengthen health systems to manage the pandemic better and sustainably. In light of emerging global evidence for eligibility of new age-cohorts for primary series COVID-19 vaccination and boosting of eligible populations, Bhutan is offering COVID-19 vaccination for children above 5 years old and boosters for all eligible populations. This evolved strategy has created a demand for at least 459,205 additional doses of vaccines (accounting for 10 percent wastage), over and above the 2.2 million vaccines² received as of February 28, 2022. The RGOB is also considering expanding coverage of primary series of vaccination to additional eligible age-groups as well as additional boosters in line with evolving WHO/ Strategic Advisory Group of Experts on Immunization (SAGE) guidance.

² Astrazeneca: 0.4 million doses; Covishield: 0.55 million; Moderna: 0.75 million; and Pfizer-BioNTech: 0.2 million doses

13. **Bhutan has signed and domestically financed a contract for 250,000 doses of Moderna vaccines for its population aged 12 and older.** Approximately 36 percent of this AF will retroactively finance this contract. Additionally, Bhutan procured, using domestic finance, diagnostic test kits (RT-PCR and Rapid Diagnostic Test kits) to swiftly detect and manage the spread of Omicron variant in the value of US\$1.6 million. It also intends to seek retroactive financing for this expenditure, for which payments were made in January 2022.

14. **Bhutan intends for its public health facilities to remain in a high state of alertness for fast-tracked management of future waves of the pandemic and to complete the goals for vaccinating and boosting the entire eligible population with COVID-19 vaccines.** It intends to employ the proceeds from the proposed AF, minus reimbursements for eligible retroactive expenditures, to procure (A) equipment and/or health commodities comprising test kits, drugs, consumables, PPEs, etc., necessary to sustain its emergency COVID-19 response; and (B) additional vaccines for (i) primary series vaccination of hitherto unaddressed populations (as evidence of vaccine efficacy and safety emerges for such populations and is recommended by WHO/SAGE), and (ii) booster dose vaccination of eligible populations (in line with WHO/SAGE guidance); as well as finance (C) consultant costs associated with implementing the Project over the extended period.

15. **Bhutan is tenaciously pursuing its goal of safeguarding its entire population from COVID-19 in line with emerging evidence on safety and efficacy of vaccines for various population groups.** It is assisted in this effort with donations of vaccines (bilateral and through the COVAX Advance Market Commitment (AMC) facility) (refer to Table 2) and with technical assistance to implement its rigorous and ambitious plans for effectively managing the pandemic (refer to Box 1).

Box 1: Supportive Roles for Partner Agencies in Implementation

WHO	Support
Technical leadership for <ul style="list-style-type: none"> - vaccine introduction, - support to National Immunization Technical Advisory Group (NITAG) on COVID-19 vaccination policy objectives, strategy, targets and vaccine safety issue, - developing guidelines, and - conducting training on Adverse Events Following Immunization (AEFI) surveillance, vaccine pharmacovigilance, etc. 	Technical assistance
United Nations Children’s Fund (UNICEF) <ul style="list-style-type: none"> - Development of a roadmap for improved integration of COVID-19 vaccine deployment with Expanded Programme on Immunization (EPI), - Supporting quantification and forecasting of supply needs, - Supporting procurement and installation of quality cold chain rooms at national level, and - Supporting design and implementation of Risk Communication and Community Engagement (RCCE) strategy. 	Technical assistance
Global Vaccine Alliance (GAVI)/COVAX <ul style="list-style-type: none"> - Providing vaccines for prioritized 20% of the population and beyond, and - Providing technical assistance for vaccination and cold chain 	Technical and financial assistance

(a) Vaccines Readiness Assessment

16. **Bhutan completed a vaccine readiness assessment in January 2021 collaboratively with the World Bank, WHO, UNICEF and GAVI using the VIRAT-VIRAF 2.0 tool.** The assessment identified gaps across several readiness domains (refer to Table 1) and identified mechanisms to address them. The assessment has been consistently updated over time (last update as of December 2021) with the latest version confirming Bhutan’s high state of readiness to fully vaccinate its eligible population.

Table 1: Summary of Vaccination Readiness Findings from the VIRAT/VIRAF 2.0 Assessment

Readiness domain	Readiness of government	Key gaps to address before deployment
Planning and coordination	Phase-wise vaccination of different population groups is proposed in approved National Vaccination and Deployment Plan (NVDP) (Refer to Table 2) Readiness: Complete	None
Budgeting	Adult vaccination and adolescent vaccination is completed using vaccines secured through COVAX, donations and procurement using domestic resources. UNICEF and WHO provide technical support in vaccine deployment. Readiness: in progress	Resource gap exists to fully vaccinate newly eligible age cohorts and administer boosters
Regulatory	All requirements of VRAF / VIRAF tool pertaining to this domain including expedited approval pathways for vaccines, regulatory procedure streamlining, import permit issuance and expedited lot release waiver generation have been completed. Readiness: Complete	None
Prioritization, targeting, surveillance	Prioritization was done based on the WHO fair allocation framework. With input from the National Immunization Technical Advisory Groups (NITAG), the process of prioritization, identification of priority population and coordination for surveillance has been completed. Readiness: Complete	None
Service delivery	Standard Operating Procedures (SoPs) for infection prevention and control and PPE have been updated, vaccine transport and waste management contractual arrangements are in place. Readiness: Complete	None
Training and supervision	Trainings of healthcare workers for COVID-19 vaccination are completed/ongoing, where refreshers required. Readiness Complete	None
Monitoring and evaluation	Ministry of Health (MOH) has established M&E systems and procedures, which are captured in the NVDP. Paper based and digital tools are being used to capture vaccination details of eligible populations. Readiness: Complete	None
Vaccine, cold chain, logistics, infrastructure	An in-depth assessment for vaccine storage capacity completed to confirm ability to vaccinate eligible population in Bhutan. Readiness: Complete	None
Safety	Adverse Events Following Immunization (AEFI) surveillance is integrated	None

Readiness domain	Readiness of government	Key gaps to address before deployment
surveillance	with Bhutan Vaccine System (BVS) for real time reporting and monitoring of AEFIs through the web portal, by the NITAG and Regional National Immunization Technical Advisory Groups (RITAGs), in coordination with families, schools and teachers on daily basis. Readiness Complete	
Demand generation and communication	RCCE strategy for information awareness, demand generation, and rumor control deployed. Readiness: Complete	None

17. **Bhutan’s robust preparation and readiness for COVID-19 vaccine deployment has been instrumental in its high vaccination coverage.** The systems established and leveraged for ensuring full vaccination of 95 percent of eligible population above 12 years of age will be judiciously used for deploying vaccination for children 5-11 years of age, as well as boosters for eligible populations, in a campaign mode, as per vaccine availability.

(b) National Vaccination and Deployment Plan (NVDP)

18. **The RGOB prepared a NVDP based on the findings of the VRAF/VIRAT 2.0 assessment and gap analysis undertaken in January 2021.** This plan was updated as of October 10, 2021 to guide Bhutan’s intent to expand coverage of COVID-19 vaccination to its adolescent population 12-17 years of age. The Drug Regulatory Authority (DRA) of Bhutan approved administration of and the NITAG recommended use of Moderna vaccines for the adolescents 12-17 years of age. With this revision in NVDP, Bhutan will vaccinate at least 80 percent of the population, with targets set for different phases of vaccination (refer to Table 4). With the availability of safe and effective COVID-19 vaccines for children below 5 years of age, the NVDP was amended as of December 2021 to guide Bhutan’s intent to vaccinate as well as boost eligible populations below 5 years of age and safeguard their health (accounting for 92 percent of its population above 5 years of age). Vaccine acceptance in Bhutan is high as evidenced by its excellent experience with the introduction of new vaccines, trust and confidence in routine immunization program, high immunization coverage (97 percent), absence of anti-vaccine lobbyists and high political commitment to safeguard the population from COVID-19 through evidence-based preventive strategies. The demand for booster doses is expected to be very high.

