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# INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT AND INTERNATIONAL DEVELOPMENT ASSOCIATION

**PROJECT PAPER** 

ON A

PROPOSED ADDITIONAL FINANCING

TO THE

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

WITH AN ADDITIONAL IBRD AND IDA FINANCING OF UP TO US\$12 BILLION (OF WHICH UP TO US\$6 BILLION FROM IDA AND UP TO US\$6 BILLION FROM IBRD)

October 13, 2020

Human Development Practice Group

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# ABBREVIATIONS AND ACRONYMS

AF	Additional Financing
AIIB	Asian Infrastructure Investment Bank
BFP	Bank Facilitated Procurement
CDC	Center for Disease Control and Prevention
CEPI	Coalition for Epidemic Preparedness Innovations
COVAX AMC	COVID-19 Vaccines Global Access Advance Market Commitment
COVAX Facility	COVID-19 Vaccines Global Access Facility
COVID-19	Coronavirus Disease 2019
CERC	Contingent Emergency Response Component
DO	Development Objective
EOC	Emergency Operations Center
EPI	Expanded Programme on Immunization
ESCP	Environmental and Social Commitment Plan
ESF	Environmental and Social Framework
ESRS	Environmental and Social Review Summary
FM	Financial Management
FMFA	Financial Management Framework Agreement
FTCF	Fast Track COVID-19 Facility
Gavi	Global Alliance for Vaccines and Immunizations
GDP	Gross Domestic Product
GHP	Global Health Platform
GRS	Grievance Redress Service
HNP	Health, Nutrition, and Population
IBRD	International Bank for Reconstruction and Development
IDA	International Development Association
IFC	International Finance Corporation
ILR	Ice Lined Refrigerators
IMF	International Monetary Fund
IPF	Investment Project Financing instrument
M&E	Monitoring and Evaluation
MPA	Multiphase Programmatic Approach
mRNA	Messenger RNA
РАНО	Pan American Health Organization
PAD	Project Appraisal Document
PrDO	Program Development Objective
PPE	Personal Protective Equipment
PPSD	Project Procurement Strategies for Development
R&D	Research and Development
SEP	Stakeholder Engagement Plan
SPRP	Strategic Preparedness and Response Program, also known as Global COVID-19 MPA
STEP	Systematic Tracking of Exchanges in Procurement
UNICEF	United Nations Children's Fund
WBG	World Bank Group
WHO	World Health Organization

# AF- COVID-19 Strategic Preparedness and Response Program (Global COVID-19 MPA AF) - P175450

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Country	Product Line	Team Leader(s)				
World	IBRD/IDA	David Wilson, Jumana Qamruddin, Mary T. Mulusa				
Project ID	Financing Instrument	Resp CC		Req CC	Practice Area (Lead)	
P173789	Investment Project Financing	HHNGE (9323)		HHNDR (10049)	Health, Nutrition & Population	
Expected Approval Date			Expected	l Program Clos	ing Date	
October 13, 2020			31-Dec-2025			
Financing & Implementation Modalities						
[√] Multiphase Programmatic Approach [MPA]			[√] Conti	ngent Emergei	ncy Response Component (CERC)	
[ ] Series of Projects (SOP)			[√] Fragil	e State(s)		
$[\checkmark]$ Performance-Based Co	onditions (PBCs)		[√] Small State(s)			
[] Financial Intermediarie	s (FI)		$[\checkmark]$ Fragile within a Non-fragile Country			
[] Project-Based Guarantee			[√] Conflict			
[] Deferred Drawdown			$[\checkmark]$ Responding to Natural or Man-made disaster			
[] Alternate Procurement Arrangements (APA)			$[\checkmark]$ Hands-on, Enhanced Implementation Support (HEIS)			

# **Development Objective**

#### 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.

### **BASIC INFORMATION – ADDITIONAL FINANCING (P175450)**

Project ID	Project Name	Additional Financing Type	Urgent Need or Capacity Constraints
P175450	AF- COVID-19 Strategic Preparedness and Response Program (Global COVID-19 MPA AF)	Scale-up	Yes



Financing instrument	Product line	Approval Date	Bank/IFC Collaboration
Investment Project Financing	IBRD/IDA	October 13, 2020	No

# PARENT MPA FINANCING DETAILS (US\$, Billions)

Board Approved MPA Financing Envelope:	6.0
of which Bank Financing (IBRD):	3.9
of which Bank Financing (IDA):	2.1

# Summary - Parent (US\$, Billions)

Source of Funds	Approved	Committed		Percentage Committed
IBRD	3.9	2.2		56.4%
IDA	2.1	1.7		81%
MPA Program Financing Envelope				
of which Bank Financing (IBRD):		6		
of which Bank Financing (IDA):			6	

### SUMMARY FINANCING – Global COVID-19 MPA

Total Program Cost	6	12	18	
	USŞ Billions	US\$ Billions	US\$ Billions	
	Current Financing	Proposed Additional Financing	Total Proposed Financing	

# COMPLIANCE

# Policy

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

[ ] Yes [ ] No



### I. BACKGROUND AND RATIONALE FOR ADDITIONAL FINANCING

1. The proposed Additional Financing to the existing COVID-19 Strategic Preparedness and Response Program utilizing the Multiphase Programmatic Approach ("Global COVID-19 MPA") will significantly expand Bank support to client countries for COVID-19 vaccination, with the aim to support vaccination of 1 billion people globally. An effective and safe COVID-19 vaccine is the most promising path forward for the world to reopen safely, building on global efforts to develop treatments and to expand testing capacity. The timing of potential vaccine development was not known when the Global COVID-19 MPA was first approved, but global vaccine development efforts are now progressing rapidly. Production is already underway of vaccine candidates that may be approved for use before the end of 2020. Many highincome countries are making large-scale advance purchases to reserve supply for their populations and have the systems in place to get people vaccinated efficiently. The proposed approval of an envelope of US\$12 billion (\$6 billion from IDA and \$6 billion from IBRD) in financing will be critical to expand affordable and equitable financing for vaccine purchase and deployment. It also sends a signal to potential suppliers that Bank financing is available for the demand for vaccines from low- and middle-income countries, providing an incentive for production capacity at levels that can also supply developing economies at affordable prices, not only high-income countries. The Bank's proposed Global COVID-19 MPA AF is expected to enable vaccination for up to 750 million people, with potential surge capacity for an additional 250 million people in the poorest countries (depending on the delivered price of approved vaccines) while scaling support to strengthen immunization delivery, with design flexibility at the country level. The proposed AF is a scale-up of planned vaccination activities already anticipated in the Global COVID-19 MPA and will be a key contribution to the WBG's overall COVID-19 response.

2. **The COVID-19 pandemic has had massive global impact and continues to spread**. Since December 2019, following the diagnosis of the initial cases in Wuhan, Hubei Province, China, the number of cases has increased rapidly and the number of affected countries continues to grow. On March 11, 2020, the World Health Organization (WHO) declared a global pandemic. As of September 29, 2020, about 33.5 million people have been infected and over 1 million have died. The pandemic has caused the largest global economic contraction since the Great Depression began in 1929, driving millions of people into poverty. The economic recovery is expected to be slow. Figure 1 below details the exponential global spread of COVID-19. The virus continues to spread globally at an average weekly rate of 8 percent of new confirmed cases and an average weekly rate of 3 percent of new confirmed deaths. Furthermore, despite many countries having reached lower levels of transmission, a 'second wave' may cause a resurgence in cases during the fourth quarter of 2020.

3. **The World Bank Group's initial response to the pandemic was quick.** On March 3, 2020, the World Bank Board of Executive Directors endorsed urgent actions supporting client countries' response to the COVID-19 pandemic. Subsequently, the Board approved the establishment of a US\$12 billion WBG Fast Track COVID-19 Facility (FTCF or "the Facility") to assist IBRD and IDA countries in addressing the global pandemic and its impacts.<sup>1</sup> 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 Bank used emergency procedures to prepare the Global COVID-19 MPA<sup>2</sup> for the first time at global scale. On April 2, 2020, less than a month later, the Board approved a US\$6 billion financing envelope for the Global COVID-19 MPA. The WBG financing allocated specifically for health response has included US\$ 6 billion for the Global COVID-19 MPA, US\$ 2.7

<sup>&</sup>lt;sup>1</sup> http://documents1.worldbank.org/curated/en/260231584733494306/pdf/Proposal-for-a-World-Bank-COVID-19-Responseunder-the-Fast-Track-COVID-19-Facility.pdf

<sup>&</sup>lt;sup>2</sup> The Global COVID-19 MPA can be used with both Investment Project Financing (IPF) and Program for Results (PforR).

billion in existing Bank portfolio redirected to COVID-19 response, and US\$ 4 billion in IFC's Global Heath Platform. With the proposed AF, this would approach a total of US\$ 25 billion.





