



Policy Paper

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ADB's Support to Enhance COVID-19 Vaccine Access

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Asian Development Bank

ABBREVIATIONS

ADB	– Asian Development Bank
ADF	– Asian Development Fund
APVAX	– Asia Pacific Vaccine Access Facility
COL	– concessional ordinary capital resources lending
COVAX	– COVID-19 Vaccines Global Access
COVID-19	– coronavirus disease
CPRO	– COVID-19 Pandemic Response Option
CRW	– crisis response window
DMC	– developing member country
DMF	– design and monitoring framework
DRF+	– Expanded Disaster and Pandemic Response Facility
EAL	– emergency assistance loan
FCAS	– fragile and conflict-affected situation
GAVI	– Gavi, the Vaccine Alliance
GDP	– gross domestic product
IDA	– International Development Association
IMF	– International Monetary Fund
LIBOR	– London interbank offered rate
M&E	– monitoring and evaluation
MFF	– multitranches financing facility
OCR	– ordinary capital resources
PIC	– project investment component
PIC-11	– Pacific island countries
PPE	– personal protective equipment
RRC	– rapid response component
RRP	– report and recommendation of the President
SIDS	– small island developing states
SPS	– Safeguard Policy Statement
SRA	– stringent regulatory authority
TA	– technical assistance
TASF	– Technical Assistance Special Fund
TSCFP	– Trade and Supply Chain Finance Program
UN	– United Nations
UNICEF	– United Nations Children’s Fund
WHO	– World Health Organization

NOTE

In this report, “\$” refers to United States dollars unless otherwise stated.

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EXECUTIVE SUMMARY

To meet the unique challenges developing member countries (DMCs) face on vaccine access, the Asia Pacific Vaccine Access Facility (APVAX) is proposed. It will provide a comprehensive framework and resource envelope of \$9 billion to support fast, high quality, safe and equitable vaccine access by DMCs. Upon approval of the APVAX, the Asian Development Bank (ADB) will prepare and process country-specific financing proposals for individual DMCs. The APVAX will take advantage of common objectives and results frameworks across individual country-specific financing proposals to minimize transaction costs while still reflecting the unique needs of individual DMCs. The approach recognizes different readiness levels among DMCs and provides them with the flexibility to join and utilize the APVAX when they are ready.

The APVAX will be flexible, providing advance resources to finance urgent vaccine procurement and complementary financing for vaccine delivery, distribution, and administration, with streamlined business processes that maintain appropriate due diligence. It will also offer DMCs the option to choose from different components under a risk-based and demand-driven approach.

Through its strong emphasis on partner coordination, the APVAX will ensure an efficient division of labor between International Organizations, bilateral donors and other actors. It will also provide an effective platform for knowledge transfer and learning across DMCs and will encourage rapid adaptation as knowledge about vaccine effectiveness, distribution and delivery continues to evolve.

Country-specific financing proposals prepared under this framework will meet ADB's high development impact, governance, anticorruption, accountability, and safeguard standards. Effective governance practices are necessary to translate resources into desired development outcomes and to promote efficient delivery of services. The proposal will also establish a robust monitoring and evaluation approach to assess the impact of ADB's vaccination support. During project design, ADB will conduct gender analyses to reduce gender gaps and mitigate exclusion risks for women, girls and other marginalized groups.

The framework will balance the immediate support DMCs need against the medium-term engagement necessary to sustain national vaccination programs over a 3-year availability period. ADB's interventions will also be shaped by its institutional experience and comparative advantage.

I. INTRODUCTION

1. This paper proposes the establishment of the Asia Pacific Vaccine Access Facility (APVAX). It will provide a resource envelope and mechanism for support to developing member countries (DMCs) as they procure and deliver coronavirus disease (COVID-19) vaccines safely and effectively. Following Board approval of the APVAX, the Asian Development Bank (ADB) will prepare country-specific financing proposals (or country projects) to meet the unique needs of DMCs. These financing proposals will employ fast-tracked business processes, enhancing ADB's ability to process support faster and with lower transaction costs. The APVAX and the policy variations described in this paper are proposed for 36 months from Board approval and may be extended for up to 24 months subject to the outcome of a review and prior Board approval.

II. BACKGROUND AND CONSTRAINTS

A. Background

2. **Economic and social impact of the pandemic.** COVID-19 has had a devastating impact across the globe. As of 1 December 2020, more than 64 million positive cases had been confirmed globally, causing more than 1.48 million deaths.¹ The scale and scope of the COVID-19 pandemic is unprecedented in recent times. In Asia and the Pacific, countries have had mixed success in containing the spread of the virus. More than 17.0 million positive cases have been confirmed in the region, causing more than 295,000 deaths. The number of new daily COVID-19 cases remains high in some regional economies, is flattening or subsiding in others, and reviving in still others in second or third waves. Many countries, particularly in developing Asia, have mounted strong responses to mitigate the pandemic's impacts, but significant challenges remain.

3. The economic and social effects of the pandemic are similarly devastating. In June 2020, ADB estimated that global economic losses could range from \$6.1 trillion to \$9.1 trillion, equivalent to a loss between 7.1% and 10.5% of global gross domestic product (GDP). About 22% of the global loss will be in developing Asian economies, where the impact is estimated at \$1.3 trillion–\$2.0 trillion, or 5.7%–8.5% of regional GDP. As the pandemic persists, developing Asia is projected to contract by 0.7% in 2020—the first regional GDP contraction since the early 1960s. Developing Asia excluding the newly industrialized economies will contract by 0.5%.² The estimated number of poor in the region is likely to reach 192 million by the end of 2020 using the \$1.90 poverty line, or to 896 million using the \$3.20 poverty line, reversing poverty reduction achieved over the past 3–4 years.³ Workplace closures continue to disrupt labor markets around the world, leading to losses in working hours. During the first three quarters of 2020, 9.9% of labor income lost due to working-hour losses in Asia and the Pacific.⁴ Growth is forecast to rebound to 6.8% in 2021, but this will leave the output level substantially below expectations before COVID-19 with significant downside risks.

4. **ADB's initial coronavirus response.** On 18 March 2020, ADB announced a \$6.5 billion initial package to address the immediate needs of its DMCs as they responded to the COVID-19 pandemic. On 13 April 2020, ADB's Board of Directors approved an enhanced \$20 billion package to help its DMCs address the impacts of the COVID-19 pandemic along with special policy

¹ [Johns Hopkins Coronavirus Resource Center](#) (accessed 1 December 2020).

² A full list of economies included in developing Asia is available in the [Asia Development Outlook](#).

³ ADB. 2020. *Asian Development Outlook 2020 Update*. Manila.

⁴ ILO. 2020. *ILO Monitor: COVID-19 and the World of Work. Sixth edition*. Geneva.

variations to streamline its operations for quicker and more flexible assistance.⁵ As part of the package, ADB expanded the resources available for nonsovereign operations and established the COVID-19 Pandemic Response Option (CPRO) under the Countercyclical Support Facility. Through CPRO, ADB made up to an additional \$13 billion available in regular ordinary capital resources (OCR) to help DMCs implement effective countercyclical expenditure programs to mitigate the impacts of the pandemic, with a focus on the poor and vulnerable. All special policy variations introduced under ADB's Comprehensive Response to the COVID-19 Pandemic will be available until July 2021.⁶

5. As of 31 October 2020, ADB had committed about \$12.5 billion in financial and technical assistance (TA) resources. This included \$8.3 billion in CPRO commitments that are helping finance countercyclical economic stimulus packages in 19 countries⁷ and \$2.2 billion for other sovereign COVID-response projects, including contingent disaster financing. Support to the private sector included about \$163.5 million in direct financing to supply medicines and essential services through working capital support; and \$3.5 billion in trade and supply chain finance, and microfinance programs. ADB also provided \$56 million of rapid grants under the Asia Pacific Disaster Response Fund for immediate humanitarian and health emergency expenses in 29 member countries. About \$100 million in TA supported member countries with (i) implementing CPRO; (ii) strengthening hospitals and laboratories; (iii) training frontline health workers; (iv) initiating risk communications; and (v) addressing urgent needs, including procurement of personal protective equipment (PPE), diagnostic and medical equipment, and food. In addition, ADB mobilized \$8.0 billion in cofinancing commitments, including \$5.9 billion for CPRO operations and \$1.8 billion in nonsovereign operations.

6. ADB will continue to support DMCs in building back better and more resilient economies and catalyzing a green economic recovery, while also remaining ready to support other COVID-19 response measures. This support will continue to use the remaining resources of ADB's \$20 billion comprehensive response package along with resources allocated through regular country programming and advisory services.⁸

7. **Lessons from initial coronavirus response.** ADB's initial response to the COVID-19 pandemic focused on several immediate issues facing DMCs. ADB's package helped DMCs to (i) procure emergency PPE and other necessary medical equipment to slow the spread of the pandemic; (ii) mobilize additional TA, risk communications, and knowledge support to develop national plans and strategies for responding to the health, social, and economic impacts of the pandemic; (iii) expand the provision of private finance to support trade, supply chains, and microenterprises; (iv) map supply chains for companies manufacturing and distributing goods critical to fighting COVID-19; (v) undertake critical countercyclical fiscal expenditure programs to

⁵ ADB. 2020. *ADB's Comprehensive Response to the COVID-19 Pandemic*. Manila. The package expanded ADB's \$6.5 billion initial response, adding \$13.5 billion in resources to help ADB's DMCs counter the severe macroeconomic and health impacts of the crisis. The \$20 billion package included \$2,281 million in Asian Development Fund (ADF) grants and concessional ordinary capital resources lending (COL), comprising \$704 million in additional concessional resources (\$100 million in ADF grants and \$604 million in COL from the Disaster Response Facility under ADF 12), \$930 million mobilized through the reprogramming of ADF 12 grants and COL country programs, \$281 million in savings and cancellations generated from ongoing projects, and \$366 million generated from reallocations of existing resources from ongoing projects.

⁶ ADB's Comprehensive Response to the COVID-19 Pandemic Policy specifies that an initial review of ADB's COVID-19 response efforts will be conducted within 8 months of Board approval. The review will be conducted by the end of 2020. Based on the findings of this review, ADB will submit to the Board of Directors an assessment of whether an extension of the special policy variations beyond the initial 15-month period is necessary and appropriate.

⁷ In addition, \$1.5 billion in CPRO for Thailand has been approved but not yet committed.

⁸ ADB. 2020. *Work Program and Budget Framework, 2021–2023*. Manila.

mitigate the economic damage of the pandemic and provide targeted social protection for vulnerable groups, especially women; and (vi) adapt country programs to begin supporting DMCs in building back better and more resilient economies.⁹

8. Knowledge services and flexibility in fund usage were critical for ADB to enable DMCs to urgently respond to the COVID-19 pandemic. ADB's rapid response gave DMCs additional fiscal space to (i) formulate solutions for addressing the social and economic impacts of the pandemic and (ii) design longer-term measures needed for a sustainable and green economic recovery. As the COVID-19 pandemic has progressed, ADB's support must keep pace. More targeted approaches that make the best use of ADB's limited resources will be necessary to further mitigate the impact of the pandemic. ADB's initial support has also highlighted the direct and indirect impacts of COVID-19 on DMCs. For some DMCs, high rates of infection, lockdowns, business closures, and social distancing have severely reduced labor productivity and caused supply disruptions. In others, the loss of income due to quarantines and rising unemployment have reduced household consumption, investment, and access to social services. Impacts from COVID-19 have been far reaching and differential across social groups, occupations, and locations. Women have been disproportionately affected because of their overrepresentation in sectors hardest hit by the pandemic—manufacturing, textiles and garments, care services, hospitality, and tourism—and in vulnerable forms of employment with the least protection, such as informal workers, self-employed workers, domestic workers, and daily wage and contributing family workers.¹⁰ Many DMCs have also reported drastic increases in gender-based violence as lockdowns and quarantine measures often confine women with their abusers, with limited options for seeking help and support.¹¹ The extreme uncertainty about the path, duration, magnitude, and impact of the pandemic has emphasized the need for ADB to be flexible and adaptive in its approaches. ADB needs to be able to respond quickly to changing DMC circumstances, while providing the long-term strategic vision for an inclusive, sustainable, and green economic recovery.

9. **Next phase of ADB's response.** Non-pharmaceutical interventions such as mobility and travel restrictions, school closures, physical distancing, expanded testing to detect cases, contact tracing, and quarantine and isolation have reduced the spread of COVID-19. However, these measures significantly constrain economies and only slow transmission. DMCs also face fiscal stress. The elimination of COVID-19 is difficult to achieve because the virus is highly infectious,¹² but widespread vaccinations can help to control transmission in combination with non-pharmaceutical interventions. DMCs are therefore preparing to deploy COVID-19 vaccines as soon as possible. Appropriate policies, financing, and knowledge support will be needed to meet vaccine planning, procurement, delivery, and communication needs and to carefully manage the risks of introducing a new vaccine into populations. Agile, flexible, and timely ADB financial and knowledge support can play an essential role in helping DMCs meet these challenges.

B. Sector issues

10. **Rapid pace of vaccine development, competition over supply.** As second and third waves of infection emerge globally, DMCs are challenged to keep citizens safe while managing

⁹ The interim policy review of ADB's Comprehensive Response to the COVID-19 Pandemic will provide more detailed analysis of these lessons. It will be available in the first quarter of 2021.

¹⁰ UN Women. 2020. *The First 100 Days of COVID-19 in Asia and the Pacific: A Gender Lens*.

¹¹ UN Women. 2020. *A Guide for Action to Stem Increasing Violence Against Women amid the COVID-19 Pandemic in Asia and the Pacific*. Action Brief.