19. **The MOH has successfully deployed vaccines (AstraZeneca and Covishield vaccines requiring cold chain of 2-8 degrees centigrade; and Moderna vaccines requiring cold chain of -20 degrees centigrade) through its conventional supply chain and cold chain.** Leveraging the ability of Moderna vaccines to be stored at 2-8 degrees once removed from -20 degrees environment, Bhutan has made these vaccines available to its health centers, primary health centers, and vaccination sites. Separately it has established an ultra-cold chain (-70 degree centigrade) storage and supply chain to successfully deploy Pfizer vaccines. Helicopters have been pressed into service to deliver Pfizer vaccines to remote areas.

20. **Surveillance of AEFI has been integrated into BVS for real time reporting and monitoring of any AEFIs through its web-portal.** The NITAG and RITAG monitor AEFI cases on a daily basis. Since the start of the COVID-19 vaccination campaign, 8,526 minor AEFI cases (1.8 percent of total vaccinations) and 45



major AEFI cases (0.01 percent of total vaccinations) were reported. The identified AEFI cases are managed in line with the approved protocol with full oversight of the NITAG and RITAG.

21. **With regards to indemnification, the RGOB has confirmed that modalities are in place to enter into indemnity and liability agreements.** Box 2 provides additional information. Bhutan's NVDP clarifies that the Bhutan DRA is responsible for (i) the assessment of COVID-19 vaccines' safety and efficacy, and (ii) the authorization of the vaccines deployed in the country.

22. **With the increasing availability of safe and effective vaccines to prevent and minimize the spread of the pandemic, Bhutan has resolutely developed a strong vaccine portfolio** through bilateral diplomacy with friendly nations and neighbors, direct procurement from manufacturers using domestic resources and credits, and donations through the COVAX AMC facility to be delivered and administered before December 2023 (refer to Table 5).



Table 2: National Vaccine Coverage and Acquisition Plan

[Based on the available estimates as of February 28, 2022]

Source of financing (IBRD, IDA, TF, Govt, Other)	Population Targeted (out of 756,131 total population)		Vaccines				Number of doses needed (2 doses per person with 10% wastage)	Estimated total US\$ (millions)	World Bank's VAC Status of the vaccine	Contract Status	Vaccines already arrived in the country	
	%	Number	Source	Name	Price (\$/dose)	Shipping (\$/dose)					Name	Doses
Stage 1: (Phase 1, Phase 2 and Phase 3 of NVDP + immunocompromised persons)												
Government of India	79	- 522,558 adults >18 years; and - 75,960 adolescents 12-17 years	Donation from India	Covishield	free	free	1,316,739	Not known	Approved	Already received	Covishield	550,000
COVAX donation			US Government donation	Moderna	free	free		Not known	Approved	Already received	Moderna	500,000
G2G			Donation from Denmark, Bulgaria, Croatia	AstraZeneca	free	free		Not known	Approved	Already received	AstraZeneca	432,100
COVAX grant			COVAX	Pfizer	free			Not known	Approved	Already received	Pfizer	5,850
RGOB			RGOB	Pfizer	N/A	N/A		Not known	Approved	Already received	Pfizer	198,900
RGOB+ IDA (cost share)			RGOB+IDA	Moderna	N/A*	N/A		N/A	Approved	Already received	Moderna	250,000
Stage 1 total							1,316,739					1,936,850
Stage 2: (Phase 4 Children less than 12 years and Pregnant Women of Phase 4 of NVDP)												



Source of financing (IBRD, IDA, TF, Govt, Other)	Population Targeted (out of 756,131 total population)		Vaccines				Number of doses needed (2 doses per person with 10% wastage)	Estimated total US\$ (millions)	World Bank's VAC Status of the vaccine	Contract Status	Vaccines already arrived in the country	
	%	Number	Source	Name	Price (\$/dose)	Shipping (\$/dose)					Name	Doses
RGOB+ Donors	13	- 11,000 pregnant women, - 83,226 children 5-11 years of age,	Various sources including Domestic, IDA and ADB	Moderna/Pfizer	-	-	207,297	-	Approved	-	Pfizer	270,000
Stage 2 total												
NATIONAL TOTAL		756,131					207,297					2,206,850**
Stage 3: First single dose booster dose for eligible population >5 years of age												
RGOB + Donors	92	- 533,588 population >18 years - 75,960 population 12-17 yrs - 83,226 population 5-11 years	Various sources including Domestic, IDA and ADB	Moderna/Pfizer			762,018		Approved		-	-
Stage 3 total							762,018					-

* Information has been provided to the Bank in confidence and remains restricted from public access unless and until there is prior written consent to disclose.

**RGOB has donated 230,000 and 150,000 doses of AstraZeneca to Nepal and Thailand respectively.

Box 2: Liability and Indemnification Issues in Vaccine Acquisition

Background.

- The rapid development of vaccines increases **manufacturers’ potential liability** for adverse effects following immunization (“AEFI”).
- Manufacturers want to protect themselves from this risk by including immunity from suit and liability clauses, **indemnification** provisions and other **limitation of liability** clauses in their supply contracts.
- **Contractual provisions and domestic legal frameworks** can all operate to allocate that risk among market participants, but **no mechanism will eliminate this risk entirely**.

For COVAX-financed vaccines for AMC countries

- COVAX has negotiated model indemnification provisions with manufacturers for vaccines purchased and supplied under the COVAX AMC.
- In providing vaccines through COVAX AMC, COVAX requests COVAX AMC participants to have in place an indemnity agreement directly with manufacturers, and the necessary indemnity and liability frameworks for that purpose – either in the form of the COVAX model indemnification arrangements or prior bilateral arrangements with manufacturers.
- The COVAX Facility will have a no-fault compensation mechanism to provide compensation for AMC countries as part of its risk mitigation strategy. This will cover vaccines supplied only through COVAX AMC.
- Bhutan will have to consider what it will take to implement these indemnification provisions (including statutory implementation) and how they can avail of the benefits of the no-fault compensation scheme.

For vaccines purchased directly from the manufacturers (outside of COVAX)

- Bhutan will need to enter into direct indemnification arrangements with manufacturers.
- Bhutan has cabinet approval (Cabinet approval vide letter No. C-3/95/2021/976 dated July 16, 2021) to provide statutory immunity for manufacturers, except for claims or liabilities resulting from: (a) willful misconduct or gross negligence of a manufacturer; or (b) a quality defect in the approved vaccine due to failure to comply with good manufacturing practices.
- To date, Bhutan has entered into agreements with Pfizer and Moderna for the purpose of vaccines purchase outside of COVAX.
- Adoption of any such indemnification provisions would have to be in accordance with Bhutan’s own national strategy and framework. As per Bhutan’s own national strategy, in case of AEFI, treatment, care and support will be provided free of charge like any other health care services.

World Bank Assistance. The World Bank may assist the country through: (a) sharing information on (i) statutory frameworks in Organization for Economic Cooperation and Development (OECD) countries and other developing countries; and (ii) sharing overall experience in other countries; and (b) providing training and workshops for government officials to familiarize them with the issues. For World Bank-financed contracts, the World Bank can provide HEIS.

II. DESCRIPTION OF ADDITIONAL FINANCING

A. Proposed Changes

23. **The changes proposed for this AF include:**

- a. *Component Costs*
 - i. Increase Sub-component 1.1 allocation by US\$1.6 million to purchase COVID-19 test kits.
 - ii. Increase Sub-component 1.2 allocation by US\$1.1 million to further support interventions to strengthen health systems.
 - iii. Increase Sub-component 1.3 allocation by US\$7.25 million to purchase additional COVID-19 vaccines.
 - iv. Increase Component 3 allocation by US\$0.05 million to finance consultant costs associated with implementing the Project over an extended time frame.