Source: World Health Organization. Coronavirus Disease (COVID-19) Weekly Epidemiological Update. Data as received by WHO from national authorities, as of 27 September 2020, 10 am CEST.

Week reported

4. Since the initial FTCF response, the WBG has significantly expanded its support for countries as they deal with COVID-19 and its overall impacts. In March 2020, the WBG announced that the institution has the capacity to provide up to US\$160 billion in total financial support through June 2021 to help countries address the social and economic impacts of the pandemic. On June 16, 2020 the Board endorsed the WBG COVID-19 Crisis Response Approach Paper, outlining priorities for supporting countries into the longer term, including a continued focus on saving lives; protecting the poor and vulnerable; ensuring sustainable business growth and job creation; and strengthening policies, institutions, and investments for rebuilding better. By September 30, 2020, the Bank had committed nearly US\$22 billion in new financing for the overall COVID-19 response, of which more than 50 percent has disbursed. In addition to new financing, the Bank restructured funds in existing projects in at least 68 countries to focus on COVID-19 response, many of these through the use of contingent emergency response components (CERCs). By September 30, 2020, IFC had committed nearly US\$6 billion in new financing, reflecting new investments in more than 300 companies as well as extending trade finance and working capital lines to clients.

5. The Global COVID-19 MPA provides a critical and highly effective operational programmatic framework for the Bank's emergency health response to COVID-19 with FTCF resources. The program development objective (PrDO) of Global COVID-19 MPA is "to prevent, detect and respond to the threat posed by COVID-19 and strengthen national systems for public health preparedness". At the time of the approval of the Global COVID-19 MPA, and in the absence of a safe and effective COVID-19 vaccine, immediate needs were focused on early detection, diagnosis, confirmation, and treatment of patients (including those afflicted with other chronic conditions that increase the risk of COVID-19 severity and mortality). The Global COVID-19 MPA provided a common operational framework to support individual countries' specific needs in preventing the spread of the disease and limiting immediate socioeconomic losses, as well as strengthening public health and essential medical care structures and operations to build resilience and reduce the

risk from emerging and re-emerging pathogens.

6. **The original Global COVID-19 MPA is flexible, allowing countries to tailor their response.** Countries can choose from a menu of activities grouped under 6 components, ensuring that the COVID-19 response is tailored to meet countries where they are in terms of context, needs, and epidemiological profile. Support for therapeutics and vaccines, when available, were among the interventions anticipated for COVID-19 surveillance, prevention and control, and case management (in categories 1 through 6). The 6 components in the Global COVID-19 MPA include:

- Component 1: Emergency COVID-19 Response
- Component 2: Strengthening Multi-sector National Institutions and Platforms
- Component 3: Supporting National and Sub-national, Prevention and Preparedness
- Component 4: Community Engagement and Risk Communication
- **Component 5:** Implementation Management and Monitoring and Evaluation
- **Component 6:** Contingency Emergency Response Component (CERC)

### Implementation Progress of the Global COVID-19 MPA

7. As of September 17, 2020, financing for 81 operations totaling \$3.9 billion had been approved under the Global COVID-19 MPA. On April 2, 2020, the Board approved the IBRD/IDA financing of the Global COVID-19 MPA in the overall amount of US\$6 billion equivalent, including the first 25 operations under the Global COVID-19 MPA in the amount of US\$1.9 billion. By September 2020, a total of US\$3.9 billion, or 65 percent of the total initial envelope for the program, had been committed with a total disbursement of US\$1.20 billion (See Table 1). 88 percent of approved projects are effective, with average effectiveness timelines of 27 days; 87 percent of effective projects are disbursing. World Bank support has also leveraged significant financing—in addition to the original US\$6 billion, an additional US\$500 million in co-financing and US\$200 million in parallel financing from the Asian Infrastructure Investment Bank (AIIB) has been mobilized in support of Global COVID-19 MPA.

WB Lending Group Total	Commitments under the Global COVID-19 MPA (US\$bn)	Disbursements under the Global COVID-19 MPA (US\$bn)	Co-Financing/Parallel Financing supporting the Global COVID-19 MPA (US\$bn)
IBRD Countries	US\$ 2.3 bn	US\$ 0.67 bn	US\$ 0.7 bn
IDA Countries	US\$ 1.6 bn	US\$ 0.53 bn	
Total	US\$ 3.9 bn	US\$ 1.20 bn	US\$ 0.7 bn

#### Table 1: Commitments, disbursements, and co-financing under the Global COVID-19 MPA as of September 17, 2020

#### Early Insights from the Global COVID-19 MPA

8. **The Global COVID-19 MPA is on track to achieving its PrDO.** Box 1 highlights some of the key support financed by Global COVID-19 MPA country projects.

9. The design and implementation approach of the Global COVID-19 MPA is enhancing the impact and performance of country projects in their COVID-19 response. Access to the Global COVID-19 MPA by all eligible IBRD and IDA countries enabled the Bank to tailor its support to specific countries' needs while having global reach. Based on lessons learned from previous Bank responses to global health crises and outbreaks, the Global COVID-19 MPA is



supporting clients to help establish the appropriate balance between immediate actions needed to address the pandemic in the short term, and a longer-term development agenda given systemic shortcomings with respect to core public health functions and preparedness (see Box 1).

#### Box 1. Examples of country-specific support under the Global COVID-19 MPA

The projects financed under the Global COVID-19 MPA are supporting countries to contain the virus and ensure access of vulnerable households to preventive and essential health, water, and sanitation services across a range of contexts:

- India's US\$1bn COVID-19 response project has supported the establishment of 15,000 COVID-19 treatment facilities; 1,314,646 dedicated isolation beds (without oxygen); 231,093 oxygen-supported isolation beds; and 62,717 ICU beds, including 32,575 ventilator beds. COVID-19 testing capacity has also been scaled up. As of September, the laboratories' network undertaking COVID-19 tests were expanded to 1,678 (1,040 government and 638 private), and daily testing increased to 1.15 million with an average of 800 tests per million population. The Bank support is also helping India improve overall implementation and service delivery and strengthen center state coordination in a complex federal system.
- Fragile countries, such as **Afghanistan**, **the Democratic Republic of Congo**, **Haiti**, **and Yemen** are acquiring vital medical equipment through Global COVID-19 MPA-funded projects. In Afghanistan, for example, the 150,000 PPEs will be used by 6,821 frontline health workers to enable them to scale up the identification and management of up to 10,000 hospitalized COVID-19 patients. In Papua New Guinea, clients have procured 6,846 infection, prevention, control (IPC) supplies and 31,200 PPEs. These are being distributed and used throughout the country's 22 provinces to help prevent the transmission of COVID-19.
- In **Ethiopia**, Bank financing is being used for the procurement of critical inputs to operationalize the national response, such as PPE for frontline health workers providing essential (including non-COVID-19 related) health services. Initial results include: (i) establishing a national Public Health Emergency Operation Center (PHEOC) to coordinate the preparedness and response efforts for COVID-19 using an Incident Management System; (ii) improving the national capacity for COVID-19 testing; (iii) setting-up screening points and temporary isolation units; and (iv) establishing surveillance and contact tracing mechanisms such as toll-free call centers that are running 24/7.
- In many countries, Bank-funded emergency health response projects support innovative solutions. In **Bangladesh** for example, the Global COVID-19 MPA-funded project is supporting small business to produce and supply 33,000 personal protective equipment kits and 82 million masks.

10. **In addition, the Global COVID-19 MPA**: (i) facilitates a high degree of agility and flexibility to support project preparation and implementation, which will continue to be critical going forward; (ii) has anticipated procurement challenges upfront and established an innovative arrangement when needed relying on extensive hands-on support in identifying suppliers and negotiating prices and other conditions through Bank Facilitated Procurement (BFP – see Box 2); (iii) enhances the exchange of effective, cross-sectoral, technical-level coordination, both internally and externally, through putting in place a Bank-wide, dedicated corporate COVID-19 Task Force and the HNP Practice Emergency Operations Center (EOC), overseen by a Bank-wide Steering Committee; and (iv) supports clients to include least-burdensome measures to ensure responsible collection and processing of personal data necessary as part of the crisis response.<sup>3</sup>

#### Box 2. Early Experience with Bank Facilitated Procurement under the Global COVID-19 MPA

The rapid onset of the pandemic led to significant disruption in supply chains, making it difficult for many clients to access critically needed medical equipment and PPE. To help with these challenges, the Bank took the unprecedented step of offering Bank Facilitated Procurement (BFP), in which the Bank facilitates access to suppliers and negotiates prices, lead times, and other conditions, at no cost to clients, who remain responsible for entering into contracts. This facilitation support includes hands-on

<sup>&</sup>lt;sup>3</sup> The IPF operations under the Global COVID-19 MPA employ the ESF, including its consultation requirements.



assistance in outsourcing logistics, dashboards to track demand and supply efficiently, a web-based E-catalog for countries to easily compare products and prices and initiate purchases in real time (see http://bfpcatalog.org/), and extensive guidance supporting informed decisions while accelerating processing. 63 client countries have participated in BFP, more than 3,000 suppliers have been contacted, and more than 200 products are on offer, worth more than US\$ 1 billion. Key lessons have been that by aggregating demand, BFP affords better market access and more favorable conditions, while also helping build clients' own capacity to procure effectively. The results were possible because of the fit-for-purpose approach and modern procurement tools introduced by the 2016 Procurement Framework, including the Industry Engagement Program.