¹² P-Y. Geoffard and T. Philipson. 1996. Disease Eradication: Private versus Public Vaccination. *American Economic Review*. 87(1): 222-30.

the economic impacts. An effective vaccine could help restore confidence among governments and citizens, but global demand and restricted vaccine supply pose significant challenges for DMCs. Promoting DMCs' access to safe and effective vaccines is a key priority for ADB's COVID-19 response. Effective vaccination programs can break the chain of virus transmission, save lives, and mitigate the economic damage of the pandemic by restoring confidence in people's ability to work, travel, and socialize safely.

11. Vaccine development is proceeding rapidly. Eleven vaccine candidates are in stage III clinical trials; more than 250 other candidates are at earlier stages of testing. The World Health Organization (WHO) is currently on track to include some vaccines on its Emergency Use Listing by as early as December 2020, and DMCs may register them for widespread use between February and March 2021. However, current vaccine production capacity restrictions will mean that demand for approved vaccines will far exceed supply for the foreseeable future. Developed economies are moving quickly to secure advance access to early quantities of vaccines; many are also managing risk by securing access to two or more vaccine candidates. This situation places extreme pressure on DMCs to act quickly to ensure access to COVID-19 vaccines for their populations. Initial global demand may also lead to higher prices or unbalanced contracts that significantly reduce manufacturers' liabilities and distort equitable allocation. In March and April 2020, high demand for scarce PPE resulted in average prices rising by more than tenfold. A comprehensive and coordinated approach, with close support from technical and development partners, is essential to ensure DMCs access safe vaccines at commercially reasonable prices.

12. **Global vaccine access for lower- and middle-income countries.** DMCs require committed financial resources to engage in early negotiations with manufacturers, or to secure advance purchase agreements through multilateral platforms such as the COVID-19 Vaccines Global Access (COVAX) facility.¹³ COVAX ensures that the most suitable candidate vaccines get the backing they need to maximize the probability of success. It invites global participation to pool demand and resources to support procurement of COVID-19 vaccines. COVAX will negotiate 5 to 10 advance purchase agreements at the highest possible volume and most reasonable price for vaccine candidates meeting technical threshold criteria. Through COVAX, vaccine doses for up to 20% of the total population will be made available and distributed equitably among participating countries. Priority is given to health workers and other frontline workers and then the most vulnerable segments of the population (the elderly and populations with underlying comorbidities as COVAX has deemed them high-risk groups because they have significantly elevated risk) when vaccines become available. As of 24 November 2020, 189 countries and territories had joined the COVAX facility, including 92 low- and middle-income countries (29 of which are ADB DMCs)¹⁴ eligible to secure doses partly paid for with donor financing. However, while pooled procurement may allow DMCs to obtain their first vaccine doses earlier, supply restrictions under COVAX suggest there will likely be delays in obtaining sufficient vaccines to reach herd immunity.¹⁵ Thus, DMCs may seek to obtain doses of vaccines through other means. Larger loans and financing can be provided to DMCs to support vaccine procurement and delivery, including advance purchase of vaccines through mechanisms such as COVAX or direct purchase from manufacturers.

¹³ A summary description of the COVAX facility is in Appendix 7.

¹⁴ Afghanistan, Kyrgyz Republic, Pakistan, Tajikistan, and Uzbekistan in Central and West Asia; Mongolia in East Asia; Federated States of Micronesia, Fiji, Kiribati, Marshall Islands, Papua New Guinea, Samoa, Solomon Islands, Tonga, Tuvalu, and Vanuatu in the Pacific; Bangladesh, Bhutan, India, Maldives, Nepal, and Sri Lanka in South Asia; and Cambodia, Indonesia, Lao People's Democratic Republic, Myanmar, Philippines, Timor-Leste, and Viet Nam in Southeast Asia.

¹⁵ Herd immunity is a concept used for vaccination, in which a population can be protected from a certain virus if a threshold of vaccination is reached.

13. **Vaccine delivery challenges and risks.** Differences between vaccine production timelines and country readiness present additional challenges. In addition to prioritizing segments of populations to receive the first available doses and developing strategies for achieving broader coverage, many countries will need to prepare their vaccine delivery systems for the introduction of a COVID-19 vaccine. For example, immunization systems in many countries focus on delivering childhood vaccines through health clinics rather than adult vaccinations. Adaptations are needed to deliver vaccines to adult populations including older persons, such as adapting existing or establishing new distribution channels, updating vaccine information and monitoring systems, identifying campaign venues, mobilizing community groups working with hard to reach populations, and preparing communication tools. Most vaccines will follow a two-dose regimen at unique time periods. Thus, organizing campaigns effectively to ensure the highest percentage of the target cohort receives two doses where necessary is essential. Successful implementation of national vaccination strategies will also depend on other variables, such as transport, storage and logistics infrastructure, and a vaccine's specific transportation and storage requirements. Some of these novel vaccines require more stringent cold chain storage than countries currently are equipped to provide. Other variables include the capacity of health facilities, the effectiveness of the vaccines, the sufficiency of medical personnel, prioritization of recipients based on strategic vaccination objectives, and community attitudes towards COVID-19 and the safety and efficacy of vaccines. All COVID-19 vaccines will require rigorous pharmacovigilance, or safety monitoring. Tracking vaccine delivery and potential adverse health events caused by vaccinations will be critical to ensuring safe, efficient, and effective delivery. Where more than one multi-dose vaccine is on the market at the same time, it will be essential to track which vaccine individuals received in the first dose and when, so they can receive a second dose of the same vaccine. These procedures, which will be critical for success, will require bolstering information systems, reporting documents, and training of health workers and logisticians. The successful introduction of a new vaccine requires listening and appropriately tailoring responses to a country's needs and priorities. Many of these variables are country-specific and rapidly changing and will require additional analysis and investments by governments.

14. **Balancing regional and country-specific approaches.** Vaccination programs will likely have some common objectives and features across countries. Lessons that emerge in one country could be relevant to others in the region. Because virus transmission across borders remains a risk, regional approaches to disease surveillance, storage, transportation, and distribution of vaccines and medical supplies are likely to be effective for many DMCs. As such, a regional approach that provides comprehensive support under a common framework is necessary to provide some public goods that benefit all countries. At the same time, individual country needs are likely to differ based on geography, country readiness and other factors. Striking an appropriate balance between regional and country-specific approaches will be critical for success.

15. **Financing and capacity constraints.** DMCs face the challenge of developing and implementing effective vaccination strategies in the midst of the COVID-19 pandemic, which has placed extraordinary demands on the public sector, even as it has constrained their ability to deliver critical services. Severe economic impacts of the pandemic combined with the immediate health and social protection needs have put a heavy burden on public resources, while reduced economic activity has depressed domestic revenues in many DMCs. Non-pharmaceutical interventions to slow the spread of the virus through social distancing and quarantine arrangements have challenged the ability of governments to meet, coordinate, and mount a physical presence to implement response programs in affected communities.

16. **Incorporating lessons learned.** The successful implementation of national immunization programs relies on several key factors including: (i) ensuring the purchase of sufficient doses of vaccines to supply the target group; (ii) undertaking strong public awareness and advocacy campaigns for the new vaccine and the access prioritization criteria to educate the public, generate community support, address gendered and other barriers to access, and ensure outreach to the most vulnerable and disadvantaged, including women; (iii) assessing options for collaborating with existing community-based organizations on the ground to speed up messaging and trust building; (iv) ensuring adequate cold chain capacity at all levels of the distribution and supply chain to ensure equity; (v) identifying gaps and undertaking sufficient training of health workers on the new vaccine; and (vi) establishing a robust monitoring, tracking, and feedback system that can quickly identify emerging or future challenges. For example, the WHO delivered 32 million doses of vaccine to 34 countries in the WHO Africa Region during the influenza (H1N1) pandemic in 2009. Because of delivery challenges, most vaccine doses were distributed after the main transmission periods and when countries were in the post-pandemic phase of the response. COVAX, the global community, and development partners must ensure that these types of shortages and delays do not recur with COVID-19 vaccines. ADB needs to move quickly to ensure adequate financing and appropriate modalities that meet the vaccine planning, procurement, distribution, and delivery needs of DMCs.

17. **Demand for support.** To enhance vaccine access, DMCs are requesting the following:

- (i) developing comprehensive national COVID-19 vaccination plans including (a) the identification of gaps in vaccine procurement or production, distribution, and delivery systems; (b) priority population identification; (c) monitoring; (d) large-scale communications efforts such as demand generation, risk communication, surveillance, and testing; and (e) community engagement;
- (ii) establishing robust systems and infrastructure for transporting, storing, deploying, and tracking vaccine delivery, including health worker capacity building and pharmacovigilance—especially because adequate data will be crucial for monitoring adverse events and preventing delayed or interrupted supplies; and
- (iii) ensuring adequate financial resources to purchase vaccines and other associated goods for the production of vaccination (such as glass vials and syringes) and services required for their effective and safe distribution.

18. DMCs are expected have many common needs as they seek to acquire and deliver vaccines to their citizens. However, their specific requirements are likely to differ as financing availability, geographic and demographic characteristics, vaccine-specific requirements, infrastructure conditions, transport and logistics networks, and health sector capacity influence the readiness of DMCs to procure or produce, distribute, and deliver vaccines safely and effectively. ADB's response should strike a balance between applying common approaches for country projects that support timely processing and enabling country-tailored support based on individual needs.

19. **Development partner coordination on the vaccination response.** ADB support for COVID-19 vaccines must be undertaken in close coordination with other development partners, including the WHO; the United Nations Children's Fund (UNICEF); Gavi, the Vaccine Alliance (GAVI); the World Bank; bilateral partners, and other development partners. ADB is coordinating locally, regionally, and globally through memorandums of understanding (MOUs), administrative arrangements, and collaborations with these partners. At the country level, ADB will join these partners in conducting assessments and explore mechanisms for collaboration through parallel or cofinancing. This coordination is essential to achieve a fair and equitable framework for vaccine

access, as well as to reduce the risk of duplicating efforts among development partners or driving up vaccine prices by countries competing for the scarce supply. For all sovereign, ADB-financed vaccine support operations, a functioning development partner collaboration platform will be required as part of project due diligence.¹⁶ At a minimum, the country platform should ensure coordination on issues such as preparation of needs assessments, vaccination strategy development, risk and communications programs, fiduciary tasks of procurement (including harmonization of commercial terms) and financial management, and safeguards for medical waste management. Where existing mechanisms are insufficient or where coordination mechanisms for vaccine responses are not in place, ADB TA and staff resources may be necessary to establish a functioning mechanism. This coordination platform should comprise representatives from all relevant stakeholders and government agencies to ensure ADB's approach is consistent with the government's national vaccination approach and to avoid overlapping of support. Coordination with the private sector on financing and logistics management, particularly concerning cold transport and storage, is also required.

20. Assessment of existing financing modalities. Several ADB modalities have characteristics that are aligned with the needed support, although each have their own challenges and gaps. The multitranche financing facility (MFF) provides a framework for supporting strategic, long-term plans for large-scale and complex investments, while providing the flexibility to define the details of interventions in phases through tranches. The emergency assistance loan (EAL) modality offers useful lessons in streamlining project preparation to accelerate processing, while retaining appropriate due diligence.¹⁷ The policy-based loan (PBL) provides useful lessons on how a positive list of permissible expenditures can help balance flexibility and speed. The results-based loan provides guidance for use of program procurement and financial management systems owned by DMC counterparts. For the private sector, ADB's Trade and Supply Chain Finance Program will also play a role. Appendix 6 provides a more detailed comparison of some existing financing modalities. This proposal considers lessons learned from these modalities, while recognizing they may not be well calibrated to meet DMCs' needs during this unique crisis. As such, an innovative approach is required.

21. Novel financing arrangement. A novel financing arrangement is proposed to allow ADB to respond better to (i) the urgent demand for vaccine access; (ii) the complexities of vaccine procurement, distribution, and delivery; and (iii) the need to balance flexibility and timeliness with a clear results chain, and full compliance with ADB fiduciary, environmental, and social due diligence. The proposed modality will incorporate the strengths of existing instruments, while modifying requirements to ensure they are appropriate to the conditions being faced by DMCs during the COVID-19 pandemic.¹⁸ It will build on lessons learned from ADB's initial comprehensive COVID-19 response, including the CPRO.

¹⁶ Where available, ADB will leverage development partner coordination platforms led by the United Nations.

¹⁷ ADB. 2019. *Review of the 2004 Disaster and Emergency Assistance Policy*. Manila.

¹⁸ The APVAX proposal draws lessons and good practices from across a range of ADB financing instruments to provide a tailored novel financing arrangement. A summary of key modality features includes (i) adopting the principle of sector development loans by allowing for the combination of two financing instruments into a single operation to provide more flexibility and better meet DMCs different vaccine financing needs; (ii) adopting abbreviated processing procedures from emergency assistance lending to streamline project preparation and advance project commitment; (iii) modifying the concept of a "positive list" from policy-based lending to tie quick-disbursing funds to specific expenditure items and enhance ADB's control of fund usage and strengthen results links; and (iv) adopting the financing terms and conditions from ADB's COVID-19 Pandemic Response Option to better manage the impact of expanded lending headroom on ADB's financial sustainability.

III. PROPOSED RESPONSE: THE ASIA PACIFIC VACCINE ACCESS FACILITY

22. To meet the unique challenges DMCs face on vaccine access, the APVAX is proposed.¹⁹ It will provide a broad framework and resource envelope to support vaccine access by DMCs. Following Board approval of the APVAX, ADB will prepare and process country-specific financing proposals (or country projects) for individual DMCs, taking account of other donors' and agencies' interventions and ADB's in-country and global capacity.²⁰

23. Each country project will be aligned with the APVAX's overarching objectives and expected results. This results framework architecture enables ADB to respond rapidly to DMC needs, while ensuring projects are strategically aligned and focused on results. The deadline for Board of Directors approval for new country-specific financing proposals under the APVAX will be 31 December 2023.