Table 3: Project Cost and Financing

Project Components	Original Project Cost	Proposed AF	Total Revised Project Cost
	US\$ million		
Component 1: Emergency COVID-19 Response	4.74	9.95	14.69
Sub-Components 1.1: Case Detection, Confirmation, Contact Tracing, Recording, Reporting	0.70	1.60	2.30
Sub-Component 1.2: Health System Strengthening	2.04	1.10	3.14
Sub-component 1.3: Covid Vaccination	2.00	7.25	9.25
Component 2: Community Engagement and Risk Communication	0.01	0.00	0.01
Component 3: Implementation Management and Monitoring and Evaluation	0.25	0.05	0.30
Component 4: Contingency Emergency Response	0	0	0
Total Costs	5.00	10.00	15.00

- b. *Results Monitoring Framework*: Details of proposed changes to results monitoring framework are provided in Section VII of the Project Paper. The end dates of all indicators are extended till December 31, 2023, to ensure the level of preparedness and responsiveness of the health system to the ongoing pandemic is maintained through the life of the project.
- c. *Project closing date*
 - i. Extend the closing date of the original Credit to December 31, 2023.

Table 4: Priority Groups for Vaccination in Bhutan

Ranking of vulnerable group, or inclusion in which phase	Population group	Number of people	% of population
First	- High risk workers in the healthcare facilities - Active front-liners - Elderly Population >60 years - People with co-morbid conditions*	598,518	79.00
Second	- Passive front-liners - Students (12+ years, functional) - Teachers and staff of schools and institutions (functional) - People with other co-morbid conditions **		
Third	- Remaining population residing in Bhutan 12-59 years who do not fall under any of the above risk population groups - Immunocompromised patients***		
Fourth	- Population <12 years - Pregnant women	94,226	13.00
Total		692,774	92.00
First single dose booster	All eligible population >5 years of age	692,774	92.00
Total		771,608	100.00

*People with co-morbid conditions include: heart disease, diabetes mellitus, chronic respiratory diseases (chronic obstructive pulmonary disease, asthma, Interstitial lung disease, active pulmonary tuberculosis, obesity, cancers, chronic kidney disease and chronic Liver Disease.

**Other co-morbid conditions include: hypertension, cerebrovascular accident, neurological illness, overweight (BMI: 25-30).

*** Currently, inadequate evidence about the licensed vaccine safety in these groups. As per the recommendation of the studies in these population groups, the priority will be revised accordingly.

24. **Based on existent technical guidance for COVID-19 vaccination and boosting, the AF will support boosting of at least an additional 10 percent of Bhutan's eligible population (Table 4).** The AF may support vaccines for additional age groups and additional boosters, as may be recommended by WHO/SAGE with new evidence for their efficacy emerging in the future. Table 5 provides a summary of COVID-19 vaccine sourcing and Bank financing.

Table 5: Summary of COVID-19 Vaccine Sourcing and Bank Financing

National plan target (population %)	Source of vaccine financing and population coverage			Specific vaccines and sourcing plans	Doses purchased with Bank finance (2 doses assumed)	Estimated allocation of Bank financing (US\$)
	COVAX grant	Bank-financed				
		Through COVAX	Through direct purchase			
(This AF) - Vaccination : 28,800 (3.8%) - Boosting: 193,976 (28%)			- MD (3.8%) - MD/PZ (28%)		- N/A* - N/A* and N/A**	Purchase-N/A* Deployment-N/A*
First +		-	-	- Grant from India (AZ, SII)	N/A	Purchase-

National plan target (population %)	Source of vaccine financing and population coverage			Specific vaccines and sourcing plans	Doses purchased with Bank finance (2 doses assumed)	Estimated allocation of Bank financing (US\$)	
	COVAX grant	Bank-financed					Other*
		Through COVAX	Through direct purchase				
Second + Third: 79%	PZ (1.0%)	-	MD (6%)	- Grant from USA (MD) - Grant from Denmark (AZ) - Grant from Bulgaria (AZ) - Grant from Croatia (AZ) - Domestic (PZ) - Domestic (MD)	N/A*	N/A* Deployment- N/A*	
Fourth: 19%		-		- ADB (PZ, 11%)	N/A**		
First single dose booster: 92%			- MD/PZ (28%)		N/A**	N/A**	

*Other: Includes coverage by the government, bilateral and other MDBs; AZ=Astrazeneca, MD=Moderna (Spikevax), SII= Serum Institute of India, PZ=Pfizer-BioNTech

N/A = Not Applicable

N/A* = Information has been provided to the Bank in confidence and remains restricted from public access unless and until there is prior written consent to disclose

N/A** = Not Available

25. **In accordance with the provisions under the MPA-Program, retroactive financing will be available for this AF in response to urgent needs for vaccine procurement.** Retroactive financing up to 60 percent of the AF Credit amount (up to US\$6 million equivalent) will be allowed for eligible expenditures paid by the Government from October 01, 2021. The Bank will review government expenditures for eligibility to be reimbursed.

B. Sustainability

26. **There is strong political commitment in Bhutan to mobilize financial resources for COVID-19 response, including for vaccine purchase and deployment.** Bhutan's participation in the COVAX AMC program, commitment of domestic resources towards a strong COVID-19 health response, and willingness to borrow resources from multilateral development banks to complement the immediate and medium-term domestically financed COVID-19 health response demonstrates the government's commitment to its strategy to minimize the impact of COVID-19 on its population and its economy. This coupled with its engagement with other donors and UN agencies for technical assistance to inform its strategy for COVID-19 health response, particularly vaccine deployment, alludes to effectively leveraging available resources for maximal impact. Additionally, in contributing to emergency COVID-19 health response as well as health systems strengthening, the AF will contribute to long-germ pandemic preparedness.

III. KEY RISKS

27. **The overall residual risk to achieving the PDO with the AF is Moderate.** The restructured project has demonstrated satisfactory performance thus far in launching and sustaining a strong COVID-19 health response, in collaboration and coordination with key stakeholders, including technical and multi-lateral agencies, achieving high vaccination, and boosting rates, strong compliance on environment and social



safeguards, strong fiduciary performance, including significant procurements already concluded that are proposed to be retroactively financed by this AF. While uncertainties remain in securing and administering vaccines to populations above 5 years old and booster shots, given Bhutan's very encouraging performance with vaccinating and boosting populations above 12 years of age, a Moderate residual risk rating for the AF is recommended. The remnant risks are associated with Environment and Social in terms of (a) engaging and securing the trust and acceptance of the last remaining unreached populations with final dose of primary series and booster doses in full consultation and collaboration with community influencers/stakeholders and (b) appropriate management of vaccine waste. The Project will continue to implement recommends strategies and mitigation measures articulated in SEP and ESMF to ensure all populations in Bhutan have access to the interventions deployed by the Project and harm to the environment on account of project interventions is minimized.

IV. APPRAISAL SUMMARY

C. Technical, Economic and Financial Analysis

28. The Technical, Economic and Financial summary for this AF is consistent with the analysis presented in the Restructuring Paper of the Project, approved December 15, 2021.

D. Financial Management

29. **The Financial Management (FM) appraisal summary comprising financial management systems, fund flow and reporting arrangements, risks mitigation measures and disbursement arrangements for this AF are consistent with the analysis presented in the Restructuring Paper of the Project,** approved December 15, 2021. Accordingly, the AF will be implemented using the existing RGOB's financial management systems. These comprise budgeting including separate financing item code, accounting, funds flow, internal control, reporting, and external audit. Project funds will be deposited in advance into the Designated Account (DA) maintained in Ngultrum at the Bank of Bhutan Ltd. and operated by Department of Macroeconomic Affairs (DMEA) of Ministry of Finance. The Project would report the expenditure on a quarterly basis, within 45 days of the close of the quarter, in the form of IUFs. Disbursements would be made based on Statement of Expenditures, replenishing the funds in the DA after adjusting for past disbursements. The DA will be segregated and used only to deposit advances for the Project. The funds flow arrangement will also include issuance of UN Commitments for disbursement to UN agencies based on submission of withdrawal applications in the system. The funds flow will take place through a government budget fund account (BFA) and the internal controls will be based on Financial Rules and Regulations (FRR) 2016.