## **COVID-19 Vaccine Potential and Progress**

11. COVID-19 vaccination, along with improved diagnostics and therapeutics, is essential to protecting lives and enabling the world to reopen safely. The global economy will not recover fully until people feel they can live, socialize, work, and travel with confidence. Given the centrality of limiting the spread of COVID-19 to both health and economic recovery, providing access to COVID-19 vaccines will be critical to accelerate economic and social recovery. June estimates from the WBG's Global Economic Prospects suggest that the economies of IBRD and IDA members would lose US\$53 billion in economic activity per month throughout 2021 in a downside scenario.<sup>4</sup> In addition to immediate impacts, income losses, disruptions in health services, and school closures are likely to generate long-term negative impacts resulting in loss of human capital. For example, recent simulations suggest that COVID-19-driven school closures translated into a loss of 5% of the human capital of the current school-age children cohort. This loss is of the same order of magnitude of the average global improvement in human capital in the past decade.<sup>5</sup> Although projections vary and entail significant uncertainty, the benefits of a vaccine that enables economic recovery would be large. Furthermore, vaccinations have significant health and economic externalities, and their full social value is usually not reflected in vaccine market prices. Some therapeutics that can treat COVID-19 infections are also promising as part of a comprehensive approach to tackle the virus—one therapeutic, corticosteroid dexamethasone, has been shown to reduce mortality among those on ventilation by a third.

12. There are now reasons to be cautiously optimistic about a COVID-19 vaccine, and some manufacturers are confident they will have sufficient data from Phase III trials by the final quarter of 2020.<sup>6</sup> Humans' longstanding ability to develop immune responses to coronaviruses, the stability of this virus (it mutates four times more slowly than seasonal influenza viruses), as well as the pace of innovation and new technologies in vaccine development provide grounds for optimism. The first candidate vaccine emerged on February 22, 2020, just 42 days after gene sequencing of the virus was completed. At the time of the Board approval of the Global COVID-19 MPA, vaccine research was just beginning. As of September 2020, there were more than 250 vaccine candidates being pursued, with 32 in human trial stage and at least 10 having progressed to the large-scale human clinical trial phase, which is the last stage before regulatory approval. At least US\$6.7 billion has already been invested in vaccine research and development (R&D) globally.

13. Vaccine production plans are already underway, but production capacity depends on expected demand, and production scale-up takes time. Hence, it is important to ensure that developing countries signal demand, namely by securing financing arrangements to access vaccines. Vaccine production typically requires 6-18 months for a conventional vaccine, but COVID-19 vaccine production is advancing far more rapidly. Production of the leading vaccine candidates is already underway to have stockpiles available in case clinical trials prove effectiveness. Vaccine producers

<sup>&</sup>lt;sup>4</sup> World Bank Group, Global Economic Prospects, June 2020; World Bank staff calculations with WDI data.

<sup>&</sup>lt;sup>5</sup> World Bank (2020). The Human Capital Index 2020 Update: Human Capital in the Time of COVID-19, Washington D.C.

<sup>&</sup>lt;sup>6</sup> This includes Pfizer, the world's largest pharmaceutical company

cumulatively declare that under the most optimistic scenarios, they may have 300 million doses by October 2020, a billion doses by end-2020, two billion doses by mid-2021, and eight billion doses by end-2021. Independent analysts estimate more conservative production, with a range of 1 billion to 4 billion doses potentially available by the end of 2021. Furthermore, the types of candidate vaccines that are ultimately approved will also determine how fast production can scale. Vaccines using traditional approaches may use existing facilities, but novel mRNA or DNA-based vaccines would require new facilities, which may cost upwards of US\$500 million each. Whatever the actual production may be, the reality is that there will be a constraint in the availability of vaccine doses at least initially. This availability constraint due to production realities and market dynamics poses a risk to ensuring equitable and affordable access to vaccines globally.



#### Figure 2: Publicly known advance purchases of COVID-19 vaccines as of August 27

Source: Modified by team from Callaway, E. 2020. "The unequal scramble for coronavirus vaccines — by the numbers." Nature 584, 506-507.

14. It is critical that the international community ensures equitable and affordable access for low- and middleincome countries. These countries are at a disadvantage and may not be able to secure timely access to vaccines. Highincome countries have reserved a significant share of expected global vaccine supply and greatly distributed their risk, with one country making advance purchases of more than five doses per capita from a pool of potential vaccine candidates (see Figure 2). Some high-income countries have placed capital at risk to pre-finance production in return for first access to vaccines at lower cost. Countries representing 13 percent of global population have already reserved 51 percent of the initial supply of COVID-19 vaccines, and some estimates suggest that 61 percent of the world's population might not have access to a vaccine before 2022<sup>7</sup>. Competition for vaccine purchasing will only increase once approved production commences, and countries with vaccine production capacity could face strong political pressures

<sup>&</sup>lt;sup>7</sup> Oxfam. 2020. Small group of rich nations have bought up more than half the future supply of leading COVID-19 vaccine contenders. Available at: https://www.oxfam.org/en/press-releases/small-group-rich-nations-have-bought-more-half-future-supply-leading-covid-19



to retain the vaccines produced within their borders. These trends represent risks to low- and middle-income countries being able to adequately source vaccines for their populations. These COVID-19 developments are in line with global experience, which reflects the importance of supporting low- and middle-income countries to secure vaccines. During the last major global pandemic the world faced, the 2009 H1N1 (Swine Flu) outbreak, high-income countries bought almost all vaccine supplies, leaving almost no supply for developing countries. A major lesson for the COVID-19 pandemic is that mechanisms are needed to ensure available financing for countries with less purchasing power and to incentivize expanded production, so there is more supply to reserve. Vaccine access for developing economies also has global implications, as global integration and economic recovery in a highly interconnected world will not be possible if many countries are left behind. Investments in R&D and product development and advance market mechanisms offer complementary push-pull approaches, with push mechanisms such as CEPI financing R&D and pull mechanisms such as advance purchases providing volume and demand assurances to signal market viability.

15. COVID-19 vaccine deployment will be an unprecedented effort in terms of population coverage. Even with considerable doses of an effective and safe vaccine in hand, many countries will face major challenges deploying those vaccines at scale—especially the Bank's IDA client countries Many countries are used to vaccinating successive cohorts of infants, not most adults -up to about 70% of their entire population which is what may be required for 'herd' immunity – all at once.. And even after almost 50 years since the Expanded Programme on Immunization (EPI) was launched, capacity for child immunization remains weak and inequitable in many countries: about 20 million children are still under-immunized and 1.3 million die each year from vaccine-preventable diseases. An intense focus on expanding immunization capacity will therefore be required, and countries must ensure that their health systems can effectively implement a comprehensive COVID-19 vaccine deployment strategy. This includes functional, end-to-end supply chain and logistics management systems for effective vaccine storage, handling, and stock management; rigorous cold chain control; robust service and coverage tracking systems; well trained, motivated and supervised vaccinators, tailored large-scale communication and outreach campaigns at household, community and national level; peoplecentered service delivery models that reach different target populations effectively; and effective political leadership. Countries will also need to consider and put in place any needed institutional frameworks for the safe and effective deployment of vaccines, including around ensuring voluntary vaccination practices; regulatory standards for vaccine quality; guidelines for acceptable minimum standards for vaccine management including cold chain infrastructure; and policies to ensure robust governance, accountability, and citizen engagement mechanisms.