24. **Access criteria.** DMCs will be required to meet a series of access criteria to avail themselves of the sovereign financing under the APVAX. These should be documented in individual country-specific financing proposals. The access criteria are (i) demonstrated adverse impact of the COVID-19 pandemic,²¹ (ii) completion of a needs assessment acceptable to ADB and a national vaccination allocation plan that indicates prioritization of vaccine access consistent with international norms and safeguards against exclusion of marginalized and vulnerable groups,²² and (iii) the presence of an effective development partner coordination mechanism and a clear role for ADB within this platform (para. 19).

25. In line with the principles of flexibility and responsiveness, the APVAX will have two distinct but complementary components for country-specific financing proposals. These components may be processed simultaneously as a single report and recommendation of the President (RRP) or as separate RRP's over time. DMCs may select any mix of these two components that best addresses their vaccine access needs. The components are described in paras. 26–27.

26. **Rapid response component.** The rapid response component (RRC) is intended to provide flexible and timely financing for vaccine procurement and logistics costs based on a list of acceptable expenditure items that ADB and the DMC have agreed upon. The RRC will focus on critical diagnostic and analytical work to prepare for vaccinations, payments to COVAX, procurement of vaccines, and logistics for bringing vaccines from the place of purchase to the DMC. Because the needs of DMCs will probably differ and evolve over time, a master list of eligible expenditures is outlined under this proposal. Eligible expenditure items to be financed under the RRC will be drawn from that master list, agreed upon with the DMC, and documented

¹⁹ The APVAX access criteria, vaccine eligibility and due diligence requirements will apply to all ADB operations which support access to COVID-19 vaccines including those financed from regular country allocations, changes in project scope, or additional financing.

²⁰ Such proposals may include ADB financing support provided in connection with sovereign guarantee operations. In each case, the proposals must comply with the requirements of the APVAX with respect to access criteria, vaccine eligibility, and eligible expenditures.

²¹ This may include social, health, or economic impacts, or a combination of those impacts. The expected development impacts of the introduction of a COVID-19 vaccine should also be explained as part of the rationale and results monitoring sections of project documentation.

²² A governor's letter that confirms the DMC's commitment to implement its COVID-19 vaccination allocation plan should be included as an attachment to the country-specific financing proposal. The plan should include arrangements and planning to manage incremental medical waste and procurement arrangements. The governor's letter should affirm the DMC's commitment to following the APVAX vaccine eligibility criteria. If known, the DMC may also indicate selected vaccines or vaccine candidates.

in the RRC project proposal.²³ Vaccine procurement must strictly adhere to the eligibility criteria (para. 29). Although alternative disbursement procedures may be employed,²⁴ the RRC is by default an advance financing instrument based on a set of eligible expenditures, with policy and procedural flexibility to enable expediency. Advance financing for eligible expenditures will be provided in accordance with the advance fund procedure described in ADB's Loan Disbursement Handbook (2017, as amended from time to time). Advance financing will be allowed for up to 6 months of eligible expenditures to be financed through the account or 50% of the total RRC financing amount, whichever is lower, if justified by the DMC's procurement planning and associated time frames, as documented in the country project proposal. However, ADB Management may approve a higher ceiling where justified by exceptional circumstances, provided that requisite financial management, procurement, and other due diligence requirements have been met.²⁵ Liquidation of expenditures will follow standard procedures outlined in ADB's Loan Disbursement Handbook.²⁶ All DMCs may avail themselves of the RRC, subject to meeting the access criteria set out in para. 24.²⁷ Detailed business processes for the RRC are in Appendix 1 of this paper.

27. Project investment component. The project investment component (PIC) will support investments in systems for the successful distribution, delivery, and administration of vaccines along with associated investments in building capacity, community outreach, and surveillance. The PIC makes use of streamlined project preparation procedures while drawing on due diligence specific to vaccination support needs. The PIC may support physical infrastructure and civil works for vaccine delivery, including cold chain storage and transportation, vehicles, distribution, delivery infrastructure, processing facilities, and other physical investments. The PIC may also be used to support the expansion or establishment of manufacturing capacity for COVID-19 vaccines and other vaccines. In addition, DMCs may use the PIC for institutional or capacity strengthening activities, particularly where a medium-term investment is required. These may include providing training and capacity support for health workers, enhancing public communications and outreach to support vaccine programs, and developing surveillance systems to monitor and track implementation progress. The PIC is structured as a standalone investment project. Due diligence requirements, including enhanced procurement support for the PIC, are discussed in Appendix 1.

28. Appropriateness of modality. The APVAX will provide a framework and resource envelope accessible under a consistently applied set of eligibility criteria. However, it will

²³ An indicative master list of acceptable expenditure items is in Appendix 4. The agreed list of acceptable expenditure items for each RRC may comprise the master list or a subset of it. ADB's Sustainable Development and Climate Change and Procurement, Portfolio and Financial Management Departments will oversee the agreed list of eligible expenditure items for each RRC. The required steps in the preparation and processing of RRC project proposals include a review and endorsement of the agreed list of eligible expenditure items for each RRC, and confirmation of its alignment with the master list, which SDCC and PPF will also oversee.

²⁴ While advance fund is the default disbursement procedure (subject to adequate financial management capacity) under the RRC, project teams will assess the appropriateness of alternative disbursement methods (i.e., reimbursement, direct payment, commitment procedures) during the processing of RRC projects, as necessary.

²⁵ The amount allowed for advance financing under the RRC is subject to the combined outstanding balance of advance financing and the percentage approved for retroactive financing not exceeding 60% of the approved RRC financing amount, as specified in para. 34(i).

²⁶ ADB. 2017. Loan Disbursement Handbook. Manila.

²⁷ Given its quick-disbursing nature and use of domestic budgetary systems, RRC operations should include a debt sustainability assessment as a linked document. The assessment should provide an up-to-date analysis of the DMC's public debt situation. If a DMC is deemed to be at moderate or high risk of debt distress, then an explanation of the DMC's medium-term debt strategy should be provided along with how ADB's financing will be used to support a return to debt sustainability, including for grant-eligible DMCs. Reference to recent assessments by the World Bank or International Monetary Fund (IMF) and any ongoing IMF programs should be included, where relevant. A formal IMF assessment letter is not required.

recognize different readiness levels among DMCs and will provide them with the flexibility to join and utilize the facility when they are ready. The APVAX will be fast and flexible, providing advance resources to finance urgent vaccine procurement and complementary financing for vaccine delivery, distribution, and administration. It will offer streamlined business processes while seeking to maintain appropriate due diligence. The facility will also provide DMCs with the option to choose from different components under a risk-based and demand-driven approach. The RRC manages risk through a narrowly prescribed set of expenditures with low procurement, financial management and safeguards risks, and is critical to provide advance financing for DMCs' most urgent needs while ensuring a focus on results. Through its emphasis on partner coordination, the APVAX will provide an effective platform for knowledge transfer and learning across DMCs. It will also encourage rapid adaptation as knowledge about vaccine distribution and delivery continues to evolve. Finally, the platform will strike a balance between the immediate needs of many DMCs and the medium-term engagement necessary to sustain national vaccination programs over the 2 or more years that will be required to effectively contain the disease.

29. **Promoting procurement of safe and effective vaccines.** To be eligible for ADB financing under the RRC, vaccines must meet one of the following criteria, which were selected to ensure public health safety, reduce deaths and disease burden, and reduce societal and economic disruption while supporting fast access to vaccines for DMCs and recognizing the importance of the Asian vaccines marketplace and manufacturers:²⁸

- (i) the vaccine has been selected for procurement through COVAX on behalf of its participating countries,²⁹ or
- (ii) the vaccine manufacturer is prequalified by the WHO, or
- (iii) the vaccine is authorized by a stringent regulatory authority (SRA) for manufacture in an SRA country or the SRA has authorized its manufacture in a non-SRA country.³⁰

30. ADB is also committed to the highest degree of harmonization and collaboration with the COVID-19 Vaccines Global Access Facility. To this end:

- (i) DMCs may use all or part of the RRC proceeds to procure vaccines directly from manufacturers by applying the criteria in para. 29, or they may make payments and contributions to COVAX to procure vaccines through, or secure its participation in, COVAX.
- (ii) A policy variation is proposed to waive the application of ADB's Procurement Policy: Goods, Works, Nonconsulting, and Consulting Services (2017, as amended from time to time) for vaccines to be procured through COVAX. Instead, such vaccines will be procured using the procurement arrangements described in Appendix 7.

²⁸ In addition, for each of these criteria, the vaccines must be authorized by the DMC's relevant national regulatory authority for distribution and administration in the DMC. If a DMC does not have a national regulatory authority for these purposes, alternative arrangements may apply on an exceptional basis, under which the DMC nevertheless assumes responsibility for the selection, distribution, and administration of the vaccines in the DMC. More information on the conditions is in Appendix 3.

²⁹ Vaccines procured under the COVAX facility will be required to be prequalified by the WHO or at least have marketing authorization from an SRA. If acceptable to the receiving country, emergency use listing by the WHO may be acceptable on an exceptional basis.

³⁰ A Stringent Regulatory Authority is any one of a current list of 35 national regulatory authority deemed by the World Health Organization to meet the highest regulatory standards.

31. In addition, ADB is closely coordinating with global and regional vaccines and health systems experts, as well as existing technical platforms, to provide regular advice and capacity building to ADB project teams and DMCs on the latest advancement on vaccine research and implementation.

32. Procurement of COVID-19 vaccines and critical medical equipment and other supplies financed by the APVAX can be expedited by removing member country procurement eligibility restrictions. In financing the procurement of goods and services with OCR or Special Funds established by ADB—such as the Asian Development Fund (ADF) and the Technical Assistance Special Fund (TASF)—ADB follows the member country procurement eligibility restrictions set out in para. 7 of ADB's Procurement Policy: Goods, Works, Nonconsulting, and Consulting Services (2017, as amended from time to time). Procurement of goods and services with ADF resources is also subject to Section 4.03 of the Regulations of the Asian Development Fund.³¹ Absent Board approval of a waiver of ADB's member country procurement eligibility restrictions for a specific ADB operation, the ability to apply universal procurement is generally limited to certain types of OCR and ADF cofinanced operations, for which the Board has previously approved blanket waivers.³²

33. Consistent with ADB's Comprehensive Response to the COVID-19 Pandemic (footnote 3), a waiver of the procurement eligibility restrictions set out in the Procurement Policy: Goods, Works, Nonconsulting, and Consulting Services (2017, as amended from time to time) and ADF Regulations is proposed to permit the procurement of goods, works, and services from ADB member and nonmember countries to be financed by the APVAX.³³ This will enable procuring parties to consider sourcing outside ADB member countries for vaccines supply, PPE for health care personnel, and services related to vaccine delivery and administration. It would remove any obstacles to working with the United Nations (UN) and other international agencies on procurement because of the application of their universal procurement eligibility requirements. In addition, where an RRC project is cofinanced, the vaccine eligibility criteria set out in para. 29 shall continue to apply to the procurement of any vaccines financed in whole or in part by the RRC project.³⁴

34. **Retroactive Financing.** DMCs may avail of ADB's existing retroactive financing mechanisms to support vaccine access, as follows:

- (i) Retroactive financing and/or advance contracting will be permitted on a project-by-project basis.³⁵ ADB and the government will agree on the retroactive financing percentage based on the DMC's needs. Special consideration will be given to the possibility of a small number of high-value expenditures, specifically related to vaccine acquisition. The loan and grant proceeds will be disbursed following ADB's Loan Disbursement Handbook (2017, as amended from time to time) and detailed

³¹ ADB. 2017. *Regulations of the Asian Development Fund*. Manila.

³² ADB. 2013. *Blanket Waiver of Member Country Procurement Eligibility Restrictions in Cases of Cofinancing for Operations Financed from Asian Development Fund Resources*. Manila; and ADB. 2015. *Enhancing the Operational Efficiency of the Asian Development Bank*. Manila.

³³ Financing DMC's procurement of vaccines through direct procurement from manufacturers in ADB nonmember countries is subject to the criteria set out in para. 29.

³⁴ If any RRC project proposes the use of a cofinancier's vaccine eligibility criteria, rather than ADB's eligibility criteria, the RRP shall set out sound justifications. The proposal shall be submitted to the Board for approval.

³⁵ Retroactive financing is the financing of project expenditures incurred by the borrower prior to the effective date of the related loan agreement. The advance financing procedure is a disbursement procedure where ADB makes an advance disbursement from the loan account for deposit to an advance account to be used exclusively for ADB's share of eligible expenditures. ADB. 2017. *Loan Disbursement Handbook*. Manila.

arrangements ADB and the government agree upon. These will be documented in the country-specific financing agreements. Under the RRC, the combined outstanding balance of advance financing and the percentage approved for retroactive financing may not exceed 60% of the approved RRC financing amount.³⁶ The advance financing and retroactive financing may not exceed their respective ceilings.

- (ii) A policy variation is proposed to permit retroactive financing up to 30% of the approved APVAX financing amount.³⁷ Expenditures must have been incurred after the declaration of the COVID-19 emergency, or if an emergency has not been officially declared, the allocation by the government of resources to respond to the COVID-19 pandemic.

IV. RESOURCE ALLOCATIONS AND COUNTRY CEILINGS FOR VACCINE SUPPORT

A. Making Available Additional Resources for Vaccine Support

35. **Approach.** The APVAX will make available additional resources above existing country allocations under the parameters described in paras. 35–58. This additional support will enable DMCs to access financing for the safe and effective purchase and distribution of vaccines, while continuing to invest in Strategy 2030 objectives and supporting a sustainable, green, and inclusive economic recovery.