30. **Retroactive Financing.** Approvals have been secured from the Regional Vice President to exceptionally increase the retroactive financing limit from 20 to 60 percent of the credit for eligible expenditures incurred by the government between October 1, 2021 and the date of the signed Financing Agreement. Retroactive expenditures would be reimbursed to the government, following a FM review of the expenditures and as soon as the AF is effective.

31. **Internal Audit.** The internal auditor of MOH will review project activities of each of the spending unit at least once every financial year. The Royal Audit Authority will carry out the external audit the



Project's consolidated annual financial statements each year in line with terms of reference agreed with the Bank and submit it within six months after the end of the financial year.

E. Procurement

32. **As with the parent Project, procurement under the AF will be carried out in accordance with the World Bank Procurement Regulations for IPF Borrowers**, November 2020 ("Procurement Regulations") and the approved Procurement Plan. The AF will continue to be subject to the World Bank's Anti-Corruption Guidelines (ACGs), dated October 15, 2006, revised in January 2011, and July 1, 2016. The AF will also continue to use the Systematic Tracking of Exchanges in Procurement (STEP) to plan, record and track procurement transactions.

33. **The major procurement expected under the AF is vaccines.** Other non-vaccine procurement will likely include diagnostic kits and other items based on need. Consultant services will mainly include hiring/retaining the individual consultants for the extended period of the Project.

34. **The PIU of the parent Project will continue to carry out procurement under the proposed AF.** The procurement arrangements, including methods of procurement and Bank's review requirements will remain the same as the parent Project with availability of flexibilities under fast-track procurement. As was agreed during the preparation of the parent Project, the World Bank will continue with HEIS to the MoH. In addition, the option for Bank Facilitated Procurement will remain available. The Project Procurement Strategy for Development (PPSD) along with the procurement plan, including the appropriate methods of procurement and the Bank's review requirements, have been updated to incorporate activities under the AF. Contracts for vaccines will be subject to the World Bank's prior review irrespective of value and procurement approach.

35. **As previously stated, retroactive financing will be provided for eligible payments under contracts implemented by the MoH** if: (i) the procurement procedures, including publication of contract award information, are consistent with the Bank's Procurement Regulations; and (ii) the contractor/supplier/consultant has explicitly agreed to comply with the relevant provisions of the World Bank's ACGs, including the World Bank's right to inspect and audit all accounts, records, and other documents relating to the project that are required to be maintained pursuant to the Financing Agreement.

36. **Procurement risks include** (i) The market for COVID-19 vaccines is uncertain and complex and limited market access by RGOB due to advance orders by other countries and potentially insufficient bargaining power; (ii) lack of procurement capacity of the PIU; (iii) delay in procurement decision making; (iv) lack of coordination between the PIU and other divisions and units, and (v) weaknesses in procurement processing by MOH identified from the Bank's procurement post review of the parent project's contracts awarded before June 30, 2020, which are being followed up with the PIU and lessons learnt incorporated in the mitigation measures for the AF.

37. **Procurement risks will be mitigated through the following mitigation measures:** (i) availability of flexible arrangements under fast-track procurement; (ii) procurement of vaccines in WHO's approved list using Direct Selection method to purchase directly from manufacturers; (iii) technical assistance through HEIS including BFP; (iv) retaining the procurement consultant for the proposed AF; (v) training of

the relevant government officials on procurement, contract management, and fiduciary due diligence; (vi) PIU ensuring consistency in procurement approach between the procurement plan and actual procurement, (vii) maintaining complete procurement records including evaluation reports, minutes of contract negotiations, contract agreements, with timely uploading of procurement documents in STEP, and (viii) the World Bank’s procurement oversight through increased implementation support including prior review of all contracts for vaccines and conducting procurement post review by the Bank at least once annually or more frequently based on need. The residual procurement risk after mitigation remains Substantial due to the uncertainty and complexity of the market for supply of Covid-19 vaccines.

F. Legal Operational Policies

	Triggered?
Projects on International Waterways OP 7.50	No
Projects in Disputed Areas OP 7.60	No

G. Environmental and Social

38. The Environment and Social (E&S) appraisal summary for the AF is consistent with the analysis presented in the Restructuring Paper of the Project, approved December 15, 2021. The E&S documents, specifically, Environment and Social Commitment Plan, ESMF, SEP, and LMP, have been updated to reflect the AF components, including the activities being retroactively financed, and address emerging risks and disclosed in-country on February 26, 2022.³

H. Gender

39. The appraisal summary for gender for the AF is consistent with the analysis presented in the Restructuring Paper of the Project, approved December 15, 2021. This proposed AF is aligned with the measures instituted by the Project to address gender gaps. These included (a) free, equitable and gender-sensitive access to testing, tracing, isolation/quarantine and treatment facilities as part of the COVID-19 health response; (b) provision of gender-sensitive COVID-19 vaccination and boosting facilities in campaign mode through gender-balanced vaccination teams; (c) near universal uptake of COVID-19 vaccination and booster doses by eligible population >12 years of age; (d) gender-sensitive community engagement and risk communications, particularly targeting pregnant and lactating women; (e) toll-free helplines to register and refer incidents of sexual exploitation and abuse (SEA)/ sexual harassment/GBV to appropriate agencies for redress; (f) training contractors and vendors engaged in project-financed works contracts to identify and report on GBV; and (g) tracking coverage of COVID-19 primary series vaccination and boosting through gender disaggregated PDO indicators. Given Bhutan’s exemplary performance on gender-sensitive COVID-19 health response, there is limited scope to identify additional appropriate options to further strengthen the gender-sensitivity of COVID-19 Health response.

³ <https://www.moh.gov.bt/additional-financing-bhutan-to-bhutan-covid-19-emergency-response-and-health-systems-project-disclosure-of-updated-safeguards-documents/>



I. Climate Vulnerability and Resilience

40. The climate vulnerability and resilience appraisal summary for the AF is consistent with the analysis presented in the Restructuring Paper of the Project, approved December 15, 2021. Bhutan is vulnerable to risks of extreme temperature, drought, geo-physical hazards, strong winds, extreme precipitation and flooding. Historical records indicate an increase in annual temperatures of just under 1°C over the 20th century in Bhutan, with daily minimum temperatures increasing at a greater pace than daily maximum temperatures. Flooding is considered to be the most significant climate-related hazard faced by Bhutan. The impact of flooding on human health and livelihoods is expected to grow and could be 4 percent of GDP by the 2030s. Climate models project a significant increase in the likelihood of heatwaves and droughts. Higher temperatures are projected to also contribute to increased snowmelt which could change patterns of river discharge and water availability. A climate and disaster risk screening is completed for the AF using the rapid screening assessment tool. Climate and geophysical hazards are assessed to pose a moderate risk to the project activities and risks to the outcome as well as service delivery under the project are assessed to be low. The moderate and low risks are on account of this AF largely retroactively financing vaccines and diagnostic test kits that have already been successfully procured and deployed for Bhutan’s population, without the identified risks having materialized. Since this AF is only mostly financing the procurement of COVID-19 diagnostic test kits and vaccines, there is limited scope of accruing any climate co-benefits on account of adaptive or mitigation measures.

J. Citizen Engagement

41. Mechanisms to engage citizens, and target beneficiaries more specifically, in providing ideas and feedback on program delivery are helpful in identifying gaps at the point of service delivery (information availability, access to testing and vaccination, access to relevant care, equal treatment etc.), build community knowledge and confidence, establish trust, ensure governments respond to community needs (including vulnerable groups), and thus to optimize the impact of the COVID-19 emergency response.