# Vaccine cost estimates for IDA and IBRD countries

16. Although there remains considerable uncertainty about final prices, it is hoped that manufacturers and partners engaged in mobilizing COVID-19 vaccines for developing countries will offer low prices. The cost of different vaccine coverage scenarios can be estimated using initial market indications of vaccine prices.<sup>8</sup> For the purposes of Table 2, cost estimates at US\$4 per dose in low- and lower-middle income countries and US\$6.5 in upper-middle income and high-income countries have been used. Incremental costs for deployment<sup>9</sup> are estimated US\$1 per dose, making the

<sup>&</sup>lt;sup>8</sup> One frontrunner vaccine is already priced at below US\$3 to US\$5 per dose in high-income countries. This vaccine candidate and another prominent one are both priced at up to US\$3 per dose in low-income countries. The manufacturer of another leading candidate has agreed to US\$10 per dose in the US (for what is hoped to be a single-dose regiment); their price for developing country purchase is not yet confirmed. Vaccines using innovative technologies such as mRNA vaccines may cost \$20-40 per dose. <sup>9</sup> Incremental deployment costs include expanded cold chain capacity, needles and syringes, training of vaccinators, additional vaccinators, registration and communication campaigns. An estimated average has been presented. In practice, deployment costs will vary over time, possibly with lower initial costs as the vaccine is provided first to health workers, who may be reached

total vaccine dose plus delivery US\$5 in low and lower-middle income countries and US\$7.5 in upper-middle income and high-income countries. It is expected that a two-dose vaccine regiment may be required for most candidates. The estimates assume coverage of at least 20 percent of the population in all member countries without substantial domestic production capacity and plans. The 20 percent coverage would correspond to the initial WHO Allocation Framework target for priority immunization, which proposes an initial proportional allocation to enable all countries to cover 20 percent of their population, focusing first on workers in health and social care settings, then the elderly and younger people with an underlying condition that places them at higher risk for death, such as diabetes, hypertension, cardiovascular disease, chronic respiratory disease, and obesity (BMI>30). The estimates also take into account for the need to stretch further in IDA countries, which have fewer alternative sources of financing for vaccines.

17. Based on these assumptions, an Additional Financing of US\$12 billion is proposed (up to US\$6 billion from IDA), to the Global COVID-19 MPA. Based on assumptions derived from current information on vaccine prices, while acknowledging the uncertainty, this financing would cover vaccinations for up to 1 billion people in IDA and IBRD countries (see Table 2). This would enable coverage of at least 20 percent of the population in both in IDA and IBRD countries, totaling approximately 750 million people, with additional surge capacity to cover up to 250 million more people in IDA countries depending on final vaccine prices. Committing to this coverage scenario would be a major confidence boost to client countries, other financiers, and vaccine producers that there are sufficient global resources and commitment for bold vaccine action. It also reflects the Bank's focus on IDA countries, which will have fewer alternative options for vaccine purchase financing and require more investment on health systems and health service delivery to ensure robust supply chains for the deployment of COVID-19 vaccines. Individual country projects will be sized based on specific country needs. This will reflect countries' own vaccination strategies; alternative sources of financing for vaccines; and trade-offs between alternative uses of available Bank resources.

Lending group	Population. size	Number of people covered	Number of vaccine doses	Cost per vaccine dose (US\$)	Total cost (US\$ bn)
IBRD <sup>(a)</sup>	2 billion	400 million	800 million	US\$ 7.5	US\$ 6 bn
IDA +Blend	1.7billion	350-600 million <sup>(b)</sup>	700 million – 1.2 billion	US\$ 5	US\$ 6 bn
Total	3.7 billion	750 million – 1 billion	1.5-2 billion		US\$ 12 bn

Table 2: Estimated coverage for	r \$12 billion	, ensuring at least 2	20 percent coverage	e in IDA and IBRD	countries
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(a) Cost estimates do not include countries with significant domestic vaccine production capacity and plans including China, India, and Russia. (b) Range estimates cover 20 to 35 percent of the country populations.

# Rationale for Additional Financing

18. The proposed Additional Financing to the Global COVID-19 MPA will play a crucial role in enabling affordable and equitable access to vaccines globally for low- and middle-income countries. The economic impact from the pandemic has been devastating. As economies and countries seek to reopen, it will be critical for developing economies to reach a minimum level of vaccination coverage to be able to start rebuilding their economies safely and engage in international trade and other global economic activity. To achieve this, countries need to secure financing for vaccine

inexpensively, then rising until economies of scale and scope and other delivery efficiencies reduce delivery costs, before rising again for the last mile.



purchase and start preparing their health systems for the implementation of large-scale COVID-19 vaccination programs now. However, the Bank's client countries that are least able to negotiate with global vaccine manufacturers and most in need of immunization systems strengthening also have the fewest financing options. This includes the poorest countries, as well as middle-income countries, many of which are experiencing catastrophic economic and fiscal impacts due to the pandemic. Without financing and delivery capacity in place, delayed purchase and deployment of vaccines in these low- and middle-income countries will exacerbate existing disparities both in public health services provision and in the ability of countries to recover socially and economically. Delays in access to vaccination also pose clear risks to long-terms gains in human capital development, especially for developing economies.

19. The proposed Additional Financing can efficiently provide a substantial portion of financing needed for vaccine purchase and deployment in IDA and IBRD countries through scaling up COVID-19 vaccination efforts under the existing Global COVID-19 MPA. The proposed Bank financing could help purchase as many as 2 billion vaccination doses<sup>10</sup> and ensure strong immunization systems for COVID-19 vaccine deployment. This will have a direct impact on the health of a massive number of vulnerable people and contribute to large-scale vaccination coverage in every IDA and IBRD member country that participates in the program. Many Bank client countries are trying to manage priorities within highly constrained resource envelopes, which have become even more limited due to the impacts of the pandemic. Securing the resources to be able to prepare for vaccine deployment now will be crucial to ensure effective health service delivery efforts in the future.

20. The AF for the Global COVID-19 MPA will send a strong signal of demand from low- and middle-income countries for safe and effective COVID-19 vaccines. In addition to high-income countries already being actively engaged in expanding production (push) and advance payment commitments (pull), some countries with vaccine production capacity may reserve some production for domestic use. Vaccine producers and investors require clear signals of market demand and purchasing power to make production capacity installation and expansion decisions,<sup>11</sup> and early investments in vaccine manufacturing capacity have large net benefits for countries at all income levels.<sup>12</sup> A clear commitment of Bank financing will send an important initial signal of the demand and financing available for low- and middle-income countries so that production capacity can be planned accordingly. The market's production capacity response will increase further once countries begin using Bank financing to engage in vaccine purchases, either through advance purchase to reserve future production or direct purchase by the countries once effective vaccines come on the market.

21. The expanded financing through the AF for the Global COVID-19 MPA will also allow client countries to take advantage of unprecedented investment in COVID-19 research and development, namely by developed countries. There has been unprecedented high-income country investment in R&D and production, which Bank clients can benefit from, especially if COVID-19 vaccine prices for developing countries are affordable and sufficient quantities are made available to developing countries on a timely basis. There is also significant investment in production. Major vaccine developers have indicated they will voluntarily license immediate generic production for lower-income countries, and some have already committed to allocate a proportion of the produced doses to these countries. Donors, such as the Bill and Melinda Gates Foundation, in collaboration with Gavi and the Vaccine Alliance, are expected to provide upfront capital to some of these vaccine developers to accelerate the manufacture and delivery of up to 100 million vaccine

<sup>&</sup>lt;sup>10</sup> Based on assumption of 2 dose regimen per person.

<sup>&</sup>lt;sup>11</sup> The economic and health benefits of a vaccine increase the sooner an effective vaccine can be deployed globally. By credibly signaling demand, advance purchases can speed up the process of building capacity and supply.

<sup>&</sup>lt;sup>12</sup> Athey et al. (2020).



doses for lower-income countries as early as the first half of 2021. Without financing and embedded technical support, IDA and IBRD countries may not be able to capitalize on these opportunities through timely purchase and effective implementation when the vaccine becomes available.

22. The increased financial and technical support by the Bank for vaccine purchase and deployment at country level will accelerate efforts by other development partners. At the country level, making funds available for vaccine purchase and deployment will establish an enabling environment for other donors, multilateral development banks, and UN agencies to also support countries to reach an even higher coverage level (see Box 3 below on working with partners). At the global level, the Bank investment will reinforce the COVAX Facility<sup>13</sup>, which is co-led by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI) and WHO. Its aim is to accelerate the development and manufacture of COVID-19 vaccines and to promote equitable access to COVID-19 vaccines. By negotiating prices on behalf of countries, providing upfront reservations and commitments to manufacturers through advance purchase agreements or advance purchase options, the COVAX Facility expedites the process of bringing vaccines to market atscale. The facility invests in a diverse and actively managed portfolio of candidates, thereby maximizing the probability of success. Facility's vaccine portfolio consists of the 9 vaccines funded by CEPI, with 8 in clinical trials, including one (AstraZeneca) is in Phase III. BMGF's portfolio of 9 vaccines is also being considered for inclusion, however most are in early Phase I or pre-clinical phases.