36. To ensure available resources are equitably allocated across DMCs, ADB will establish country ceilings under the APVAX for each DMC. These ceilings represent the resources that may be used by each DMC to finance the RRC and PIC components of the APVAX. Given its quick-disbursing advance financing features, the total financing for a DMC under the RRC will not exceed its APVAX country ceiling, regardless of funding source.³⁸ Where a DMC's APVAX operation includes a PIC, combined financing of RRC and PIC may exceed the APVAX country ceiling if financing above the country ceiling is mobilized from available resources from its regular country allocations.³⁹

37. While additional resources will be provided, ADB will also work closely with DMCs to identify savings, cancellations, or options for reprogramming to ensure the efficient use of ADB capital and to minimize additional financing requirements.

38. ADB financing for vaccines will be provided in close coordination with other development partners, including the World Bank Group, the WHO, COVAX, GAVI, and bilateral and multilateral partners at global, regional and country levels. During the processing of all operations, ADB will establish a clear division of labor with other agencies and coordinate with other development partners to harmonize financial management arrangements for accounting, controlling, and reporting the funds. All operations will be prepared as part of a coordinated country approach for vaccine support and aligned with government response plans.

³⁶ As with advance financing, in exceptional circumstances and where justified by a DMC's planned expenditures, Management may consider exceeding the 60% cap on retroactive and advance financing. In such cases, the rationale and justification should be clearly presented in the RRP and/or project documentation.

³⁷ A 30% ceiling for retroactive financing is considered appropriate given the urgency of support needs.

³⁸ ADB may also provide financing for vaccine response operations through its existing modalities and using available country resources.

³⁹ Additional country allocation under the APVAX will be prioritized for DMCs that lack substantial access to alternative sources of capital on reasonable financial terms and sufficient domestic vaccine production capacity.

B. Determining Individual Country Ceilings

39. **Approach.** While national vaccination strategies will vary by country, a vaccination rate of up to 70% of a population may be required to achieve a substantial level of “herd” immunity from COVID-19.⁴⁰

40. ADB financing for vaccines will be based on needs. The primary determinant will be a DMC’s total expected vaccination cost based on its population size—and therefore the number of doses the government will be required to acquire, administer, and monitor to achieve a level of herd immunity that can sustainably mitigate the impacts of the COVID-19 pandemic.

41. In light of the massive global effort required, as well as the potential for ADB to be a major or sole provider of large-scale vaccine financing in its DMCs, ADB will adopt a burden sharing approach, whereby a portion of each DMC’s vaccine financing needs can be supported with ADB financial resources. In line with Strategy 2030’s differentiated approach, it is reasonable for ADB to adopt a higher burden share for lower-income and lower middle-income DMCs for sovereign operations in recognition of their more limited access to alternative sources of capital to finance vaccine support.⁴¹ ADB will adopt a burden share of up to 20% of estimated vaccination costs for group C DMCs and up to 30% of estimated vaccination costs for group A and B DMCs. These burden share amounts are intended for the establishment of individual country ceilings. The contribution of ADB financing to an individual APVAX operation will follow applicable cost-sharing arrangements for that DMC.

42. To ensure an equitable allocation of resources, ADB will establish minimum and maximum country limits for vaccine support. In recognition of the limited access to alternative sources of capital available to most small island developing states (SIDS), an access floor of \$10 million is proposed;⁴² a ceiling of \$1.5 billion is proposed for large DMCs, subject to available resources. Given the scarcity of ADF resources and to ensure that sufficient grants remain available for additional COVID-19 response and recovery efforts, a maximum amount of \$100 million from ADF resources may be applied for a DMC under the APVAX. Financing ceilings of \$500 million from concessional OCR resources and \$1.5 billion from regular OCR resources may also be applied to individual country ceilings, as eligible (Table 1).

Table 1: Maximum Amounts by Funding Source

Fund Source Caps	Maximum amount per country (\$ million)
ADF	100
COL	500
Regular OCR	1,500

ADF = Asian Development Fund, COL = concessional OCR lending, OCR = ordinary capital resources.
Source: Asian Development Bank.

⁴⁰ World Bank. 2020. *COVID-19 Strategic Preparedness and Response Program (Global COVID-19 MPA)*. Additional Financing. P175450. Washington, DC.

⁴¹ ADB uses a three-tier DMC classification system: group A (concessional assistance-only countries), group B (OCR blend countries), and group C (regular OCR-only countries). ADB. 2019. *Classification and Graduation of Developing Member Countries*. Operations Manual. OM A1. Manila.

⁴² The access floor is applied to DMC’s whose estimated ADB burden share is less than \$10 million. In these cases, DMCs may propose APVAX RRC operations up to \$10 million, subject to available funding sources. In line with the APVAX approach, a DMC may also choose to exceed the \$10 million ceiling subject to using the PIC component and by utilizing regular resource allocations.

43. **Assumptions.** Based on the latest available information from COVAX, DMCs will face a unit cost of about \$10.55 per dose for upcoming COVID-19 vaccines. While accurately estimating additional supply and logistics costs is challenging, it may be reasonable to assume that incremental costs for deployment will be about 30% of the purchase price.⁴³

44. An additional cost of 50% of the purchase price per dose may also be applicable to DMCs classified as fragile and conflict-affected situations (FCAS) and SIDS because of the high costs of transport and logistics in these countries. A two-dose vaccine regimen may be required for most vaccines.

C. Aggregate Financing Requirements

45. Based on ADB's approach and cost assumptions, the total expected cost of vaccinating 70% of the population (assuming this is the target of national vaccination strategies to achieve herd immunity) in each DMC has been estimated. The differentiated ADB burden shares equivalent to 30% for group A and group B DMCs and 20% for group C DMCs, along with the FCAS and SIDS premium for logistics and distribution costs and the relevant funding source ceilings, are applied to the total estimated cost.

46. The estimated maximum financing requirement for the APVAX is \$9.0 billion, comprising \$6.8 billion in regular OCR, \$1.9 billion in concessional OCR, and \$263 million in ADF (Table 2). The maximum financing requirements are determined after applying the minimum and maximum country limits to these estimated costs.

Table 2: Indicative Financing Requirement by Funding Source(\$)

Total Eligible Amount	9,027,000,000
Regular OCR	6,853,000,000
Concessional OCR	1,911,000,000
ADF	263,000,000
of which DRF	57,500,000

ADF = Asian Development Fund, OCR = ordinary capital resources, DRF = disaster response facility under ADF 13.

Note: Indicative financing requirements are rounded up to the nearest million at the country level.

Source: Asian Development Bank.

D. Allocation of ADB Resources

47. A maximum of \$6.8 billion in regular OCR resources will be required to finance the APVAX. While additional regular OCR allocations will be made available to meet DMC demand, resources for APVAX operations may also be derived from reprogramming of regular resource allocations or from the reallocation of savings and cancellations, where feasible.

48. A maximum of \$1.9 billion in concessional OCR resources will be required to finance the APVAX. These resources would be mobilized by advancing concessional ordinary capital resources lending (COL) allocations from future years of the ADF 13 cycle. These resources may also be mobilized from unutilized COL resources from 2020 and from savings and cancellations.⁴⁴

⁴³ The assumptions made for potential logistics costs and FCAS and SIDS premium are approximations based on past and ongoing vaccine operations. Actual costs will vary across and within countries and will be subject to a wide range of factors not captured in these estimates.

⁴⁴ About \$400 million in unutilized COL resources and savings and cancellations from ongoing operations are currently expected from 2020. An amount of about \$300 million in savings and cancellations may be expected over the next three years.

49. A maximum of \$263 million in ADF resources will be required to finance the APVAX. These resources will be mobilized from reprogramming of existing and future country programs under ADF 13 and by utilizing savings and cancellations. To contribute towards these needed resources, ADB will make available additional grants from the ADF 13 Expanded Disaster and Pandemic Response Facility (DRF+).

50. The DRF+ provides grants for relief, early recovery, and reconstruction following disasters and emergencies triggered by public health emergencies, including epidemics and pandemics. As part of this programmatic response, \$5 million will be made available for group A countries at high risk of debt distress and \$2.5 million for group A countries at moderate risk of debt distress.⁴⁵ The supplement of grant resources from the DRF+ to support the vaccine response is estimated at \$57.5 million, including a \$40 million regional allocation for Pacific group A countries. Assuming that all eligible DMCs access the maximum available amount of DRF+ resources for their vaccine response, about \$202 million would remain available under the DRF+ for allocation during the ADF 13 period.

51. During public health emergencies, the DRF+ is triggered when a grant-eligible group A country has (i) declared a public health emergency through the relevant government department (e.g., office of the President or Prime Minister); and (ii) the WHO has declared a public health emergency of international concern under the WHO's global alert and response system in accordance with the International Health Regulations (2005).⁴⁶ The criteria are aligned with those adopted for the World Bank's International Development Association (IDA) 19⁴⁷ Crisis Response Window (CRW).⁴⁸ As part of its response to COVID-19, IDA management requested a blanket waiver of the first access criteria to the CRW in April 2020 to make CRW resources available to all IDA-eligible countries. To ensure that all ADF countries benefit from additional ADF resources, a policy variation is proposed to waive the DRF+ requirement for declaration of a public health emergency by a grant-eligible group A country.

52. Multiyear planning is a key tool for national immunization programs. To support countries in the development and implementation of their immunization plans, ADB's country ceilings will be available for Board of Directors approval until 31 December 2023.⁴⁹ In addition to comprehensive annual updates on APVAX implementation, ADB will also include a review of utilization of concessional resources during the midterm review of ADF 13. This will be complemented by the Independent Evaluation Department's review of the APVAX, which will be conducted after the first year of implementation.

⁴⁵ An additional allocation of COL will be made available for group A countries at low and moderate risk of debt distress.

⁴⁶ ADB. 2020. *Concessional Assistance Policy for the ADF 13 Period*. Manila.

⁴⁷ World Bank. 2020. *IDA19: Ten Years to 2030: Growth, People, Resilience*. Washington, DC.

⁴⁸ The CRW is part of the IDA 19 framework. It responds as a last resort to severe economic crises, natural disasters, and public health emergencies; and responds at an earlier juncture to slower-onset crises, such as disease outbreaks and food insecurity. CRW resources may be used to address public health emergencies that are of potential international importance. CRW resources can be used only when (i) the affected country has declared a national public health emergency; and (ii) the WHO has declared that the outbreak is of potential international importance, under WHO's Global Alert and Response System, in accordance with the International Health Regulations, 2005. IDA's executive directors approved a blanket waiver of the first condition in March 2020. *World Bank. 2020. Proposal for a World Bank Covid-19 Response under the Fast Track Covid-19 Facility*. Washington, DC.

⁴⁹ In March 2019, Niue became the 68th and most recent member of the ADB. Niue has not yet received a country classification. Provided that Niue's classification occurs within the 3-year availability period of the APVAX, it will become eligible for an additional country allocation based on the same approach.

53. If additional headroom made available under the APVAX is not used by an individual DMC,⁵⁰ the unused amounts may be made available and, when necessary, reallocated to provide additional headroom for PIC investments under the APVAX or to expand other COVID-19 response projects and programs. Reallocations will be limited to 50% of the original country ceiling of the DMC. Initial priority for reallocations will be given to DMCs with APVAX country ceilings that would be capped by the funding source maximum amounts established in Table 1. Concessional assistance countries, FCAS countries, and SIDS will also be prioritized, depending on eligible funding sources (Table 1).

54. **Subregional allocation for small island developing states of the Pacific.** The smaller Pacific island countries (PIC-11)—the Cook Islands, Kiribati, the Marshall Islands, the Federated States of Micronesia, Nauru, Palau, Samoa, Solomon Islands, Tonga, Tuvalu, and Vanuatu—will face substantial fixed costs to access, procure, and deliver COVID-19 vaccines. This will include surveillance, logistics, contractor mobilization, service fees, and capacity building needs, which may in some instances exceed per capita funding levels of larger countries by many multiples. The PIC-11 also face severe health system capacity constraints coupled with highly remote and sparse populations. A coordinated regional effort between DMCs and development partners will be required to effectively address these challenges. To enhance flexibility and promote efficiency in the use of ADB resources under the APVAX, a subregional allocation for the PIC-11 is proposed instead of individual country ceilings.⁵¹ The size of the subregional allocation would be equivalent to the cumulative total of individual country ceilings. However, ADB would be able to allocate these resources flexibly across the PIC-11 according to individual country needs and demands.⁵² Resources from the subregional allocation may also be used to finance joint costs across the PIC-11 including for pooled procurement and joint regional approaches to project implementation (para. 52).⁵³ Amounts accessed under the DRF+ to support regional APVAX operations in group A countries may also be allocated flexibly across these DMCs. The total amount made available will be based on the allocation principles described in para. 50.⁵⁴ DMCs within the regional approach would remain eligible to access financing sources only according to their respective country classifications.⁵⁵

55. The APVAX subregional allocation would support ADB's ability to build on the model of vaccine procurement and distribution developed under the Systems Strengthening for Effective Coverage of New Vaccines in the Pacific Project, which was approved for \$25.1 million on 8

⁵⁰ A decision by a DMC not to utilize their additional APVAX headroom may be communicated to ADB Management through the relevant Board of Directors suite.

⁵¹ ADB. (forthcoming). Pacific Approach, 2021–2025. Manila.

⁵² Individual PIC-11 DMC's may also request a stand-alone APVAX operation outside of the regional allocation. In this case, the applicable country headroom would be allocated to that DMC and deducted from the subregional allocation for the remaining PIC-11 DMCs.