K. Jobs & Economic Transformation

42. The COVID-19 pandemic has caused loss of livelihoods due to morbidity and mortality globally. Bhutan’s economy, which relies heavily on tourism, has suffered losses largely on account of morbidity and continued lockdowns to manage community transmission of the pandemic. Over 16 percent of the working population (largely youth), is employed in the tourism sector, and has also faced highest morbidity. Vaccinating and boosting eligible populations above the age of 5 with safe and effective vaccines is critical to safeguarding their health and the nation’s economy, by way of reducing mortality, morbidity, and mutations that have the propensity to perpetuate the pandemic. COVID-19 testing, tracing, treatment, vaccinations and boosters, which this AF proposes to finance, will support a COVID safe population that can get back to jobs and livelihoods and help the economy recuperate, thereby meeting the corporate commitment to support jobs and economic transformation.

V. WORLD BANK GRIEVANCE REDRESS

43. **Communities and individuals who believe that they are adversely affected by a World Bank (WB) supported project may submit complaints to existing project-level grievance redress mechanisms**

or the WB’s Grievance Redress Service (GRS). The GRS ensures that complaints received are promptly reviewed in order to address project-related concerns. Project affected communities and individuals may submit their complaint to the WB’s independent Inspection Panel which determines whether harm occurred, or could occur, as a result of WB non-compliance with its policies and procedures. Complaints may be submitted at any time after concerns have been brought directly to the World Bank's attention, and Bank Management has been given an opportunity to respond. For information on how to submit complaints to the World Bank’s corporate Grievance Redress Service (GRS), please visit <http://www.worldbank.org/en/projects-operations/products-and-services/grievance-redress-service>. For information on how to submit complaints to the World Bank Inspection Panel, please visit www.inspectionpanel.org.

VI SUMMARY TABLE OF CHANGES

	Changed	Not Changed
Results Framework	✓	
Components and Cost	✓	
Loan Closing Date(s)	✓	
Implementing Agency		✓
Project's Development Objectives		✓
Cancellations Proposed		✓
Reallocation between Disbursement Categories		✓
Disbursements Arrangements		✓
Legal Covenants		✓
Institutional Arrangements		✓
Financial Management		✓
Procurement		✓
Other Change(s)		✓

VII DETAILED CHANGE(S)



MPA PROGRAM DEVELOPMENT OBJECTIVE

Current MPA Program Development Objective

The Program Development Objective is to prevent, detect and respond to the threat posed by COVID-19 and strengthen national systems for public health preparedness

Proposed New MPA Program Development Objective

EXPECTED MPA PROGRAM RESULTS

Current Expected MPA Results and their Indicators for the MPA Program

Progress towards the achievement of the PDO would be measured by outcome indicators. Individual country-specific projects (or phases) under the MPA Program will identify relevant indicators, including among others:

- Country has activated their public health Emergency Operations Centre or a coordination mechanism for COVID-19;
- Number of designated laboratories with COVID-19 diagnostic equipment, test kits, and reagents;
- Number of acute healthcare facilities with isolation capacity;
- Number of suspected cases of COVID-19 reported and investigated per approved protocol;
- Number of diagnosed cases treated per approved protocol;
- Personal and community non-pharmaceutical interventions adopted by the country (e.g., installation of handwashing facilities, provision of supplies and behavior change campaigns, continuity of water and sanitation service provision in public facilities and households, schools closures, telework and remote meetings, reduce/cancel mass gatherings);
- Policies, regulations, guidelines, or other relevant government strategic documents incorporating a multi-sectoral health approach developed/or revised and adopted;
- Multi-sectoral operational mechanism for coordinated response to outbreaks by human, animal and wildlife sectors in place;
- Coordinated surveillance systems in place in the animal health and public health sectors for zoonotic diseases/pathogens identified as joint priorities; and
- Mechanisms for responding to infectious and potential zoonotic diseases established and functional; and
- Outbreak/pandemic emergency risk communication plan and activities developed and tested

**Proposed Expected MPA Results and their Indicators for the MPA Program****COMPONENTS**

Current Component Name	Current Cost (US\$, millions)	Action	Proposed Component Name	Proposed Cost (US\$, millions)
Emergency COVID-19 Response	4.74	Revised	Emergency COVID-19 Response	14.69
Community Engagement and Risk Communication	0.01	Revised	Community Engagement and Risk Communication	0.01
Implementation Management and Monitoring and Evaluation	0.25	Revised	Implementation Management and Monitoring and Evaluation	0.30
Contingency Emergency Response Component	0.00	No Change	Contingency Emergency Response Component	0.00
TOTAL	5.00			15.00

LOAN CLOSING DATE(S)

Ln/Cr/Tf	Status	Original Closing	Current Closing(s)	Proposed Closing	Proposed Deadline for Withdrawal Applications
IDA-66270	Effective	31-Dec-2022	31-Dec-2022	31-Dec-2023	30-Apr-2024

Expected Disbursements (in US\$)

Fiscal Year	Annual	Cumulative
2020	1,844,172.88	1,844,172.88
2021	1,232,757.69	3,076,930.57
2022	5,890,000.00	8,966,930.57
2023	6,000,000.00	14,966,930.57
2024	33,069.43	15,000,000.00



SYSTEMATIC OPERATIONS RISK-RATING TOOL (SORT)

Risk Category	Latest ISR Rating	Current Rating
Political and Governance	● Moderate	● Moderate
Macroeconomic	● Moderate	● Moderate
Sector Strategies and Policies	● Moderate	● Moderate
Technical Design of Project or Program	● Moderate	● Moderate
Institutional Capacity for Implementation and Sustainability	● Moderate	● Moderate
Fiduciary	● Moderate	● Moderate
Environment and Social	● Substantial	● Substantial
Stakeholders	● Substantial	● Moderate
Other	● Moderate	● Moderate
Overall	● Substantial	● Moderate

LEGAL COVENANTS – Additional Financing to Bhutan COVID-19 Emergency Response and Health Systems Preparedness Project (P178656)

Sections and Description

Section I.A.1, Schedule 2: The Recipient shall maintain, at all times during the implementation of the Project, the Project Steering Committee, with functions, composition and resources satisfactory to the Association, to be responsible for, inter alia: (a) providing strategic and policy guidance on the implementation of the Project; (b) reviewing progress made towards achieving the Project’s objectives; and (c) facilitating coordination of Project activities and removal of any obstacle(s) to the implementation of the Project.

Section I.A.2, Schedule 2: The Recipient shall maintain, at all times during the implementation of the Project, such number of EPI units, with adequate number of staff and/or consultants, to be responsible for the implementation of Part 1.3 of the Project.

Section I.B, Schedule 2: The Recipient shall (a) ensure that the Project is carried out in accordance with the National COVID-19 Preparedness and Response Plan, 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 Association.

Section I.D, Schedule 2: The Recipient, through the MOH, shall ensure that the collection, use and processing (including transfers to third parties) of any personal data collected under this Project shall be done in accordance with the data protection principles contained in the Information, Communication, and Media Act of Bhutan 2018 and applicable best international practice, ensuring legitimate, appropriate, and proportionate treatment of such data

Section I.G, Schedule 2: Without limitation on Section I.A (Institutional Arrangements) above, the Recipient shall implement Part 1.3 of the Project in accordance with the plan for the Project COVID-19 Vaccine delivery and



distribution (“Vaccine Delivery and Distribution Plan”), in form and substance satisfactory to the Association, 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;
- (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 national law on Personal Data Protection if it is deemed adequate and best international practice; and
- (d) vaccine distribution plan, including action plan setting out timeline and steps for immunization.