### Box 3. Maximizing impact through global health partnerships

The Bank is on the Board of GAVI (as a founding member) and CEPI and works closely with both partners. The Bank also works closely with UNICEF and WHO under the Global COVID-19 MPA and broader global public health priorities. Both organizations, play a leading role in global vaccination efforts. The Bank is a member of the ACT-Accelerator Partnership and leads its health strengthening pillar. The Bank's increased financial and technical support for vaccine purchase and deployment will also be a part of a broader global partnership to support COVID-19 response. In addition to building on the Bank's existing robust health portfolio and efforts under the Human Capital Project, Bank vaccination support will build on other complementary initiatives underway globally and in each individual country, supported by partners that are also providing financing, health and immunization system strengthening support, and support other COVID-19 interventions.

23. In line with the original rationale and design of the Global COVID-19 MPA, the proposed Additional Financing will support government efforts to strengthen vaccination as well as strengthen national immunization systems in a way that will ensure an effective COVID-19 response and generate long-lasting benefits globally. Purchasing vaccines is just one step (and in the case of COVID-19, an important step) in a complex, multidimensional effort that involves detailed planning and implementation of vaccine deployment programs in specific country-level contexts and health systems. This includes a variety of issues such as effective wicroplanning, safe and appropriate transportation, storage, training, ancillary materials, registration, and effective vaccine logistics and information management systems and systems. Political support, social mobilization campaigns, and mechanisms that remove demand-side barriers to access are also essential to foster confidence and promote the early take-up of vaccines. The proposed Global COVID-19 MPA AF will provide financing for countries to urgently begin undertaking this range of immunization system strengthening actions. This support will build on the existing Global COVID-19 MPA as well as the broader Bank health portfolio with

<sup>&</sup>lt;sup>13</sup> Within COVAX, there are two separate and independent sources of funding. One arm is for 92 low income and lowermiddle income countries eligible for donor financed vaccines at highly subsidized prices or possibly for free. The other is the self-financing arm, under which upper-middle and high-income countries can self-finance their participation. For more information on the COVAX Facility, please visit: https://www.gavi.org/covax-facility



its established engagement with countries to strengthen health systems and health service delivery. The Bank's robust network of technical and implementation support capacity already working on the ground in IDA and IBRD client countries reflects its comparative advantage in providing this hands-on system strengthening support in addition to the direct financing of vaccine purchases.

24. **The proposed Additional Financing will form part of an expanded health response to the pandemic.** The proposed expanded support for vaccine purchases and systems strengthening is fully grounded in the WBG COVID-19 Crisis Response Approach Paper and its focus on both immediate health interventions and longer-term resilience. The activities will build on the Bank's existing health portfolio and its engagement with clients on COVID-19 response, including financing for stand-alone operations outside the Global COVID-19 MPA, including restructuring of existing operations and pipelines. On the IFC side, through its Global Health Platform (GHP) that was recently approved by the Board, IFC is able to invest in vaccine manufacturers to expand COVID-19 vaccine production globally, provided that production is reserved for emerging markets. IFC is also able to invest in production to address other potential bottlenecks, including vials, needles and syringes, and cold storage capacity. IFC has already supported the Coalition for Epidemic Preparedness Innovations (CEPI) to map COVID-19 vaccine manufacturing capacity, focusing especially on potential bottlenecks in manufacturing processes.

# Global COVID-19 MPA Program Development Objective (PrDO) and PrDO Indicators:

25. Global COVID-19 MPA's Program Development Objective (PrDO) is "to prevent, detect and respond to the threat posed by COVID-19 and strengthen national systems for public health preparedness." No changes are proposed to the PrDO indicators or existing intermediate results indicators, although additional indicators are proposed below.

# Proposed Revised Program Results Chain

26. The proposed revised program results chain for the existing Global COVID-19 MPA incorporates an expanded focus on vaccination purchase and deployment to the population. The results chain in Figure 2 illustrates the expected contribution of the Additional Financing to the Global COVID-19 MPA program development objective and the long-term outcome of reduced morbidity and mortality. Depending on their effectiveness, reduction by vaccines in morbidity and mortality will also generate a wide range of economic benefits, which are further articulated in the economic analysis section below.



# Figure 2: Results Chain of the Global COVID-19 MPA with AF (COVID-19 Vaccination)

#### **Program Framework**

27. **Given the structure and nature of the Additional Financing of the Global COVID-19 MPA, all potential recipients cannot be identified at this stage**. As with the original Global COVID-19 MPA, this calls for flexibility in some procedural requirements, including the StatComs.<sup>14</sup>

<sup>&</sup>lt;sup>14</sup> The Articles of Agreement of IBRD and IDA (IBRD Article III, Section IV, and IDA Article V, Section 1 (d)) require that before making IBRD/IDA financing, a report of a Statutory Committee (StatCom) be completed. The StatCom must include the signature of representative of the member country where the project is located. Although the Articles do not require that a StatCom be made available before the EDs approve Bank financing, it has been a long-standing practice that StatComs are in fact obtained before the EDs decide on Bank financing. For this Additional Financing, EDs' approval is being sought for the overall Additional Financing, when all possible recipients of such financing are not yet identified. Therefore, Management will obtain a StatCom from each member state that will be the recipient of the Global COVID-19 MPA Additional Financing before the funds are committed by Management (i.e.,

	Program	Proposed DO	IBRD Amount (US\$ billion)	IDA Amount (US\$ billion)	Total Amount (US\$ billion)				
Parent Project	COVID-19 Strategic Preparedness and Response Program (Global COVID-19 MPA)	To prevent, detect and respond to the threat posed by COVID-19 and strengthen national systems for public health preparedness.	3.9	2.1	6.0				
Additional Financing	AF- COVID-19 Strategic Preparedness and Response Program (COVID-19 MPA AF)	No Change	6.0	6.0	12				
Total Financing			9.9	8.1	18				

# Program Framework Table<sup>15</sup>

# II. DESCRIPTION OF ADDITIONAL FINANCING

28. **The proposed Additional Financing for scaling-up COVID-19 vaccination efforts under the Global COVID-19 MPA is a contribution to broader efforts within the World Bank Group**. In addition to this Additional Financing, Bank clients can also utilize the financing available under the original Global COVID-19 MPA, as well as financing for stand-alone IPF and PforR operations outside the Global COVID-19 MPA, including restructuring of existing operations and integration of vaccination efforts into pipeline operations.

29. The changes proposed for the Additional Financing entail scaling up activities already included in the Global COVID-19 MPA, and there will be no changes to the overall design, the PrDO, or the components of the original MPA. The specific changes proposed include:

(i) Global COVID-19 MPA Overall Financing Envelope:

30. Increase the envelope of the overall Bank financing envelope of the Global COVID-19 MPA by US\$12 billion, from up to US\$6 billion to up to US\$18 billion. The proposed increase will accommodate future purchases of COVID-19 vaccines, including through advance purchase mechanisms with associated expenditures, as well as related health systems strengthening and vaccine uptake interventions.<sup>16</sup> The Global COVID-19 MPA (including the AF) will also be supported with Trust Funds where available.

before the legal agreement is signed). Such approach is fully consistent with the requirements of the Articles, and continues the approach adopted in the original Global COVID-19 MPA.

<sup>&</sup>lt;sup>15</sup> With the proposed AF, this would approach a total of US\$25 billion for COVID-19 health financing across the World Bank Group

<sup>&</sup>lt;sup>16</sup> Additional activities eligible under the Global COVID-19 MPA may also be financed.



### (ii) Results Framework:

31. There will be no changes to the existing Global COVID-19 MPA PrDO indicators or Intermediate Results indicators. To measure overall progress in the coverage and deployment of the COVID-19 vaccine, the following proposed indicators will be added to the Global COVID-19 MPA Results Framework:

### **PrDO Indicators:**

• Percentage (%) of participating countries<sup>17</sup> that have vaccinated their priority population<sup>18</sup>, based on the targets defined in their national plans.

## Intermediate Results Indicators:

- Component 1:
  - Percentage (%) of participating countries with a national plan for Covid-19 vaccine procurement and deployment.
- Component 3:
  - Percentage (%) of participating countries with Effective Vaccine Management assessments with composite scores of 80% or higher
- Component 4:
  - Percentage (%) of participating countries with a community engagement plan for increasing demand creation for the Covid-19 vaccine by the population

32. To measure country-level progress, country projects will identify relevant indicators from these additional indicators and will add others as needed based on the specific activities included in country projects. These will be outlined in the country-level AF project papers.