⁵³ Because of their larger size, Fiji and Papua New Guinea will receive individual country allocations. However, they may also elect to participate in regional APVAX operations. The maximum amount of APVAX financing allocated to either of these DMCS will be capped at individual country ceilings and may only include eligible financing sources based on country classification. Unutilized headroom from PIC-11 DMCS may not be reallocated to Papua New Guinea or Fiji. Likewise, unutilized headroom from Papua New Guinea and Fiji may not be reallocated to other PIC-11 DMCs.

⁵⁴ This may include a maximum allocation of \$40 million based on \$5 million per DMC for Kiribati, the Marshall Islands, the Federated States of Micronesia, Nauru, Samoa, Tonga, and Tuvalu; and \$2.5 million per DMC for Solomon Islands and Vanuatu. The final amount allocated to an eligible country under the subregional allocation is capped at 100% of each DMCs annual country allocation.

⁵⁵ Individual country operations using the additional headroom will be required to submit an agreed upon positive list of eligible expenditures associated with each DMCs vaccination program or prepare estimated costs of associated project investment needs. The flexibility offered by these higher ceilings will therefore be bound by the size of eligible expenditures under the APVAX for each DMC.

November 2018.⁵⁶ The project adopts a regional approach to improving immunization outcomes through the introduction of three vaccines in Samoa, Tonga, Tuvalu, and Vanuatu. It provides a useful model of integrated project management in which targeted support to DMCs is delivered by working through UN agencies such as UNICEF to provide vaccine and cold chain procurement and expert services.⁵⁷ The regional mechanism is also helping the countries strengthen their vaccine coverage monitoring, reporting, and surveillance through the recruitment of consultants provided by the integrated project management firm. ADB will build on its experiences in using these regional vaccine approaches in the design of additional support for Pacific SIDS through the APVAX.

Table 3: Additional Vaccine Response Resources

	Country Ceilings by Funding Source	Of Which PIC-11 Subregional Allocation	Funding Sources
ADF	\$263 million	\$80 million	DRF+, front-loading, savings and cancellations, reprogramming
COL	\$1.9 billion	\$15 million	Additional resources, savings and cancellations, reprogramming
Regular OCR	\$6.8 billion	\$15 million	Additional resources, savings and cancellations, reprogramming
Total	\$9.0 billion	\$110 million	

ADF = Asian Development Fund, COL = Concessional OCR Resources, DRF+ = Expanded Disaster Response Facility under ADF 13, OCR = Ordinary Capital Resources, PIC-11 = Pacific island countries.

Note: These amounts reflect total of country ceilings for all DMCs. In 2021, the total sovereign regular resource allocation under Work Program and Budget Framework, 2021–2023 for (i) ADF including performance-based allocation and 1st allocation batch under the ADF 13 allocation pool is \$750 million, (ii) concessional OCR is \$3.8 billion, and (iii) regular OCR is \$16.7 billion.

E. Pricing and Financial Terms

56. The following general financial terms and conditions will apply:⁵⁸

- (i) Eligibility for financing sources will be determined at the time of fund commitment during the 3-year availability period of the APVAX. If a DMC's country classification changes between Board of Directors approval of the APVAX and fund commitment, updated country ceilings will be provided based on eligible financing sources for that DMC.
- (ii) Eligibility for concessional resources will be determined according to the classifications and requirements in ADB's Concessional Assistance Policy (2016), the Concessional Assistance Policy for the ADF 13 Period (2020), and related operational policies and procedures.
- (iii) During this exceptional emergency, the proportion of COL for financing vaccine response in group A countries at moderate risk of debt distress may be higher or lower than 50%, subject to resource availability. Such an option should be agreed

⁵⁶ Additional financing of \$19.82 million is being proposed to expand the scope of the current project to further strengthen the health systems' routine immunization programs and community engagement activities, and to prepare health systems to safely introduce COVID 19 vaccines.

⁵⁷ ADB. 2010. *Strengthening the Partnership between the Asian Development Bank and the United Nations Children's Fund: Procurement Arrangements*. Manila. ADB agreed to use UNICEF's Supply Manual and Human Resources Manual for the procurement of associated goods, equipment, and services (including consulting services); and the procurement of goods, equipment, and services in a nonmember country or the procurement of goods, equipment, and services produced in a nonmember country.

⁵⁸ ADB will call for DMCs' requests for financial assistance under the vaccine facility and will report to the Board of Directors within 1 month of Board approval of the APVAX.

upon in coordination with the government, the International Monetary Fund, and the World Bank.

- (iv) DMCs that have graduated from ADB assistance are not eligible to access vaccine response headroom. Because India does not have access to concessional assistance, it will be eligible for the terms and conditions and country ceilings offered to group C DMCs for the purposes of this proposal.
- (v) All approved and committed amounts would be subject to applicable commitment fees.
- (vi) Differentiated pricing of maturity premiums approved under ADB's Diversification of Financing Terms for Regular OCR Sovereign Lending Operations under Strategy 2030⁵⁹ will be applicable from 2021 onwards.
- (vii) ADB will transition from the London interbank offered rate (LIBOR) to an alternative reference rate in accordance with generally applicable ADB policies and procedures, including ADB's Preparing for the Reference Rate Transition of ADB's Sovereign Loans.⁶⁰
- (viii) A DMC's access to vaccine financing indicated by their country ceiling is not automatic. Eligibility requires satisfactory demonstration of all relevant access criteria and due diligence requirements, and approval steps.

57. **Rapid response component.** Financing for agreed upon eligible expenditures under the RRC will be provided with the following terms and conditions:

- (i) Group C lending terms for loans at or below \$500 million will comprise interest rates set at a spread of 50 basis points over LIBOR, a rebate or surcharge reflecting the cost of funds, a term of 10 years including a grace period of up to 3 years, and a commitment charge of 15 basis points per year on the undisbursed loan balance.
- (ii) Group C lending terms for incremental loan amounts above \$500 million will comprise interest rates set at a spread of 50 basis points over LIBOR, a rebate or surcharge reflecting the cost of funds, a term of 5 years including a grace period of up to 3 years, and a commitment charge of 15 basis points per year on the undisbursed loan balance.
- (iii) Group A and B lending terms will be equivalent to those applicable to each category under stand-alone policy-based loans, up to the applicable APVAX country ceilings for ADF and concessional OCR resources.⁶¹

58. **Project investment component.** Financing provided for agreed eligible expenditures under the PIC will be provided at terms and conditions equivalent to stand-alone project investments for group A, B, and C DMCs.

V. RISKS, BUSINESS PROCESS, AND DUE DILIGENCE

A. Risks

59. ADB recognizes several risks that need to be carefully managed to ensure the success of individual country operations. All operations will be required to assess relevant risks and include mitigation strategies in project documentation. These risks may include the following.

⁵⁹ ADB. 2019. *ADB's Diversification of Financing Terms for Regular OCR Sovereign Lending Operations under Strategy 2030*. Manila.

⁶⁰ ADB. 2020. *Preparing for the Reference Rate Transition of ADB's Sovereign Loans*. Manila.

⁶¹ Group B DMCs would retain the option to utilize regular OCR resources instead of COL, or a blend, if preferred.

60. **Public health risks.** The first vaccines may not be the most effective or could lead to adverse side effects. The speed of vaccine development and the rapid rollout of vaccines could lead to serious adverse events. The system for monitoring adverse events is often not fully functional in developing countries, which could lead to delayed detection and unnecessary harm to vaccinated people. This could jeopardize the credibility of vaccine delivery systems. COVAX, which is expected to be the first opportunity for most DMCs to acquire vaccines, is arranging compensation and indemnification guarantees directly. Where necessary, ADB support to strengthen capacity to detect and manage adverse events following vaccination in line with WHO recommendations should be considered under the APVAX.

61. **Political, governance, and legal risks.** Political pressure and different interpretations of safety standards may push DMCs to purchase vaccines before they have been appropriately authorized. DMCs will manage this risk by adhering to the vaccine selection criteria set out in vaccine regulatory requirements (para. 29). The politicization of vaccine prioritization and exclusion of vulnerable or marginalized groups also could present risks. These will be mitigated by requiring a vaccination allocation plan accompanied by a governor's letter confirming the government's commitment to their stated approach (footnote 22). The governance of vaccine purchase and deployment also poses risks. To ensure the roles of ADB and participating DMCs are clear, particularly with respect to vaccine selection and administration, each DMC is expected to provide legal covenants to this effect in its financing agreements with ADB. These covenants would confirm that (i) the DMC will ensure that the country-specific financing proposal is implemented in accordance with its national COVID-19 vaccination strategy or vaccination allocation plan; (ii) the DMC's relevant national regulatory authority has authorized the vaccines for distribution and administration in the DMC (footnote 28); (iii) the DMC assumes responsibility for vaccine selection (including determinations on quality, safety, and efficacy), as well as procurement, manufacturing (if applicable), distribution, marketing and administration, and associated due diligence; and (iv) the DMC will ensure the proper storage, handling, transportation, and waste management of vaccines and associated medical equipment or supplies. In addition, the DMC is expected to provide in its legal or regulatory framework for vaccine procurement, and/or financing agreements with ADB, appropriate liability limitations for the benefit of ADB. These limitations will include disclaimers with respect to the distribution, marketing, and administration of any vaccine selected by the DMC and its storage, handling, transportation into and within the DMC, and waste management, each of which remains the sole responsibility of the DMC.

62. **Macroeconomic risks.** Many DMCs are under significant fiscal pressures and face the risk of insufficient fiscal space to purchase vaccines at scale and other COVID-related response interventions. The APVAX aims to mitigate this risk by providing financing to buy vaccines and promote prioritized deployment to vulnerable groups. For the RRC, a debt sustainability assessment will analyze any potential impact additional borrowing may have on sustainable debt levels. Residual macroeconomic risk will remain as the country aims to scale up vaccine access to higher coverage levels.

63. **Institutional capacity risk for vaccine deployment risks.** Vaccine deployment, cold-chain, and distribution capacity need to be strengthened, especially for the anticipated scale and population group coverage for the COVID-19 vaccination. ADB will mitigate this risk through TA and development partner coordination to strengthen immunization systems, including conducting capacity assessments in coordination with the WHO, GAVI, UNICEF, the World Bank, and other partners.

64. **Procurement risks.** The key procurement risks associated with vaccines relates to (i) the complexity of the vaccine market because of the significant market power of vaccine manufacturers; (ii) the inability of the market to supply adequate quantities of vaccines to meet the demand; (iii) the limited market access because of advance orders by developed countries; (iv) weak bargaining position; and (v) delays in triggering emergency procurement procedures, which could delay procurement and contract implementation including payments. The APVAX will mitigate these risks by providing options to support the country's needs for direct or advance purchase, including possible TA. Specific procurement measures are discussed in para. 81.

65. **Financial management risks.** The key financial management risks relate to (i) tracking and reporting of funds; (ii) inventory and management control over the storage and distribution of vaccines; (iii) country financial management systems for managing, controlling, accounting, reporting, and auditing expenditures incurred and paid under agreed upon eligible expenditures criteria; and (iv) capacity of the executing and implementing agencies to manage, account, control, report, and audit project funds. The APVAX will assess and strengthen control systems, fund flow arrangements, and DMC financial management capacity. Specific financial management measures are discussed in para. 80.

66. **Environmental, social, and gender risks.** Key environmental risks relate to the safe disposal and management of medical waste and related occupational health and safety risks to workers and members of affected communities, particularly because of the expected scale of vaccination programs. The speed of vaccine development and their rapid rollout could also lead to significant public health risk if the eligibility criteria for vaccine access is not followed. Proposed PIC component activities could require project-related land acquisition with involuntary resettlement impacts and risks and impacts to indigenous peoples. Further social risks and impacts could also be related to possible inequity in access to vaccines, political prioritization of vaccination for some groups over others, and loss of trust by the population on the efficacy and safety of the vaccine. There could also be environmental and social impacts relating to expansion of existing facilities to enable manufacturing and/or storage and distribution of vaccines. Key social risks include inadequate communication and outreach to communities (particularly if there are cultural or religious concerns regarding vaccines), insufficient systems and data sharing established for identification and outreach to the priority groups including particularly older persons (who are most at risk from COVID-19). High risk groups such as older persons and persons with disabilities may face challenges in accessing vaccinations due to limited mobility and a lack of access to information. Women and girls may not always be able to access vaccination programs because of gender norms that restrict their mobility, health identity documentation, and access to information on vaccine availability, despite being at high risk of exposure and carrying most of the responsibility for disease caregiving. Growing evidence suggests that women are more likely to be infected, but men have higher fatality rates; men and women also differ in antibody response.⁶² Pregnant women, who are at increased risk of adverse COVID-19 outcomes, may be overlooked as a high priority group,⁶³ and those requiring essential sexual and reproductive health services may forgo medical care because of anxiety about virus exposure.⁶⁴ ADB will work closely with all stakeholders, including Community Service Organizations, to ensure vaccines are delivered in line with the DMC's stated vaccination allocation plan, and to avoid exclusion of women, girls, marginalized populations and other vulnerable groups. ADB will also continue to provide technical and implementation support for

⁶² N. Grover. 2020. Covid-19 antibodies reduce faster in men than women – study. *The Guardian*. 18 November.

⁶³ P. Dashrath et al. 2020. COVID-19 vaccine and neglected pregnancy. *The Lancet*. August.

⁶⁴ Organisation for Economic Co-operation and Development. 2020. *Response, recovery and prevention in the coronavirus (COVID-19) pandemic in developing countries: Women and girls on the frontlines*.

COVID-19 testing, surveillance, and pharmacovigilance to mitigate these risks. ADB support for COVID-19 vaccination programs will strengthen and support other important vaccines such as human papillomavirus where possible and complement ongoing support for uninterrupted sexual and reproductive health services.