Section I.H, Schedule 2: All Project COVID-19 Vaccines shall satisfy the Vaccine Approval Criteria.

Conditions

Type	Financing source	Description
Disbursement	IBRD/IDA	Retroactive Financing: No withdrawal shall be made for payments made prior to the Signature Date, except that withdrawals up to an aggregate amount not to exceed not to exceed (i) SDR 1,737,000 may be made for payments made prior to this date but on or after October 01, 2021, for Eligible Expenditures under Category (1) and (ii) SDR 2,578,000 may be made for payments made prior to this date but on or after October 01, 2021, for Eligible Expenditures under Category (3).
Disbursement	IBRD/IDA	CERC: No withdrawal shall be made for Emergency Expenditures under Category (2), unless and until: (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 (2); and (B) the Association has agreed with such determination, accepted said request and notified the Recipient thereof; (ii) the Recipient has adopted the CERC Manual and Emergency Action Plan, in form and substance acceptable to the Association.

VIII. RESULTS FRAMEWORK AND MONITORING

Results Framework

COUNTRY: Bhutan

Additional Financing to Bhutan COVID-19 Emergency Response and Health Systems Preparedness Project

Project Development Objective(s)

To prevent, detect and respond to the threat posed by COVID-19 and to strengthen national systems for public health preparedness in Bhutan

Project Development Objective Indicators by Objectives/ Outcomes

Indicator Name	PBC	Baseline	Intermediate Targets			End Target
			1	2	3	
Prevent, detect and respond to COVID-19 and strengthen health systems						
Bhutan has activated its public health Emergency Operations Centre or a coordination mechanism for COVID-19 (Text)		No	Yes	Yes	Yes	Yes
Action: This indicator has been Revised	Rationale: End line target date extended to December 31, 2023					
Percentage of suspected cases of COVID-19 cases reported and investigated based on national guidelines (Percentage)		0.00	70.00	80.00	90.00	90.00
Action: This indicator has been Revised	Rationale: End line target date extended to December 31, 2023					
Number of acute healthcare facilities with isolation capacity		1.00	2.00	3.00	3.00	3.00



Indicator Name	PBC	Baseline	Intermediate Targets			End Target
			1	2	3	
(Number)						
Action: This indicator has been Revised	Rationale: End line target date extended to December 31, 2023					
Country adopted personal and community non-pharmaceutical interventions (Text)	No	Yes	Yes	Yes	Yes	Yes
Action: This indicator has been Revised	Rationale: End line target date extended to December 31, 2023					
Percentage of population vaccinated, which is included in the priority population targets defined in national plan [by gender] (Percentage)	0.00					5.60
Action: This indicator has been Revised	Rationale: End line target enhanced and date extended to December 31, 2023					
Percentage of males vaccinated (Percentage)	0.00	50.00				50.00
Action: This indicator is New	Rationale: To track gender equity in vaccine deployment					
Percentage of females vaccinated (Percentage)	0.00	50.00				50.00



Indicator Name	PBC	Baseline	Intermediate Targets			End Target
			1	2	3	
Action: This indicator is New	Rationale: To track gender equity in vaccine deployment					
Percentage of population boosted with a single vaccine dose, in line with WHO/SAGE guidance (Percentage)		0.00	18.00			28.00
Action: This indicator is New	Rationale: To track progress with boosting of eligible population with COVID-19 vaccine doses as advised by WHO/SAGE					
Percentage of males boosted with a single vaccine dose, in line with WHO/SAGE guidance (Percentage)		0.00	50.00			50.00
Action: This indicator is New	Rationale: To track gender equity in booster dose deployment					
Percentage of females boosted with a single vaccine dose, in line with WHO/SAGE guidance (Percentage)		0.00	50.00			50.00
Action: This indicator is New	Rationale: To track gender equity in booster vaccine deployment					



Intermediate Results Indicators by Components

Indicator Name	PBC	Baseline	Intermediate Targets			End Target
			1	2	3	
Emergency COVID-19 Response						
Number of health staff trained in infection prevention and control per MoH protocols (Number)		0.00	50.00	50.00	100.00	100.00
Action: This indicator has been Revised	Rationale: End line target date extended to December 31, 2023					
Percentage of specimens submitted for SARS-COV2 laboratory testing and confirmed within WHO stipulated standard time (Percentage)		0.00	70.00	80.00	90.00	95.00
Action: This indicator has been Revised	Rationale: End line target date extended to December 31, 2023 and target enhanced to 95%					
Number of acute healthcare facilities with triage capacity (Number)		1.00	2.00	3.00	8.00	10.00
Action: This indicator has been Revised	Rationale: Date for end line target revised to December 31, 2023 and target revised to 10					
A National Vaccination and Deployment Plan (NVDP) with input from relevant bodies (NITAG, DRA, National Immunization Program, National Regulatory Authority, AEFI committee), in line with WHO guidance (Text)		No	Yes			Yes



Indicator Name	PBC	Baseline	Intermediate Targets			End Target
			1	2	3	
Action: This indicator has been Revised	Rationale: Date for endline target revised to December 31, 2023					
Potential numbers of target populations estimated who will be prioritized for access to vaccines stratified by target group and geographic location (Text)	No	Yes				Yes
Action: This indicator has been Revised	Rationale: Date for endline target revised to December 31, 2023					
Guidelines, documented procedures and tools for planning and conducting vaccine pharmacovigilance activities established (Text)	No	Yes				Yes
Action: This indicator has been Revised	Rationale: Date for endline target revised to December 31, 2023					
Community Engagement and Risk Communication						
Bhutan has contextualized its risk communication and community engagement strategies (Text)	No	Yes	Yes	Yes	Yes	Yes
Action: This indicator has been Revised	Rationale: Date for endline target revised to December 31, 2023					
Percentage of received grievances that are addressed (within specified time/protocol) (Percentage)	0.00	60.00	80.00	80.00	80.00	80.00



Indicator Name	PBC	Baseline	Intermediate Targets			End Target
			1	2	3	
<i>Action: This indicator has been Revised</i>	<i>Rationale: Date for endline target revised to December 31, 2023 and unit of measure updated from text to percentage</i>					
Implementation Management and Monitoring and Evaluation						
M&E system established to monitor COVID-19 preparedness and response plan (Text)		No	Yes	Yes	Yes	Yes
<i>Action: This indicator has been Revised</i>	<i>Rationale: The date for endline target revised to December 31, 2023</i>					
Joint supervision and monitoring visits conducted (Number)		0.00	1.00	3.00	4.00	6.00
<i>Action: This indicator has been Revised</i>						

Monitoring & Evaluation Plan: PDO Indicators

Indicator Name	Definition/Description	Frequency	Datasource	Methodology for Data Collection	Responsibility for Data Collection
Bhutan has activated its public health Emergency Operations Centre or a coordination mechanism for COVID-19		6 monthly review	MoH Records	Review of HEOC updates	MoH
Percentage of suspected cases of COVID-19 cases reported and investigated based on national guidelines		6 monthly	MoH records	Review information from MoH and laboratories	MoH
Number of acute healthcare facilities with isolation capacity		6 monthly review	MoH records	Visit health facilities	MoH



Country adopted personal and community non-pharmaceutical interventions		Will be monitored during the emergency period	Public disclosures/gazettes	Review public disclosures and national gazettes	MoH
Percentage of population vaccinated, which is included in the priority population targets defined in national plan [by gender]	Numerator- number of eligible people vaccinated with COVID-19 vaccines financed by the World Bank Denominator- total population	Six monthly	MOH records/MIS	Both paper based and digitalized MIS will collect the information on vaccines administered.	MOH
Percentage of males vaccinated	Numerator: No: of males fully vaccinated with vaccines financed by the World Bank Denominator: Total no: of individuals fully vaccinated	Six monthly	MOH records/MIS	Both paper based and digitalized MIS will collect information on vaccines administered	MOH
Percentage of females vaccinated	Numerator: Number of females fully vaccinated with vaccines financed by the World Bank Denominator: Total number of individuals fully vaccinated	Six monthly	MOH records/MIS	Both paper-based and digitalized MIS will collect the information on vaccines administered.	MOH
Percentage of population boosted with a single vaccine dose, in line with WHO/SAGE guidance	Numerator: Number of individuals boosted with a single COVID-19 vaccine dose financed by the World Bank	Six monthly	MOH records/MIS	Both paper-based and digitalized MIS will collect the information on vaccines administered	MOH