### (iii) **Project Components**

33. Vaccine purchasing will be scaled-up through Component 1 of the Global COVID-19 MPA. The support for vaccines when available, which was anticipated in the initial Global COVID-19 MPA, will be scaled up as part of the containment and mitigation measures to prevent the spread of COVID-19 and deaths under *Component 1: Emergency COVID-19 Response*. Countries will have several options for vaccine purchase and financing mechanisms, which are expected to include: i) direct purchases by countries from vaccine manufacturers, either individually or jointly with other countries; ii) purchase of excess stocks from other countries that reserve excess doses; and/or iii) advance purchase mechanisms such as participating in COVAX. The Bank's financing for advance purchase mechanisms may entail financing expenditures such as access fees, speed premia, and other upfront payments that may not be offset or recoverable if a safe and effective vaccine does not materialize. The Bank will support client countries in considering the options to access vaccines, but each country will ultimately decide which options to use based on their specific contexts and needs. It is likely that most countries will wish to hedge risks by pursuing a combination of different options, as many high-income

<sup>&</sup>lt;sup>17</sup> Participating countries are those included under both the Global COVID-19 MPA and/or the AF.

<sup>&</sup>lt;sup>18</sup> The WHO Fair Allocation Framework defines as priority population i) frontline workers in health and social care settings; ii) the elderly; iii) and people who have underlying conditions that put them at a higher risk of death. For most countries, an allocation equal to 20% of the population would be enough to cover most of the population comprising initially prioritized target groups. By initially prioritizing these groups, a vaccination program may achieve an enormous impact in reducing the consequences of the pandemic even in conditions of supply constraint.



countries are also doing.

34. **Given the unprecedented pace of vaccine development, and the need for both speed and prudence**, the Bank will accept as the threshold for eligibility of IBRD/IDA resources in vaccine purchase either (i) approval by 3 Stringent Regulatory Authorities (SRAs) in three regions or (ii) WHO prequalification and approval by 1 SRA (see Annex 1 for full list of SRAs designated by WHO). Box 4 provides a general overview of vaccine regulatory and approval processes.

#### Box 4: Regulatory and approval processes for a COVID-19 vaccine

Vaccine approval proceeds in different stages to allow for safety and efficacy to be progressively assessed. Phase I clinical trials test vaccines for safety and immunogenicity (immune response) in human volunteers. Phase II involves larger trials to test vaccines' ability to produce immunogenicity in the target population and general safety. To fully assess protective efficacy and safety of a vaccine, an extensive phase III, which entails large scale randomized clinical trials, is necessary. Phase III is followed by approval: regulators review trial results and decide whether to approve the vaccine. In Phase IV, regulators continue to monitor approved vaccines in widespread use for long-term safety. During a pandemic, a vaccine may be authorized for emergency use before full formal approval – this is likely to be the case for COVID-19 vaccines.

35. The Global COVID-19 MPA AF will support institutional strengthening measures that will enable effective vaccine deployment and provide assurance regarding the use of vaccine purchase financing. The AF may finance upfront technical assistance to support countries to establish institutional frameworks for the safe and effective deployment of vaccines. These will include: a) establishment of policies related to ensuring that there is no forced vaccination; b) acceptable approved policy for prioritized intra-country vaccine allocation; c) regulatory standards at the national level; d) appropriate minimum standards for vaccine management including cold chain infrastructure (with financing as well for the investment to meet those standards as described below); and e) the creation of accountability, grievances, and citizen and community engagement mechanisms. The policies for prioritizing intra-country vaccine allocations will follow principles established in the WHO Allocation Framework, including targeting an initial coverage of 20 percent of a country's population; focusing first on workers in health and social care settings; and then focusing on the elderly and younger people with an underlying condition which places them at higher risk.

36. The proposed AF may also support the needed systems strengthening and service delivery efforts to ensure effective vaccine deployment within countries. The AF will support investments to bring immunization systems and service delivery capacity to the level required to successfully deliver COVID-19 vaccines at scale, through Components 1-5 of the Global COVID-19 MPA. This will include financing for cold chain facilities, vehicles, and other logistics infrastructure; assessments of vaccine management capacity and training of front-line delivery workers; communications and outreach; and vaccine monitoring as well as other related investments, depending on individual country need. In providing this financing, Global COVID-19 MPA will support countries to design, adapt, and scale innovative service delivery models to ensure vaccines can be delivered through to the last mile for target populations that are appropriate across a diversity of settings. This approach will support countries to assess the health system building blocks currently in place and leverage them for enhanced immunization system performance. It will entail taking a people-centered approach to ensure country-level systems are designed practically and specifically for the people using them. To foster confidence in the vaccine and supporting systems, effective communication and outreach will be imperative to increase awareness, build trust, and reduce stigma around any COVID-19 vaccine. Global COVID-19 MPA will support countries in activities such as generating information local languages, distributing across high-penetration platforms, and fostering support and endorsement through trusted community and national leaders. Climate change adaptation and mitigation



considerations will also be sought in country-level operations processed under this AF. These include embedding energy efficiency measures in the cold chain and related logistics, climate-proofing relevant facilities and built infrastructure for the vaccine storage and distribution and ensuring the service continuity during sudden or protracted natural disasters that may disrupt the chain. This vaccine implementation support is expected to be channeled through country health systems whenever possible but may also entail financing to involve partner organizations and others at national level, as necessary.

### **III. KEY RISKS**

37. The risks and associated mitigation measures to achieving the Global COVID-19 MPA AF development objectives remain largely as identified in the initial MPA. Overall, the proposed Additional Financing supports the Global COVID-19 MPA's development objective, and aims to reduce the risk that the objective is not achieved. But given that the proposed Additional Financing is a scale-up of activities already included in the initial MPA, and that the overall risks of the COVID-19 health response due to the uncertainties and unprecedented nature of the crisis remain, there are no proposed changes to the Global COVID-19 MPA risk ratings. Specific risk assessments and associated mitigation measures for the country-level scale-up of vaccine purchase and deployment will be determined for individual country operations under the Global COVID-19 MPA, depending on each project and country context.

38. The large-scale acquisition and deployment by developing countries of recently developed COVID-19 vaccines entails certain risks. First, the first vaccines certified through the SRA mechanism may not be the most effective. Second, a mass vaccination effort stretches capacity, in particular in low-capacity environments, entailing risks. Where needed, the Bank will work with governments to partner with service providers that can acquire and/or deliver the vaccines. Another key risk is whether countries will be able to use the available financing to purchase effective vaccines in a timely way. There are trade-offs between the different vaccine purchase options: countries that wait until effective vaccines are available on the market face the risk of delayed access, while countries that engage in advance purchase face the risk of using scarce resources on vaccines that may be less effective than vaccines that are produced subsequently. The Global COVID-19 MPA mitigates these risks by supporting countries to consider the trade-offs and to determine the appropriate approach and risk balance at the country level. Global COVID-19 MPA Given the massive scale of global research and development efforts, the Global COVID-19 MPA has limited scope to mitigate all risks, but the Global COVID-19 MPA design will enable countries to tailor their response to the COVID-19 health emergency taking into consideration the progress with vaccine development efforts. The remaining risk must be considered against the risk of inaction, in which developing countries have less-timely access to the vaccine and less-effective deployment of the vaccine, potentially exacerbating development gaps and further eroding past development gains.

39. **Political and governance risks for Global COVID-19 MPA remain High**. Political pressures and different interpretations of which standards to follow may create pressure for some countries to purchase vaccines before they have been appropriately certified. Vaccines have already been approved for emergency use in some jurisdictions after only Phase I and II studies. The Global COVID-19 MPA mitigates the risk as financing will only be used for vaccines that have met the criteria laid out in para 34. Another risk is the commitment and ability of the authorities to ensure appropriate targeting of the vaccines to priority populations, based on objective public health criteria. This risk will be mitigated through the assurance mechanisms that the project will support such as the establishment of an acceptable policy and plan for prioritized intra-country allocation. There are also risks related to the governance of vaccine purchase and deployment, such as oversight of potential fraud and substandard quality, considering the global experience with accusations of supply of substandard quality of PPE in the global marketplace. Tiered pricing of vaccines may also encourage fraud. The Global COVID-19 MPA will mitigate this risk through a rigorous inspection regime and anti-



corruption guidelines for vaccine purchase and deployment, as it has done in Bank-financed PPE purchases to date. This includes traceability of supply.

40. **Macroeconomic risk to achieving the Global COVID-19 MPA objectives remains High.** Many IDA and IBRD countries are experiencing severe fiscal pressures and face the risk of not having sufficient additional fiscal space for the purchase of vaccines at scale and other COVID-related response interventions. The proposed AF specifically aims to mitigate this risk by providing financing for vaccine purchase and promoting prioritized deployment to vulnerable groups. Residual macroeconomic risk will remain as countries aim to scale vaccine access to higher coverage levels.

41. **Institutional capacity risk to Global COVID-19 MPA implementation including vaccine deployment remains High.** Vaccine deployment cold-chain and distribution capacity are currently inadequate in some countries, especially for the anticipated scale and population group coverage for COVID-19 vaccination. This risk will be mitigated by Global COVID-19 MPA financing and technical support for immunization system strengthening needs, including conducting capacity assessments in coordination with the WHO, UNICEF, and other partners.