B. Country Project Approval

67. Country-specific financing proposals for APVAX operations will follow ADB's standard sovereign investment project approval procedures,⁶⁵ while applying the following fast-track processing procedures adopted under ADB's Comprehensive Response to the COVID-19 Pandemic policy (2020):

- (i) the operations department may omit (a) processing of a project concept paper and any attachments thereto, and proceed straight to due diligence and fact-finding (with signed aide-memoire or memorandum of understanding), followed by preparation of the RRP and linked documents; and (b) interdepartmental review of the RRP and its linked documents may be exchanged for forming a One ADB team with representatives from all relevant departments who assume responsibility for ensuring due diligence and procedural requirements are followed; and
- (ii) if urgent Board approval is required for an APVAX sovereign project or additional financing, or to approve a major change in scope for an ongoing APVAX project, a special abbreviated Board consideration period of 1 week after circulation of the RRP or Major Change in Project paper (as applicable) will apply.

68. Management or the Board of Directors may propose an Informal Board Seminar for country-specific financing proposals, particularly for the first proposal for each DMC. Where appropriate, Management may propose full Board consideration of any country specific financing proposal, even if it meets the criteria for no-objection procedure. Multiple financing proposals within a single DMC may be approved, subject to staying within the country ceiling. There will be no limit for cofinancing or government counterpart financing contributions.

69. **Private sector support.** ADB's comprehensive support package to enhance vaccine access will include continued support through its nonsovereign operations and public-private partnerships operations. ADB recognizes that the private sector will play a critical role in most, if not all, stages of vaccination efforts—from production to delivery. ADB is in discussions with governments on potential public-private partnership arrangements. Because of the complex storage, logistics, and distribution challenges for vaccines, private sector warehousing and cold storage space could be purchased through a public-private partnership arrangement, as purely private solutions may not be feasible in some cases.

70. ADB is assessing three areas of potential investment into private entities to help increase access to vaccines in DMCs. ADB's nonsovereign financing will address financing needs across the entire vaccine delivery value chain, from upstream inputs to vaccine production, production, and packaging to the downstream storage and distribution of the finished products. Adequate distribution and storage facilities suited for temperature-sensitive vaccines are essential to ensure efficacy and reduce waste. ADB is engaging with vaccine manufacturers in the DMCs for potential

⁶⁵ ADB. 2017. Operations Manual D11 (Sovereign Operations). Manila; and ADB. 2017. Operations Manual L4 (No-Objection Procedure). The President is authorized to approve the administration of cofinancing for any operation subject to certain exceptions. ADB. 2015. Enhancing the Operational Efficiency of the Asian Development Bank. Manila.

financing needs to expand vaccine manufacturing facilities and secure local licensing and manufacturing rights from global vaccines developers. The Board has approved financing for the construction of three pharmaceutical distribution facilities, including cold chain facilities for vaccine storage.

71. ADB's Trade and Supply Chain Finance Program (TSCFP) is ready to launch a \$500 million facility to import vaccines and related supplies to DMCs. It will be implemented through partner commercial banks and could attract cofinancing that would leverage the facility to support \$1 billion in vaccine and related equipment imports over a year.⁶⁶ Upstream inputs, such as glass vials, syringes, and adjuvants, are needed in huge volume to respond to the forthcoming demand. Many local suppliers will need trade financing solutions to import these supplies to DMCs.

72. TSCFP has mapped the entire supply chain for goods to fight COVID-19 and is adding vaccines and related equipment to the tool. TSCFP also aims to identify the cold storage and transport distribution chain for vaccines and any bottlenecks as a new feature to tool. TSCFP is coordinating with private and public sectors to contribute data and use the tool to alleviate any bottlenecks.

C. Results, Monitoring, and Evaluation

73. **Theory of change.** The intended impact of the APVAX is to mitigate the negative health, social, and economic effects of the COVID-19 pandemic by reducing the virus' spread, morbidity, and mortality, and restoring the confidence of citizens. The APVAX will also help enhance the resilience and responsiveness of DMC health systems to public health emergencies. The expected outcome is that participating DMCs will have safely vaccinated their priority populations against COVID-19 based on the targets defined in their national plans and in congruence with routine immunization services and other health services. To support this objective, the APVAX will help ensure DMCs deploy COVID-19 vaccines in an expedited manner based on transparent COVID-19 vaccination plans, while effectively managing the risks of introducing a new vaccine rapidly. This will be done by (i) delivering COVID-19 vaccines to DMCs, (ii) enhancing DMC capacity to respond to health emergencies, and (iii) strengthening DMC immunization systems. Appendix 5 shows the theory of change for the APVAX.

74. The APVAX's results monitoring and evaluation (M&E) system balances the need for timely, flexible, and country-tailored support with the need for accountability. Each country project's design and monitoring framework (DMF) will be broadly aligned with the APVAX's theory of change, and will have at least one of the facility's outcomes as project outcome or project impact (depending on scope).⁶⁷ Project performance monitoring will follow the standard processes for investment projects, as defined in ADB's Project Administration Instructions. Data collected for indicators in project DMFs will be disaggregated by priority groups (e.g., health workers, other frontline workers), sex, age group, and other subgroups to assess the equitable distribution of benefits (e.g., by province, urban and rural area, and if possible, social groups).

75. **Board reporting.** ADB will circulate to the Board an annual progress report on the implementation of the APVAX, including safeguards implementation. The report will reflect the risks and issues (including safeguard-related ones), as well as the actions being taken to mitigate

⁶⁶ Vaccines procured under the TSCFP will be subject to the same eligibility criteria as the APVAX.

⁶⁷ Appendix 5 provides a detailed discussion of the results and monitoring and evaluation (M&E), including the APVAX theory of change.

the risks and resolve the issues, if any.⁶⁸ Before 31 July 2022 or when 50% of the APVAX amount has been utilized, whichever occurs first, ADB will conduct an interim review of the APVAX and report to the Board, including recommendations for modifications (if any). To complement this reporting, the Independent Evaluation Department will review the APVAX after the first year of implementation. In addition, the midterm review of ADF 13, scheduled for the end of 2022, will review the utilization of concessional resources for the APVAX. An update on APVAX operations will also be incorporated into ADB's weekly reporting to the Board of Directors on ADB's COVID-19 response.

76. **ADB staff resources.** DMC demand for support under the APVAX will likely place significant demands on ADB staff resources, particularly on ADB's limited supply of health experts. Ensuring ADB has the necessary skills and expertise to prepare and implement a high-quality APVAX operation will be essential. Additional health expertise will be mobilized in 2021 and will be supplemented by a range of highly technical skills from consultants for meeting the evolving needs of the APVAX operations. In parallel, ADB will repurpose and transfer existing staff positions and will share existing staff to support priority needs and maximize the use of existing resources. ADB will also partner with other development partners with more experience and capacity, especially for country assessments and the development of national vaccination strategies anchored on an effective and functioning development partner coordination mechanism. For vaccine knowledge services, ADB will provide TA to help DMCs conduct needs assessments and formulate country-specific vaccination and financing strategies (para. 86). ADB anticipates the largest demand for support will be for vaccine procurement. Strict eligibility criteria have been proposed for vaccine procurement, and ADB's substantial procurement and financial management expertise will be leveraged.

D. Due Diligence

77. The APVAX will strike a balance between timely and flexible delivery of support and appropriate oversight, due diligence, and fiduciary arrangements to ensure the effective and efficient use of ADB's resources. ADB's standard due diligence requirements for processing sovereign operations⁶⁹ shall apply to RRC and PIC, with clarifications to the following requirements as follows:

78. **Environment, social safeguards, and gender.** ADB's Safeguards Policy Statement, 2009 will be applied to all projects under the APVAX. All projects and their components will be screened and categorized to (i) reflect the significance of a project's potential environmental, involuntary resettlement, and indigenous peoples impacts and risks; (ii) identify the level of assessment and institutional resources required for the safeguard measures; and (iii) determine the consultation and disclosure requirements. Further guidance on safeguard due diligence for DMC project components (RRC and PIC) is in Appendix 1. During due diligence, project teams will ensure that women and girls are not negatively affected. Gender analysis will be conducted to inform the gender design features that directly reduce gender gaps and/or promote women's empowerment and assign a corresponding project gender categorization.

79. **Governance and anticorruption.** Country projects prepared under this framework are expected to meet ADB's high governance, anticorruption, accountability, and transparency standards. Effective governance practices are necessary to translate resources into desired

⁶⁸ The monitoring, reporting, and disclosure requirements for country projects shall comply with the Safeguard Policy Statement requirements based on their safeguard categorizations.

⁶⁹ ADB. 2017. Sovereign Operations. *Operations Manual*. OM D11. Manila; and ADB. 2017. *Staff Instruction on Business Processes for Sovereign Operations*. Manila.

development outcomes, and to promote the efficient delivery of services. Robust monitoring and evaluation will be critical tools for ADB's vaccination support. Financial management and procurement assessments will help to identify any significant risks or gaps, and strategies to mitigate these risks. ADB's Anticorruption Policy (1998, as amended to date) will apply to all country project proposals prepared under the APVAX.

80. **Financial due diligence.** Financial due diligence will be carried out for each country project proposal and follow ADB financial management guidance.⁷⁰ The project team members, in consultation with the Procurement, Portfolio and Financial Management Department's financial management division, will determine the appropriate approach and depth of financial analysis and evaluation on a case-by-case basis. The financial management assessment will follow the requirements detailed in Appendix 1. During implementation, the DMC and the executing and implementing agencies should maintain adequate financial management arrangements for the project and submit annual audited program and/or project financial statements to ADB, in accordance with financial management guidance and the conditions prescribed in the loan agreement and project documents.

81. **Procurement arrangements for rapid response component.** Procurement of goods and services will be carried out in accordance with ADB's Procurement Policy (2017, as amended from time to time) and the Procurement Regulations for ADB Borrowers (2017, as amended from time to time). For each country project proposal, a procurement assessment⁷¹ will be carried out on the executing agency. If the assessment confirms that procurement risks are low and adequate systems are in place to effectively and efficiently procure items of eligible expenditure, ADB may agree to accredit the executing or implementing agency and rely on the use of country procurement systems.⁷²

82. In addition, the following implementation arrangements consistent with the ADB Procurement Policy will apply:

- (i) A DMC may undertake direct procurement of vaccines meeting the eligibility criteria,⁷³ provided that value for money is established and commercial terms and conditions are verified as reasonable.⁷⁴
- (ii) All procurement will be subject to post-review sampling unless ADB considers, on a case-by-case basis, that its oversight is desirable given the inherent level of procurement risk. Direct contracting will be subject to prior review in all cases.
- (iii) Where vaccines will be directly procured, the DMC (or its representative) will be responsible for executing a contract directly with the manufacturers or distributors, and for administration of the contract.

⁷⁰ ADB. 2014. *Financial Management, Cost Estimates, Financial Analysis, and Financial Performance Indicators. Operations Manual*. OM G2. Manila; ADB. 2020. *Technical Guidance Note on Financial Management Assessment; and Guidance Note on Applying ADB's Financial Due Diligence Requirements in Response to COVID-19 Pandemic*. Manila.

⁷¹ The procurement assessment will follow an abbreviated Strategic Procurement Plan and project procurement-related audit.

⁷² The alternative procurement arrangements under Part XII of ADB's Procurement Policy permit ADB to rely on the procurement rules and procedures applied by an agency or entity of the borrower accredited by ADB, provided that such arrangements meet the requirements specified in Part XII.

⁷³ Information on the vaccine eligibility criteria is in para. 29 and Appendix 3.

⁷⁴ Agreements entered into with such manufacturers prior to the signing of financing agreement(s) with ADB will be subject to the rules applicable to retroactive financing described in para. 34.

83. **Procurement arrangements for project investment component.** The PIC takes advantage of allowed flexibilities within ADB's Procurement Policy and Procurement Regulations to reduce transaction costs and streamline project preparation. ADB will conduct a procurement assessment and procurement of goods, works, and services will be carried out in accordance with ADB's Procurement Policy and the Procurement Regulations for ADB Borrowers. To expedite procurement under the PIC, the following implementation arrangements consistent with ADB's Procurement Policy and Procurement Regulations will apply: (i) open competitive bidding requirements for goods, works, and services with abbreviated bidding and evaluation periods; (ii) request for quotations for goods and non-consulting services and consultants qualification selection method for consulting services may be used for higher-value, low-risk procurement if justified to ensure timely implementation; (iii) direct contracting may be used, subject to value for money being established in accordance with ADB's Procurement Regulations for ADB Borrowers with sufficient justification, such as standardization on a single vaccine type within a health system; and (iv) post-review sampling will be used to the extent possible, unless the inherent level of procurement risk requires increased ADB oversight. Direct contracting will be subject to prior review in all cases.

84. ADB may provide additional hands-on support to facilitate procurement, including bank-facilitated procurement, whereby ADB negotiates prices, terms, and conditions with approved vaccine suppliers, logistics providers, and related suppliers with whom a DMC (or its representative) may then sign direct contracts. In all cases, the DMC remains solely responsible for vaccine selection and the DMC (or its representative) is responsible for executing a contract directly with these parties, as well as for administration of the contracts. This would consolidate demand across DMCs and reduce transactions. ADB may also work directly with other development partners, such as the World Bank, to harmonize approaches to procurement and financial management for DMCs and suppliers.

85. Unless otherwise stated, the APVAX will be governed by ADB's standard investment approval and implementation arrangements.

VI. COMPLEMENTARY SUPPORT

86. **Technical assistance.** ADB will provide TA grants to support necessary due diligence and needs assessments, and to help strengthen the capacity of health systems, including development of national vaccine strategies, immunization systems, supply chains, information systems, and risk communication. These will address vaccine hesitancy, regulation, human resources, existing services, and processes; and identify likely bottlenecks and challenges in the delivery of COVID-19 vaccines. Because different vaccination priorities will have different economic consequences, TA will support economic analysis, where appropriate. TA may also support preparation and implementation of projects under the APVAX. TA grant projects are disbursed in accordance with Technical Assistance Disbursement Handbook (2020, as amended from time to time).