	Denominator: Total population of Bhutan				
Percentage of males boosted with a single vaccine dose, in line with WHO/SAGE guidance	Numerator: Number of males boosted with a single COVID-19 vaccine dose financed by the World Bank Denominator: Total population of Bhutan	Six-monthly	MOH records/MIS	Both paper-based and digitalized MIS will collect the information on vaccines administered.	MOH
Percentage of females boosted with a single vaccine dose, in line with WHO/SAGE guidance	Numerator: Number of females boosted with a single COVID-19 vaccine dose financed by the World Bank Denominator: Total population of Bhutan	Six monthly	MOH records/MIS	Both paper-based and digitalized MIS will collect the information on vaccines administered.	MOH

Monitoring & Evaluation Plan: Intermediate Results Indicators

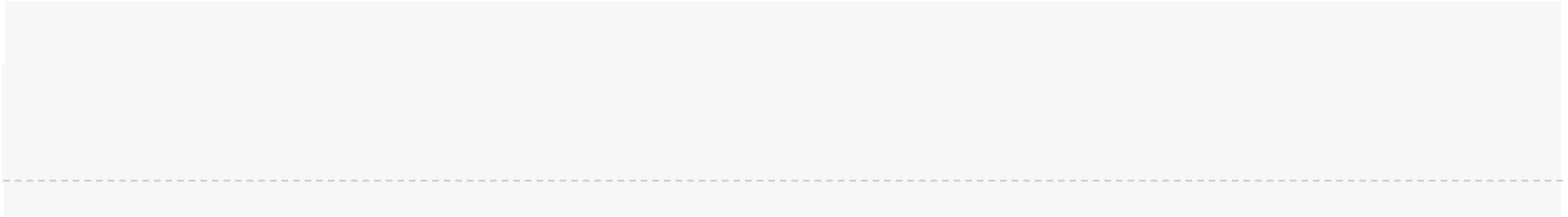
Indicator Name	Definition/Description	Frequency	Datasource	Methodology for Data Collection	Responsibility for Data Collection
Number of health staff trained in infection prevention and control per MoH protocols		6 monthly	MoH records	Review training agenda, participant list and dates of workshop/training conducted	MoH
Percentage of specimens submitted for SARS-COV2 laboratory testing and confirmed within WHO stipulated standard time		6 monthly	Lab reports	Review of lab reports	MoH
Number of acute healthcare facilities with triage capacity		6 monthly	MoH records	Review MoH records and visit the facilities	MoH/HEOC



<p>A National Vaccination and Deployment Plan (NVDP) with input from relevant bodies (NITAG, DRA, National Immunization Program, National Regulatory Authority, AEFI committee), in line with WHO guidance</p>	<p>A National Vaccination and Deployment Plan (NVDP) with input from relevant bodies (NITAG, DRA, National Immunization Program, National Regulatory Authority, AEFI committee), in line with WHO guidance and SAGE recommendations, established.</p>	<p>Recurrent</p>	<p>MOH report</p>	<p>Notification by MOH</p>	<p>MOH</p>
<p>Potential numbers of target populations estimated who will be prioritized for access to vaccines stratified by target group and geographic location</p>	<p>Potential numbers of target populations estimated who will be prioritized for access to vaccines stratified by target group and geographic location, i.e., prepare first to define, identify and estimate no. of health care workers.</p>	<p>Once</p>	<p>MOHP report/NVDP</p>	<p>Estimation by population projection and census data</p>	<p>MOH</p>
<p>Guidelines, documented procedures and tools for planning and conducting vaccine pharmacovigilance activities established</p>	<p>Guidelines, documented procedures and tools for planning and conducting vaccine pharmacovigilance activities (i.e., AEFI reporting, investigation, causality assessment, risk communication and response) are established and available.</p>	<p>Once</p>	<p>MOH reports/NVDP</p>	<p>Going through MOH records</p>	<p>MOH</p>
<p>Bhutan has contextualized its risk</p>		<p>Continuous</p>	<p>MoH records</p>	<p>Review public disclosure</p>	<p>MoH</p>



communication and community engagement strategies				of information and stakeholder engagement forums	
Percentage of received grievances that are addressed (within specified time/protocol)	<ul style="list-style-type: none"> Grievances are defined as both complaints and request for information related to COVID-19 response and access to services Specified time for response to information is 5 working days and specified time for resolution of complaints is 30 working days Denominator is total number of complaints and request for information received Numerator is number of complaints and request for information responded as per specified time. 	every six months	MoH	Information as received from the call center	MoH
M&E system established to monitor COVID-19 preparedness and response plan		Continuous	MoH records	Verify by reviewing reporting system for COVID-19	MoH
Joint supervision and monitoring visits conducted		6 monthly	MoH records	Review MoH records and WB confirms as WB will be part of the visits	MoH





ANNEX 1: SUMMARY TABLE ON VACCINE DEVELOPMENT AND APPROVAL STATUS

as of February 18, 2022

	Manufacturer / WHO EUL holder	Name of Vaccine	SRA approval received	WHO EUL ⁴		
				Platform	NRA of Record for WHO EUL	Status of assessment
1.	BioNTech Manufacturing GmbH	BNT162b2/COMIRNATY Tozinameran (INN)	United Kingdom: December 2, 2020 Canada: December 9, 2020 United States of America: December 11, 2020 European Union: December 21, 2020 Switzerland: December 19, 2020 Australia: January 25, 2021	Nucleoside modified mRNA	EMA	<ul style="list-style-type: none"> ▪ Finalized: 31/12/2020 ▪ Additional sites: <ul style="list-style-type: none"> – Baxter Oncology GmbH Germany (DP). 30/06/2021 – Novartis Switzerland. 08/07/2021 – Mibe (Dermapharm) Germany (DP). 16/07/2021 – Delpharm, Saint-Remy FRANCE (DP). 17/09/2021 – Siegfried Hameln GmbH, Germany (DP). 11/11/2021 – Patheon Italia S.p.A, Italy (DP). 07/12/2021 ▪ Shelf life extension: 09 months at -70 to -90°C. 20/09/2021 <ul style="list-style-type: none"> – Sanofi-Aventis Deutschland GmbH Germany 06/10/2021 ▪ Diluent suppliers: <ul style="list-style-type: none"> – Pfizer Perth, Australia Fresenius Kabi,

⁴ https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_18February2022.pdf



						<p>USA 18/06/2021</p> <ul style="list-style-type: none"> – Fresenius Kabi, USA 20/09/2021 – Pfizer Manufacturing Belgium 30/11/2021 <ul style="list-style-type: none"> ▪ Booster dose approved for adults 18 years of age and older 12/17/2021 ▪ Age extension to children 5 – 11 years of age 2/12/2022
					USFDA	<ul style="list-style-type: none"> ▪ Additional sites: – Pharmacia & Upjohn, Kalamazoo (DP)PGS McPherson (DP) 16/07/2021 – Exelead, Inc. Indianapolis USA 30/09/2021
2.	AstraZeneca, AB	AZD1222 Vaxzevria	<p>UK: December 30, 2020</p> <p>EU: January 29, 2021</p> <p>Australia: February 16th, 2021 (overseas manufacturing);</p> <p>March 21st, 2021 (for local manufacturing by CSL – Seqirus)</p> <p>Canada: February 26, 2021</p>	<p>Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.</p>	EMA	<ul style="list-style-type: none"> ▪ Core data finalized. 16 April 2021 ▪ Additional sites: – SK-Catalent – Wuxi (DS). 16 April 2021 – Chemo Spain. 30 April 2021 – Amylin Ohio US (DP). 23 July 2021
					MFDS KOREA	<ul style="list-style-type: none"> ▪ Finalized. 15 Feb 2021