42. **Fiduciary risks associated with Global COVID-19 MPA remain High**. The procurement and FM risks initially assessed for Global COVID-19 MPA cover risks associated with the procurement and distribution of vaccines, including fraud and corruption risks. Risks specific to vaccines include:

- **Procurement:** The key procurement risk associated with vaccines is failed procurement by countries due to (i) the complexity of the vaccines market given the significant market power enjoyed by vaccine manufactures; (ii) inability of the market to supply adequate quantities of vaccines to meet the demand especially of IBRD and IDA countries even when they have pre-committed funds for vaccine procurement; (iii) the limited market access due to advance orders by developed countries; (iv) weak bargaining power for smaller countries with low volumes; and (v) delays by countries in triggering emergency procurement procedures which could delay procurement and contract implementation including payments. The Global COVID-19 MPA AF will minimize risks by providing options to support each Global COVID-19 MPA country's needs for direct or advance purchase, including possible Bank Facilitated Procurement.
- **Financial Management (FM)**: The key FM risks relate to (i) untimely funds flow or lack of liquidity and (ii) lack of adequate controls over the transparent, prioritized distribution and application of vaccines, particularly for the most vulnerable population groups. The AF will use the same options as in the Global COVID-19 MPA to assess and strengthen control systems, facilitate the timely flow of funds, and ensure adequate liquidity to finance project activities.

43. The anticipated overall environmental and social risks remain Substantial. The measures to address social and environmental risks presented in the initial Global COVID-19 MPA remain relevant, including infection prevention and control improvements in health facilities, such as assessment and mitigation measures for medical waste risk management that will be expanded as inoculation sites expand. Experience indicates that moderate risk ratings can be expected for environment. However, the social risk is anticipated to be substantial at least in some countries, because there is a broader social risk of inequity in access to vaccines within countries, such as due to political pressures to provide vaccines to groups that are not prioritized due to need or vulnerability. Thus, depending on the severity of the pandemic in the country, this risk may reach substantial levels if certain groups believe they are underserved due to their status. This risk will be mitigated through several measures to ensure vaccine delivery targets the most vulnerable populations in accordance with criteria to be specified in the AF for each country. First, the Bank will support IDA/IBRD client countries to develop and adapt explicit, contextually appropriate, and well-communicated criteria for access to vaccines. There is consensus to first target health workers, other essential workers, and the most vulnerable populations, which will vary

by country but will include a mix of the elderly, people with co-morbidities, and people in high-population density locations such as slums and refugee camps. The Bank will also continue to provide technical and implementation support through the Global COVID-19 MPA at the country level to mitigate this risk. All targeting criteria and implementation plans will be reflected in the individual AF country projects. Another particular risk that has come to the fore based on the ongoing implementation experience of Global COVID-19 MPA is the increased incidence of reprisals and retaliation especially against healthcare workers and researchers. This risk will be mitigated through explicit inclusion in robust stakeholder identification and consultation processes at the individual operation level.

# IV. APPRAISAL SUMMARY

### A. Economic Analysis

44. The economic rationale for investment in a COVID-19 vaccine is strong, considering the massive and continuing health and economic losses due to the pandemic. As of September 29, about 33.5 million people have been confirmed to be infected by the virus and over 1 million have been confirmed to have died. Global output is projected to decline by 4.9 percent in 2020, with cumulative losses across 2020 and 2021 exceeding US\$12 trillion. The virus continues to spread globally, with new confirmed cases rising at an average weekly rate of 8 percent and new confirmed deaths rising at a weekly average rate of 3 percent. Without a vaccine, health losses due to the spreading virus will only continue, and economic growth will remain stalled. The successful development, production, and delivery of a vaccine however has the best potential to reverse these trends, generating benefits that will far exceed vaccine-related costs.

45. The primary benefit of successful vaccination will be avoiding further human health costs from death and sickness. As reflected in the Program Development Objective and results chain, the health benefits of vaccination are the primary outcome targeted by Global COVID-19 MPA. A vaccine will avoid the incalculable human wellbeing loss due to potentially hundreds of thousands of additional lives lost. It will also avoid the associated health care costs for potentially millions of additional cases of infection and associated health-related impoverishment. Global experience with immunization against diseases shows that by avoiding these and other health costs, vaccines are one of the best buys in public health. A recent analysis found that every dollar spent on expanding access to a portfolio of vaccines for children in low- and middle-income countries over this decade would return US\$16 in economic benefits.<sup>19</sup> This analysis underestimates the value of immunization, as it focuses only on a cost of illness approach for childhood vaccines and leaves out herd immunity as well as the long-term development dividend from healthier children and increased school attendance.<sup>20</sup> Estimates of return on investment using a full-income approach increases the net returns to 44 times the cost.<sup>21</sup> For the most vulnerable population groups, especially in countries without effective universal health coverage, the potential health-related costs of millions of additional cases of COVID-19 infection in the absence of a vaccine represent a significant or even catastrophic financial impact and risk of impoverishment. The pandemic is also having dire effects on other non-COVID health outcomes. Vaccination campaigns throughout the world have been suspended and routine immunization services disrupted, threatening polio eradication and potentially leading to new outbreaks of

<sup>&</sup>lt;sup>19</sup> Ozawa, S., Clark, S., Portnoy, A., Grewal, S., Brenzel, L. & D.G. Walker (2016): "Return on Investment from Childhood Immunization in Low- And Middle-Income Countries, 2011-20." Health Affairs 35:199-207.

 <sup>&</sup>lt;sup>20</sup> Bloom, D.E., Canning, D. & M. Weston (2005): The Value of Vaccination. World Economics 6: 15-39; Luyten, J. & P. Beutels (2016): "The Social Value of Vaccination Programs: Beyond Cost-Effectiveness." Health Affairs 35: 212-218.
<sup>21</sup> Ozawa et al 2016.



preventable diseases, with their own related deaths, illnesses and long-term costs.<sup>22</sup>

46. **Global deployment of a COVID-19 vaccine will also generate economic benefits by enabling economic recovery and an increase in productive activity**. The pandemic and associated mitigation measures have sharply curbed consumption, production, and new investment, resulting in huge economic losses, with estimates from the IMF indicating US\$500 billion in lost economic activity globally per month.<sup>23</sup> The IMF also forecasts that the development of a safe and effective vaccine would improve growth outcomes in 2021 even if vaccine production cannot be scaled up quickly enough to achieve herd immunity that year.<sup>24</sup> The impact of the proposed Additional Financing alone will not improve global growth outcomes. But the Bank's financing and collaboration with partners will contribute to the global deployment of a vaccine against COVID-19, especially in the Bank's client countries, helping avoid further losses by giving people and firms the confidence to return to work, travel, and conduct business as usual.

47. **Ensuring vaccine purchase and delivery in developing economies will also achieve significant distributive and poverty-reduction benefits**. High-income countries are already making large-scale advance vaccine purchases and have the purchasing power to pay higher vaccine prices. The proposed Additional Financing for COVID-19 vaccines will send a clear market signal that developing countries have massive needs and significant purchasing power. Public investment in vaccine delivery in low- and middle-income countries will also enable governments to ensure access for the poorest, likely avoiding millions of vulnerable people slipping into poverty if faced with the costs of infection. This is in addition to the benefit of strong vaccination systems for other infectious diseases.

### B. Financial Management

48. Financial Management (FM) under the Program will be carried out in accordance with the Bank Directive: Financial Management Manual for World Bank Investment Project Financing (last revised in February 2017) and documented in accordance with the World Bank's Guidance: Preparing the Project Appraisal Document (PAD) for the Multiphase Programmatic Approach (MPA) Using Investment Project Financing (IPF) (issued May 2018).

49. Flexible FM arrangements, modeled along those allowed under emergency operations, will be applied. Streamlined procedures to expedite decision making and approval of FM exceptions under country projects would be agreed for implementation. For operations engaging UN agencies, the FM arrangements are based on the Financial Management Framework Agreement (FMFA) which includes the Single Audit Principle.

50. The agencies defined in each country project will be responsible to maintain adequate financial management arrangements. The key FM risks pertaining to the implementation of the proposed country projects, together with the residual FM risk rating will be noted in the PAD for the individual country projects and will be updated during implementation.

<sup>&</sup>lt;sup>22</sup> For example, Interrupted access to HIV, TB and malaria care threatens to cause more than a million additional deaths in 2020-2021 alone. The COVID-19 pandemic has had important mental health and psychosocial effects on populations. Disruption in health services and food shortages may lead to hundreds of thousands of additional child deaths, along with tens of thousands of additional maternal deaths in 2020.Widespread service gaps are also being reported for noncommunicable diseases, including heart disease, hypertension, diabetes and cancer treatments, especially in low-income countries.