87. **Technical Assistance Special Fund.** ADB will provide additional TA resources for regional support to address the outbreak of COVID-19 in order to immediately undertake health system assessments. It will also support the development of country readiness plans to ensure DMCs have the capacity to access, introduce, manage, and monitor safe and effective COVID-

19 vaccines, as well as manage the funds in an economic and efficient manner.⁷⁵ Further, the regional TA will support design of projects on vaccine procurement and related delivery and fiduciary systems. The TASF will provide \$20 million in financing with the potential for additional cofinancing. ADB plans an additional \$30 million in TASF resources (from both TASF [donor contribution] and TASF [income transfer]), which will be available in 2021. This will be supplemented by reprogramming of 2021 TASF allocations and savings and cancellations, where possible.

88. Other special funds and trust funds, such as the Regional Cooperation and Integration Fund, the High-level Technology Fund, the Japan Fund Poverty Reduction, the People's Republic of China Poverty Reduction and Regional Cooperation Fund, and the Regional Malaria and other Communicable Disease Threats Trust Fund may also provide TA support that is aligned with respective eligibility requirements of these funds.

VII. RECOMMENDATION

89. The President recommends that the Board approve the establishment of the Asia Pacific Vaccine Access Facility (APVAX) comprising the following items:

- (i) the APVAX's term, access criteria, financing components, vaccine eligibility criteria, eligible expenditures, terms and conditions, approval of a policy variation to permit the retroactive financing amount up to a maximum of 30% of the approved APVAX financing amount, and establishment of individual country ceilings based on defined methodology, as described in paras. 1, 22–27, 29, 34(ii), 39–44, 56–57, and Appendix 4;
- (ii) approval of policy variations to waive the application of ADB's Procurement Policy (2017, as amended from time to time) for vaccines to be procured through the COVID-19 Vaccines Global Access Facility, and ADB's member country procurement eligibility restrictions for procurement under the APVAX, as described in paras. 30(ii) and 33; and
- (iii) approval of a policy variation for a limited waiver of the access criteria under the Asian Development Fund 13 Expanded Disaster and Pandemic Response Facility, which are presented in the Concessional Assistance Policy for the ADF 13 Period (2020), as described in para. 51.

⁷⁵ Regional TA 9950 currently totals \$48.3 million, of which \$33 million is financed from TASF (donor contribution), \$11 million from TASF (income transfer), \$0.3 million from the Ireland Trust Fund for Building Climate Change and Disaster Resilience in Small Island Developing States, \$2 million from the Republic of Korea e-Asia and Knowledge Partnership Fund, and \$2 million from the People's Republic of China Poverty Reduction and Regional Cooperation Fund. ADB. 2020. *Technical Assistance for Regional Support to Address the Outbreak of Coronavirus Disease 2019 and Potential Outbreaks of Other Communicable Diseases*. Manila; ADB. 2020. *Major Change in Technical Assistance: Regional Support to Address the Outbreak of Coronavirus Disease 2019 and Potential Outbreaks of Other Communicable Diseases*. Manila (April); and ADB. 2020. *Major Change in Technical Assistance: Regional Support to Address the Outbreak of Coronavirus Disease 2019 and Potential Outbreaks of Other Communicable Diseases*. Manila (November).

BUSINESS PROCESSES AND DUE DILIGENCE REQUIREMENTS

1. **Streamlined processing and approval arrangements for the rapid response component and the project investment component.** Projects may be prepared under fast-track arrangements, similar to those used for emergency assistance loans. Along the lines of the processes approved for the Asian Development Bank (ADB) response to the coronavirus disease (COVID-19),¹ concept papers and the interdepartmental circulation of reports and recommendations of the President may be eliminated in lieu of the collective participation of technical experts and nominated staff from non-operations departments in developing and processing these projects.² The members of the One ADB team (drawing on expertise from across the various departments in ADB) will have clear terms of reference and be responsible for (i) bringing solutions that reflect the views of their respective departments, offices, and sector and thematic groups; and (ii) ensuring their respective departments support the project team's decisions. Each operations department will continue to be responsible for document quality and data management and will ensure the fundamental comments of the One ADB team members have been addressed. All project due diligence (including fact-finding missions that resulted in a signed aide-mémoire or memorandum of understanding) and safeguards requirements established in the 2009 Safeguard Policy Statement (SPS) will remain in place, noting that the SPS provides the flexibility to use a framework approach when project components are prepared after Board approval.

2. **Eligible expenditures.** For each country proposal, eligible expenditures under the rapid response component (RRC) will be verified to ensure that the (i) needs identified under the RRC are required urgently and are aligned with the country's vaccination need assessment, (ii) safeguard categorization is C, and (iii) fiduciary risks can be managed and procurement risks are low. The relevant regional departments; the Sustainable Development and Climate Change Department; and the Procurement, Portfolio, and Financial Management Department will carry out due diligence under the One ADB approach.

3. **Safeguard due diligence.** This will be carried out for all projects as per the following specific requirements for the RRC and the project investment component.
 - (i) **Rapid response component.** Expenditures under this component will be designed to ensure that projects have minimal and/or no environmental or social impacts and risks. This will be confirmed by screening and categorizing potential environmental, involuntary resettlement, and indigenous peoples impacts and risks against the agreed list of eligible expenditure items to be financed under RRC advance financing. Any expenditure items identified with potential adverse safeguard impacts and risks will be subject to further assessment and management planning. Project teams will also carry out safeguard due diligence on developing member country (DMC) systems for the collection, transportation, treatment, and disposal of incremental medical waste, referencing international good practices for relevant management planning.
 - (ii) **Project investment component.** All activities under this component will be screened and categorized by SDCC for potential environmental, involuntary resettlement, and indigenous peoples impacts and risks. For proposed DMC project components with potential adverse impacts on the environment and/or

¹ ADB. 2020. *ADB's Comprehensive Response to the COVID-19 Pandemic*. Manila.

² Where technical assistance is required for project preparation, it will also be processed considering the fast-track business processes approved for use in ADB's COVID-19 response.

affected people, the borrower/client will prepare environmental impact assessments and/or initial environmental examinations, resettlement plans, and indigenous peoples plans, consistent with SPS requirements. For activities that occur within existing facilities or require an expansion of existing facilities, an audit of the facilities will be undertaken by ADB in accordance with SPS requirements.³

4. **Poverty and Social.** During due diligence projects will conduct poverty and social analysis to identify barriers and risks to access, and opportunities to strengthen delivery and outreach. The analysis will help develop baseline data for projects, ensure a focus on inclusion and inform strategies for identification of vulnerable groups, communication and outreach with communities and with targeted groups (such as older persons) and opportunities for collaboration with civil society organizations to strengthen effective delivery.

5. **Gender.** During due diligence, projects will conduct a gender analysis supported by sex-disaggregated data that thoroughly considers gender issues and highlights the constraints and opportunities specific to the project context. Gender design features that directly reduce gender caps and/or promote women's empowerment will be included in the project design, and the project team will ensure that the project will not negatively affect women or girls. Each project will assign a corresponding gender categorization in line with ADB's guidelines for gender mainstreaming and ensure that gender dimensions are duly reflected in project documentation consistent with the requirements of each category.⁴

6. **Financial due diligence.** ADB will conduct financial due diligence on all projects and include (i) a sustainability assessment of executing and implementing agencies, (ii) a cost estimates and financing plan, and (iii) a financial management assessment. Because of the risks associated with the lack of adequate controls over the transparent distribution and application of vaccines, particular focus will be given to inventory control and management. The approach for the financial management assessment depends on the component:

- (i) **Rapid response component.** The financial management systems assessment will determine the degree to which the DMC manages risks and provides assurance that program funds will be used appropriately. The assessment will confirm that the DMC government's financial management systems are capable of managing, controlling, accounting, reporting, and auditing expenditures incurred and paid under agreed eligible expenditures criteria.⁵ Where financial management risks are deemed to be substantial or high, a risk management plan must be agreed with the DMC and documented as part of the country project proposal.
- (ii) **Project investment component.** The financial management assessment will be carried out in accordance with ADB's *Operations Manual* section G2 and technical guidance note on financial management assessment.⁶ The capacity of the executing and implementing agencies to manage, account, control, report, and audit project funds should be assessed by the project team. The financial

³ In some cases, safeguard frameworks may be used, following SPS requirements. This will be limited to cases where project components and/or site locations are not yet known, preventing the completion of the assessment and management planning before Board approval.

⁴ ADB. 2012. *Guidelines for Gender Mainstreaming Categories of ADB Projects*. Manila.

⁵ ADB. 2019. *Mainstreaming the Results Based Lending for Programs*. Manila.

⁶ ADB. 2014. Financial Management, Cost Estimates, Financial Analysis, and Financial Performance Indicators. *Operations Manual*. OM G2. Manila; ADB. 2015. *Technical Guidance Note on Financial Management Assessment*. Manila.

management arrangements agreed for the project and the identified risks and proposed mitigating measures will be included in the legal agreements and/or documented in the project documents and monitored throughout implementation.

7. In all projects, the annual audited program and/or project financial statements should be submitted 6 months after the end of the fiscal year.

8. **Procurement.** The procurement of goods and services under the RRC will be carried out in accordance with ADB's Procurement Policy (2017, as amended from time to time) and the Procurement Regulations for ADB Borrowers (2017, as amended from time to time). For each country project proposal, a procurement assessment will be carried out on the executing agency. If the procurement assessment confirms procurement risks are low and adequate systems are in place to effectively and efficiently procure items of eligible expenditure, ADB may agree to accredit the executing or implementing agency and rely on country procurement systems.

9. Under the project investment component, a procurement assessment will be carried out by ADB and the procurement of goods, works, and services will be carried out in accordance with ADB's Procurement Policy (2017, as amended from time to time) and the Procurement Regulations for ADB Borrowers (2017, as amended from time to time).

**LOAN TENOR AND PRICING UNDER THE RAPID RESPONSE COMPONENT
AND THE PROJECT INVESTMENT COMPONENT**

Financing Source^c	Modality	Grace Period	Term	Interest
ROCR (Group C)^b	RRC: up to \$500 million	3 years	10 years	LIBOR+50 bps contractual spread +surcharge or rebate
	RRC: above \$500 million	3 years	5 years	LIBOR+50 bps contractual spread +surcharge or rebate
	PIC ^a	Variable	Variable	LIBOR+50 bps contractual spread +surcharge or rebate
COL (Group B)^d	RRC	5 years	25 years	2%
	PIC ^a	5 years	25 years	2%
ADF (Group A)	RRC	8 years	24 years	1% during grace period; 1.5% after
	PIC ^a	8 years	32 years	1% during grace period; 1.5% after

ADF = Asian Development Fund, bps = basis points, COL = concessional ordinary capital resources lending, COVID-19 = coronavirus disease, LIBOR = London interbank offered rate, PIC = project investment component, ROCR = regular OCR, RRC = rapid response component.

^a Regular project investment terms and conditions apply.

^b Terms and conditions are equivalent to those for group C countries under the COVID-19 Pandemic Response Option.

^c Under the PIC modality, developing member countries may avail of all regular pricing terms and conditions of regular ordinary capital resources financed project lending. From 2021 onwards, differentiated pricing approved under the Asian Development Bank's Diversification of Financing Terms for ROCR sovereign lending operations under Strategy 2030 will be applicable.

^d Group B developing member countries would retain the option to utilize regular ordinary capital resources instead of COL, or a blend, if preferred.

Source: Asian Development Bank.

VACCINE REVIEW AND ELIGIBILITY CRITERIA

1. The Asian Development Bank (ADB) will rely on existing risk-based regulatory approaches for medical products for emergency use. This will provide assurance that ADB financing is used only for vaccines that have undergone technical and scientific review processes in line with international best practices. ADB understands the complex and challenging context of deploying new vaccines rapidly. In the first phase of vaccine roll-out, vaccines will probably be authorized for emergency use only, which will require enhanced pharmacovigilance and reporting. Vaccines will undergo prequalification by the World Health Organization (WHO) and authorization by regulatory agencies, enhancing confidence in the safe deployment of effective vaccines. ADB aims to balance the need for equitable and rapid access for developing member countries (DMCs) with the need for regulatory strengthening with support for risk-based regulatory approaches. Strengthening regional regulatory approaches and advancing harmonization and coordination will support the Asia Pacific Vaccine Access Facility (APVAX) and the region in strengthening a safe marketplace for new medical products. ADB will rely on the following:

- (i) WHO prequalification as a systematic process to determine that a vaccine is (a) safe and effective, (b) manufactured by a manufacturer in compliance with WHO good manufacturing practices requirements, and (c) under the oversight of a functional national regulatory authority (NRA). This process was originally provided as a service to the United Nations Children's Fund (UNICEF) and other United Nation agencies that procure vaccines. Any vaccine manufacturer can apply for the prequalification of the vaccines it manufactures if WHO considers the NRA of the vaccine manufacturer to be functional. The prequalification includes testing performed by WHO-contracted laboratories to assess the consistency of product characteristics (e.g., potency and toxicity). An inspection of the manufacturing site is carried out by WHO to ensure compliance with good manufacturing practices, proper practices in labeling and packaging, and the presence of a post-marketing surveillance system. The continued safety and efficacy of prequalified vaccines is ensured through regular reevaluations, site inspections, and targeted testing and investigating of all product complaints and/or adverse events following immunization. All of this is done in coordination with national NRAs and control laboratories. During public health emergencies, such as the coronavirus disease (COVID-19) pandemic, a fast-track prequalification procedure can be applied; under this procedure, the dossier review takes priority over other activities and all evaluation aspects are concomitantly performed, reducing the duration of the process to 8–10 weeks.
- (ii) Stringent regulatory authorities (SRAs) schemes came about as a result of WHO observations that local regulatory approvals of countries that import essential vaccines tend to take a long time even if the manufacturing and/or exporting countries have prequalified the vaccines with WHO. To partly address this issue, WHO has promoted facilitated registrations for NRAs (of importing countries) of vaccines that SRAs have approved. The initial requirement for a country's NRA to be recognized as an SRA is the adoption of the standards of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This compliance means that the country adheres to and applies a uniform set of scientific and technical standards that is equivalent to WHO's level of assessment and evaluation. Based on their adoption of the ICH standards, national regulatory authorities were considered SRAs if they met the following criteria:

- (a) an ICH member—European Commission (European Union countries); the United States Food and Drug Administration; and Japan’s Ministry of Health, Labor and Welfare—as represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015);
- (b) an ICH observer—the European Free Trade Association—as represented by Swissmedic and Health Canada (as before 23 October 2015); and
- (c) a regulatory authority associated with an ICH member through a legally binding, mutually recognized agreement, including Australia, Iceland, Liechtenstein, and Norway (as before 23 October 2015).