					Japan MHLW/PMDA	<ul style="list-style-type: none"> ▪ Finalized. 09 July 2021 ▪ Additional site: <ul style="list-style-type: none"> – Nipro Pharma Corporation Ise, Japan. 11 October 2021
					Australia TGA	<ul style="list-style-type: none"> ▪ Finalized. 09 July 2021 ▪ Additional site: <ul style="list-style-type: none"> – Siam Bioscience Co., Ltd Thailand. 11 October 2021
					COFEPRIS (Mexico) ANMAT (Argentina)	<ul style="list-style-type: none"> ▪ Finalized. 23 December 2021
3.	Serum Institute of India Pvt.Ltd	Covishield (ChAdOx1_nCoV-19)		Recombinant ChAdOx1 adenoviralvector encoding the Spike protein antigen of the SARS-CoV-2.	DCGI	<ul style="list-style-type: none"> ▪ Finalized. 15 Feb 2021 <ul style="list-style-type: none"> – DS and DP Manjari Bk Pune. 11/12/2021
4.		COVOVAX™ COVID-19 vaccine (SARS-CoV-2 rS Protein Nanoparticle [Recombinant])		Recombinant nanoparticle prefusion spike protein formulated with Matrix-M™ adjuvant	DCGI	<ul style="list-style-type: none"> ▪ Finalized. 17 December 2021
5.	Moderna	mRNA-1273	USA: December 18, 2020 Canada: December 23, 2020 EU: January 6, 2021 Switzerland: January 12 th , 2021 UK: January 8, 2021	mNRA-based vaccine encapsulated in lipid nanoparticle (LNP)	EMA	<ul style="list-style-type: none"> ▪ Finalized. 30 April 2021 ▪ Shelf life extension to 09 months -20±5°C, 14 Feb 2022
					USFDA	<ul style="list-style-type: none"> ▪ Additional Sites. 06 August 2021 <ul style="list-style-type: none"> – ModernaTx. Norwood (DS) – Catalent Indiana, LLC (DP)



						<ul style="list-style-type: none"> – Lonza Biologics, Inc. Portsmouth, USA (DS) – Baxter, Bloomington, USA (DP)
					MFDS	<ul style="list-style-type: none"> ▪ Finalized. 23 December 2021
6.	Sinopharm / BIBP ¹ Beijing Institute of Biological Products Co., Ltd. (BIBP)	SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV)		Inactivated, produced in Vero cells	NMPA	<ul style="list-style-type: none"> ▪ Finalized. 07 May 2021 ▪ <i>2 and 5 dose presentation (new manufacturing site) -- TBC after ongoing inspection</i>
7.	Sinovac Life Sciences Co., Ltd. Sinovac Life Sciences Co., Ltd.	COVID-19 Vaccine (Vero Cell), Inactivated/ Coronavac™		Inactivated, produced in Vero cells		<ul style="list-style-type: none"> ▪ Finalized. 01 June 2021 ▪ 2 dose presentation. 30 September 2021
8.	Janssen–Cilag International NV	Ad26.COVS.2.S	USA: February 27th, 2021 Canada: March 5th, 2021 EU: March 11th, 2021 Switzerland: March 22nd, 2021 UK: May 28th, 2021 Australia: June 25th, 2021	Recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding the (SARS-CoV-2) Spike (S) protein	EMA	<ul style="list-style-type: none"> ▪ Core data finalized (US +NL sites). 12 March 2021 ▪ Additional sites: <ul style="list-style-type: none"> – Aspen RSA (DP). 25 June 2021 – Catalent Agnani Italy (DP). 02 July 2021 – Grand River Aseptic Manufacturing Inc., USA. 05 Nov 2021 – MSD (Merck), West Point/PA, USA (DP). 05 Nov 2021 – Sanofi Pasteur France (DP). 27 Jan 2022
9.	Bharat Biotech, India	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)/ COVAXIN		Whole-Virion Inactivated Vero Cell	DCGI	<ul style="list-style-type: none"> ▪ Finalized. 03 Nov 2021
10.	Novavax	NVX-		Recombinant	EMA	<ul style="list-style-type: none"> ▪ Finalized. 20 December



		CoV2373/Nuvaxovid		nanoparticle prefusion spike protein formulated with Matrix-M™ adjuvant		2021
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ANNEX 2: PROJECT DESCRIPTION

The objectives of the Project are to prevent, detect and respond to the threat posed by COVID-19 and to strengthen national systems for public health preparedness in Bhutan.

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

Component 1: Emergency COVID-19 Response

Providing immediate support to limit transmission of COVID-19 through containment strategies, including the following:

1.1. Case Detection, Confirmation, Contact Tracing, Recording, Reporting

Enhancing case detection, confirmation, tracing, recording and reporting through, *inter alia*: (a) strengthening disease surveillance systems and epidemiological capacity for early detection and confirmation of cases; (b) combining detection of new cases with active contact tracing; (c) supporting epidemiological investigation; (d) strengthening risk assessment; (e) providing on-time data and information for guiding decision-making, response and mitigation activities; (f) strengthening the health management information system.

1.2. Health System Strengthening

Strengthening of the public health system through, *inter-alia*: (a) provision of support for preparedness planning to provide optimal medical care, maintain essential community services and to minimize risks for patients and health personnel, including training health facilities staff and front-line workers on risk mitigation measures and providing them with the appropriate protective equipment and hygiene materials; (b) establishing specialized units in selected hospitals, treatment guidelines, clinical training of health workers and hospital infection control guidelines; (c) development of strategies to increase hospital bed availability; (d) rehabilitation and equipment of selected primary health care facilities and hospitals (including intensive care facilities with medical equipment and training of health teams) for the delivery of critical medical services and to cope with increased demand of services posed by the outbreak, develop intra-hospital infection control measures, including improvements in blood transfusion services; and (e) provision of support for ensuring safe water and basic sanitation in health facilities, strengthen medical waste management and disposal systems, mobilization of additional health personnel, training of health personnel, provision of medical supplies, diagnostic reagents and kits.

1.3. Covid vaccination

(a) Supporting Bhutan's health sector in the purchase of Project COVID-19 Vaccine.

(b) Strengthening Bhutan's institutional framework to enable safe and effective Project COVID-19 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.



(c) Supporting the development of Bhutan’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.

Component 2: Community Engagement and Risk Communication

Supporting information and communication activities to raise awareness, knowledge and understanding among the general population about the risks and potential impact of the COVID-19 pandemic as well as on Project COVID-19 Vaccine deployment and to address vaccine hesitancy; through, *inter alia*: (a) real-time exchange of information, advice and opinions, through a mix of communication and engagement strategies, including media and social media communications, mass awareness campaigns including “social distancing” measures, health promotion, social mobilization, stakeholder engagement and community engagement; (b) developing and distributing communication materials, awareness campaigns, training modules, training health frontline workers, printing materials, experts, symposia for advocacy, surveillance, treatment and prophylaxis.

Component 3: Implementation Management and Monitoring and Evaluation

Strengthening the capacity of the Ministry of Health (a) to implement the Project, including support for coordination of Project activities, procurement, financial management, stakeholder engagement, environmental and social risk management, monitoring and evaluation and reporting; and (b) on clinical and public health research and joint learning within and between countries, through *inter alia* provision of technical assistance, IT and communication equipment and Training.

Component 4: Contingency Emergency Response Component (CERC)

Provision of immediate response to an Eligible Crisis or Emergency.