 <sup>&</sup>lt;sup>23</sup> Based on US\$12 trillion in total cumulative output losses to the global economy across 2020 and 2021 per forecasts in the WEO Update, June 2020. "Reopening from the Great Lockdown: Uneven and Uncertain Recovery", IMFBlog, June 24, 2020.
<sup>24</sup> IMF WEO Update, June 2020.



51. Disbursement. The intention is to disburse the largest share of this operation within 12 to 18 months after approval. The speed of disbursements of the Additional Financing will be significantly influenced by the availability of vaccines. The Bank will work with Borrowers to ensure that the flow of funds is secure, so that sufficient liquidity (i.e., expedient disbursements) is available to finance the purchase of vaccines and other project activities. To support countries that are required to provide financial and risk assurances to manufacturers under advance purchase mechanisms, the Bank may adapt some of disbursement tools and arrangements, such as the Special Commitments or direct payments, at a borrower's request, to suppliers pursuant to individual supply contracts. (Through a special commitment, the Bank provides an irrevocable commitment, at a borrower's request, to reimburse a commercial bank for payments to a supplier against a letter of credit). The use of these tools and arrangements will be assessed on a case-by-case basis and will depend on the final structure and optionality of vaccine purchases to be made by borrowers and recipients under Component.

## C. Procurement

52. Procurement under the Global COVID-19 MPA AF will be carried out in accordance with the World Bank's Procurement Framework. Procurement by countries will follow the World Bank's Procurement Regulations for IPF Borrowers for Goods, Works, Non-Consulting and Consulting Services, dated July 1, 2016 (revised in November 2017 and August 2018). The Bank's procurement rules will, however, not apply to certain expenditures or upfront payments, such as speed premia, made to secure a country's participation in an advance participation mechanism for vaccines as described in this paper. The Projects will be subject to the World Bank's Anticorruption Guidelines, dated October 15, 2006, revised in January 2011, and as of July 1, 2016. Countries will use the Systematic tracking of Exchanges in Procurement (STEP) to plan, record and track procurement transactions.

53. The major planned procurement under the AF across countries is vaccines and the logistics required to deliver to the countries' ports of entry. Additional procurement to support in-country implementation will include (i) additional capacity or refurbishment of national, subnational and facility based and mobile cold chain equipment and supplies including cold rooms, ice lined refrigerators (ILR) and vaccine carriers, (ii) vehicles including refrigerator vehicles and vaccinator personnel transport, (iii) technical assistance for demand creation – including mass media and communication campaigns, (v) other technical assistance to support in-country implementation including assessments of effective vaccine management capacity and training of front-line delivery workers (iv) vaccine logistics and information management systems and information systems to monitor adverse effects from immunization. Country projects will update their project procurement strategies for development (PPSD) and procurement plans to reflect the additional procurement.

54. Vaccine manufacturers are limited, and demand is high, so manufacturers have market power which makes it more difficult for client countries to negotiate terms and conditions. In addition, high-income countries have placed capital at risk to pre-finance production in return for first access to vaccines at lower cost. The market for the associated consumables and cold chain may also experience supply chain disruptions due to increased demand for these products from countries.

55. Building on the positive experience with capital equipment and PPE and at borrowers' request, the Bank will offer Bank Facilitated Procurement (BFP) as support to countries' own procurement. BFP constitutes additional support to borrowers over and above usual Hands on Expanded Implementation Support, which will remain available. BFP will not include Bank procurement, distribution, or deployment of vaccines.



56. Procurement will be carried out by the agencies defined in each country project. Streamlined procedures for approval of emergency procurement to expedite decision making and approvals under country projects would be agreed for implementation.

### D. Legal Operational Policies

57. Each project under the program will identify if these policies are applicable in the country:

Policy				
Projects on International Waterways OP 7.50				
Projects in Disputed Areas OP 7.60				

#### E. Environmental and Social

58. The management of environmental and social risks and impacts related to COVID-19 activities under the Global COVID-19 MPA will continue to be carried out in accordance with the World Bank Environmental and Social Framework. The scope and timing of ESF requirements will continue to be appropriate to the nature and scale of the individual projects and their potential environmental and social risks and impacts. All COVID-19 operations, including all operations financed with AF, will require an Environmental and Social Review Summary (ESRS), Environmental and Social Commitment Plan (ESCP) and Stakeholder Engagement Plan (SEP) and any instruments for those activities that have direct immediate high/substantial risks. To assist the borrowers and enable application of a consistent and robust approach in managing similar types of risks related to activities required to fight COVID-19, the Bank will continue to provide templates for the instruments needed for key environmental and social risks and impacts, where and as necessary.

59. Key environmental risks will continue to revolve around properly managing, transporting and disposing the medical waste generated by the outbreak. In addition, there will be a risk of exposure to a wide range of potentially affected communities and individuals, starting with medical and health care workers, and extending from there to a wide swath of the professional and civic community. The nature of the measures taken to address these environmental risks will benefit from the experience in the medical crises described above and properly instituted accountability and citizen engagement mechanisms.

60. Regarding social risks, two types tend to predominate. The first revolves around social inclusion and nondiscrimination. In other words, ensuring that those most socially and medically vulnerable and disadvantaged are able to properly share in the benefits of the project, including getting timely access to vaccines. Moreover, that the crisis does not put the vulnerable at risk of even further stigmatization or abuse. For example, that risks of sexual exploitation, abuse and harassment (SEA/H) are not exacerbated due to the vulnerability caused by the outbreak. A second type of social risk revolves around inadequate or conflictual public engagement and lack of trusted and adequate consultation, resulting in risk of degenerating social behavior, such as hoarding or price gouging, or the inadequate practice of, or interference with, disease prevention and control. Such risk may also manifest itself in retaliation or reprisals against health care workers or community members who voice concerns over COVID related operations or policies. Proper application of the Bank's stakeholder engagement standard will be especially important to mitigate these risks.

61. Based on experience, we have ability to embed the use of the tools and measures most appropriate to address

these risks, with any adaptations that may be needed as we learn more. For example, in considering the exposure risk of healthcare workers, those exposed to the deadly Ebola suffered frequent fatalities but the mortality rate in the context of COVID-19 appears to be much lower at this point. In considering how to classify project risk, it is also important, as the Environmental and Social Framework Policy dictates, to consider a range of factors. Under the ESF, environmental and social risks associated with a project are classified as High, Substantial, Moderate or Low by considering more explicitly both, the social and environmental impacts as well as a range of factors that affect both the risks and the government's ability to manage them, such as borrower capacity, governance, and country context including stability, conflict and security.

## F. Waivers

62. Consistent with the policy waivers approved for the initial Global COVID-19 MPA, the following waivers are proposed for the Additional Financing:

- i. Enabling Management approval of financing for individual projects in the amount of \$100 million or less that are rated Substantial for E&S risks;
- ii. Where retroactive financing is sought, a limited waiver of application of the ACGs to losing bidders; and
- iii. IDA waivers, to the extent applicable to IDA19 resources.

63. In addition, given uncertainties related to the timing of the vaccine availability, to provide adequate flexibility to borrowers, it is proposed that the standard IBRD commitment fees for projects under the Additional Financing be waived for the first 18 months, starting from the date of approval of financing for each project.

### V. WORLD BANK GRIEVANCE REDRESS

64. 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. PROPOSED ADDITIONS TO THE RESULTS FRAMEWORK AND MONITORING

Action	Indicator Name	PBC	Baseline	End Target			
PrDO Indicators							
New	Percentage (%) of participating countries <sup>25</sup> that have vaccinated their priority population, based on the targets defined in their national plans.		0.00	70.00%			
Intermedia	te Results Indicators by Components						
Component 1: Emergency COVID-19 Response							
New	Percentage (%) of participating countries with a national plan for Covid-19 vaccine procurement and deployment		0.00	100.00%			
Component 3: Supporting National and Sub-national, Prevention and Preparedness.							
New	Percentage (%) of participating countries with Effective Vaccine Management assessments with composite scores of 80% or higher		0.00	70.00%			
Component 4: Community Engagement and Risk Communication.							
New	Percentage (%) of participating countries with a community engagement plan for increasing demand creation for the Covid-19 vaccine by the population		0.00	70.00%			

<sup>&</sup>lt;sup>25</sup> Participating countries are those included under both the Global COVID-19 MPA and/or the AF.



#### **ANNEX 1: WHO LIST OF STRINGENT REGULATORY AUTHORITIES (SRAs)**

The following is the list of the countries whose National Regulatory Authorities are designated as SRAs by WHO:

- Australia
- Austria
- Belgium
- Bulgaria
- Canada
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Italy

- Japan
- Latvia
- Liechtenstein
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- United Kingdom
- United States of America