2. In 2017, WHO decided to enhance the SRA scheme, including renaming it to WHO-Listed Authorities (WLA). The enhancement process has taken time, with WHO releasing in December 2019 the concept note of the WLA framework, which includes the process of evaluating and publicly designating regulatory authorities as WLAs, and its global benchmarking tool as the primary evaluation tool. Once fully implemented, the WLA framework is expected to supersede the concept of SRAs and more national regulatory agencies in Asia and the Pacific can be considered mature in their capabilities, similar to the SRA capability definition.

3. To manage the speed of vaccine development and the risks of introducing new vaccines, ADB will apply a combination of regulatory requirements as a basis for informing financing decisions for vaccines under APVAX and for managing the following:

- (i) whether and how much a vaccine will prevent infection and mitigate health consequences of infection, or both;
- (ii) how long the protection will last;
- (iii) the safety profile when administered to many unselected individuals of all ages;
- (iv) different manufacturing sites produce different versions of the same vaccine.¹

4. To address these issues and be able to make informed decisions, ADB sees a critical opportunity for the region to (i) leverage its regional network of pharmacovigilance and scientific experts to advise ADB and DMCs on the safety and effectiveness of COVID-19 vaccines that are procured bilaterally (outside the COVID-19 Vaccines Global Access [COVAX] facility); (ii) build regional capacity by harnessing, harmonizing, and sharing regulatory approaches and technical and scientific knowledge across member countries to pave the way for the harmonized implementation of regulatory approaches to the extent possible; and (iii) carefully craft the regulatory requirements for vaccine financing under APVAX.

5. The following proposed vaccine selection criteria considers the importance of safety and the latest scientific understanding of the new vaccines’ pharmacokinetics while supporting fast and equitable access for DMCs. Therefore, to be considered as eligible for ADB financing, the vaccines must meet one of the following:

- (i) the vaccine has been selected for procurement via COVAX on behalf of its participating countries;² or
- (ii) the vaccine manufacturer is prequalified by WHO; or

¹ Different versions should be demonstrated to provide the same safety and efficacy profile; this will require expertise and collaboration by the SRA that approved the first version.

² Vaccines procured under the COVAX facility will be required to be prequalified by WHO or have marketing authorization from an SRA. Exceptionally, WHO’s emergency use listing procedure may be used, if acceptable to the receiving country.

- (iii) the vaccine is authorized by an SRA for manufacture in an SRA country, or the SRA has authorized its manufacture in a non-SRA country.

6. Item (i) of the criteria acknowledges that COVAX applies a rigorous process to selecting the vaccines it procures on behalf of COVAX participating countries. This allows the financing of the COVAX-selected vaccines, either through the COVAX procurement process or other arrangements outside the COVAX process.

7. Item (ii) allows the financing of a vaccine whose manufacturer complies with WHO's prequalification review process, and the vaccine is recognized as a WHO prequalified vaccine.

8. Item (iii) recognizes the strict adherence of SRAs to standards and regulatory processes that will ensure the safety, effectiveness, and quality of any vaccine. This option allows the financing of any vaccine whose manufacturing processes have been rigorously reviewed and subsequently authorized by an SRA in either an SRA or a non-SRA country.

9. All three options require DMCs to have their respective NRA authorize the use of the vaccines, strengthen the surveillance of vaccine-related adverse events and pharmacovigilance capacity, and comply with all requirements for the enhanced monitoring of authorizing new biosimilar medical products. DMCs with no NRAs, such as the small Pacific island countries, are not required to have the NRA vaccine authorization; however, they must have accepted responsibility for vaccine selection, distribution, and administration in their country and are still required to strengthen vaccine surveillance and monitoring.

10. Recognizing the rapid developments taking place with COVID-19 vaccines and the need to continuously ensure safety while supporting fast and equitable access by DMCs, ADB will refine and enhance the vaccine selection criteria, as needed, in consultation with WHO, APVAX, and other vaccine experts. Any changes to vaccine selection criteria will be subject to Board approval.

INDICATIVE ELIGIBLE EXPENDITURE FOR THE ASIA PACIFIC VACCINE ACCESS FACILITY

1. The rapid response component (RRC) is intended to provide flexible and timely financing for eligible expenditures while maintaining clear results chains and adequate due diligence. The RRC will provide financing for vaccine procurement and the associated distribution and/or delivery costs based on an agreed list of acceptable expenditure items, under a multiyear financing plan.
2. The eligible expenditure items under the RRC will include
 - (i) services for core analytical and/or diagnostic work and policy development including needs assessments, a vaccination development strategy, regulatory gap assessments, data safety and security policies, vaccine pricing and distribution regulations, and disease surveillance;
 - (ii) advance market commitments, self-financing payments, or procurement costs for vaccines acquired through the coronavirus disease (COVID-19) Vaccines Global Access facility (irrespective of whether the developing member country (DMC) eventually procures vaccines through the facility);
 - (iii) vaccines that meet any of the eligibility requirements outlined in Appendix 3, including advance payments;
 - (iv) international logistics and related services required for the transportation of vaccines from the place of purchase to designated delivery points in the DMC;¹ and
 - (v) indirect management fees, with a reasonable percentage normally below 10% of the loan amount managed, charged as required by the United Nations agencies' financial regulations or similar authoritative guidelines.
3. The eligibility of items for inclusion under the RRC will be conditional on the satisfactory assessment of procurement, financial management, and safeguards risks, which will be prepared as part of project due diligence.
4. The project investment component (PIC) will provide targeted support for investments necessary for vaccine procurement and distribution that cannot be financed under the RRC component. DMCs may also choose to avail of the PIC for RRC-eligible items.
5. While the RRC is intended for quick and flexible financing for immediate vaccination needs, the PIC is intended to support the physical infrastructure and civil works necessary to establish safe and effective vaccine delivery mechanisms (Table A4). DMCs may also elect to undertake the procurement of non-infrastructure related goods and services (including vaccines) through the PIC, where ADB's procurement and project implementation support are deemed to offer benefits; in-country capacity is constrained; or safeguards, procurement, and financial due diligence assessments identify high risks for financing under the RRC component.²

¹ Any physical infrastructure, civil works, or other expenditures related to non-goods and services will be excluded.

² When DMCs elect to procure vaccines through the PIC, the vaccine eligibility criteria will remain the same as under the RRC.

Table A4: Indicative List of Eligible Expenditures under the Project Investment Component

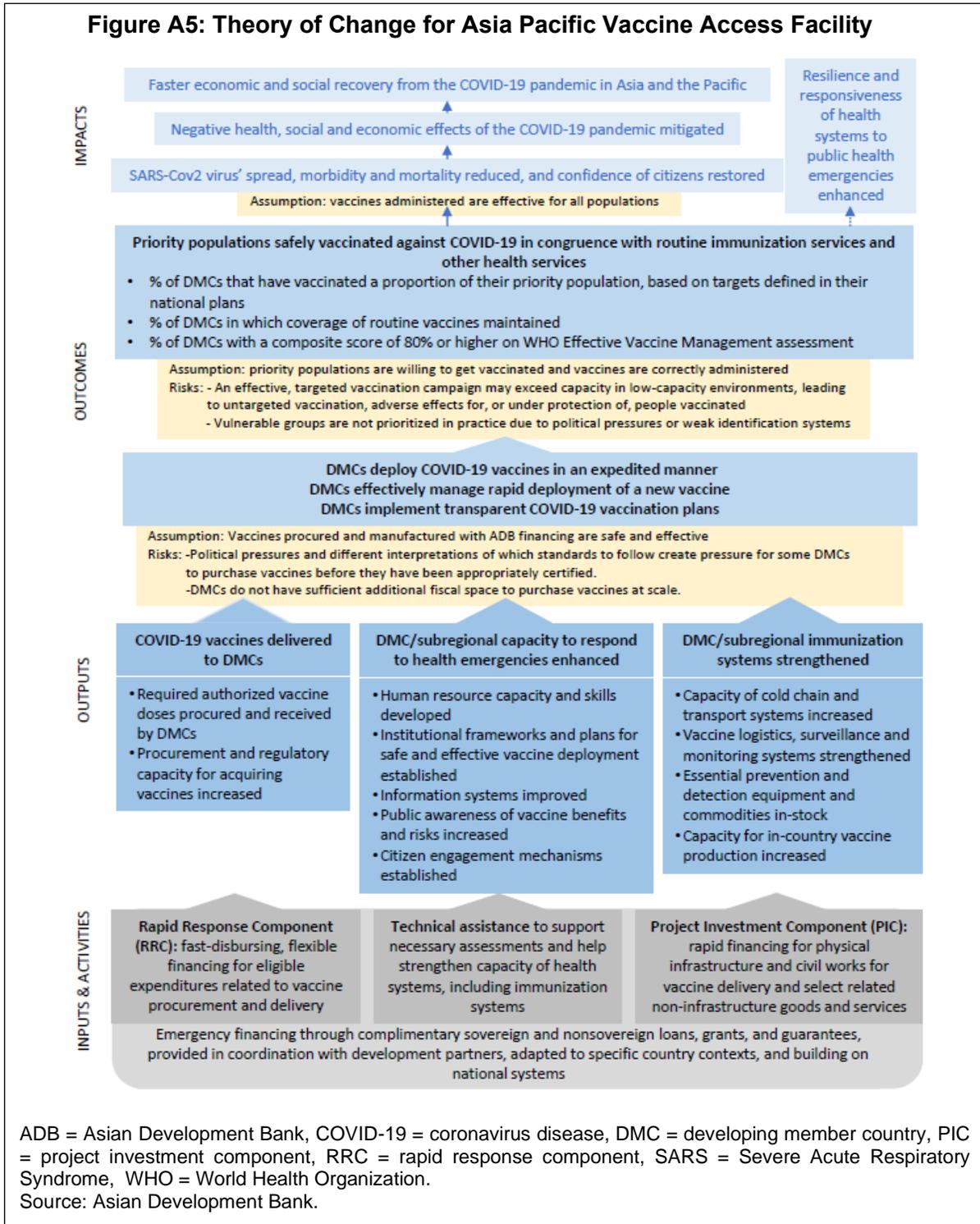
Activity	Description
Supply chain assessments and associated infrastructure investments	Assessing gaps and building infrastructure, including civil works, to support supply chain, logistic, and quality assurance systems, including support for vaccine development activities (clinical trial design/implementation, regulatory support (licensure and prequalification), and pharmacovigilance and post-marketing surveillance)
Designing coronavirus disease (COVID-19) vaccination programs	Planning for vaccine procurement, allocation strategies, innovative delivery strategies targeting the most vulnerable segments of the population, and support for adverse events monitoring and pharmacovigilance
Economic evaluations	Conducting analyses such as cost benefit, vaccine impact, budget impact, cost-effectiveness of different vaccination strategies, implementation plans, and COVID-19 vaccines; developing cost calculators; and cost of illness studies to evaluate acute and long-term costs of infection
Strengthening regulation and standards	Supporting national and regional regulation including harmonization and mutual recognition of vaccines authorization, integrated regulatory management information systems for fast exchange of product, and pharmacovigilance data to manage risks of substandard products and adverse side events
Manufacturing capacity	Assessing the potential for scaling up vaccine production at state-owned and/or private sector vaccine manufacturing firms, and establishing or expanding the manufacturing capacity in line with good manufacturing practices
Conducting market research	Supporting market research and any commercial due diligence activities of potential manufacturers, along with a basic assessment of manufacturing processes
Coordination with COVAX and other procurement	Supporting developing member countries (DMCs) to coordinate with the COVID-19 Vaccines Global Access (COVAX) facility or other sourcing mechanisms
Supporting procurement good practices	Advising on the use of appropriate procurement procedures, documents, and safeguard applications
Strengthening information systems	Developing or strengthening health information systems, including unique patient identification; and vaccine adverse events reporting systems to monitor, report, and analyze country and regional vaccine-related adverse events
Private sector engagement	Identifying and developing partnerships with the private sector (e.g., including logistics service providers) to support the development of a regional supply chain to enable DMCs to benefit from integrated logistics and operational planning related to the procurement of COVID-19 vaccines
Risk communications and community engagement	Developing and implementing risk communication and demand generation strategies and other advocacy and communications and social mobilization efforts, including specific outreach to women and vulnerable groups
Identifying health expert consultants	Establishing a health experts pool to support regional departments in designing and implementing vaccine-related projects
Delivery of vaccines	Administering vaccines, creating a registry to identify priority target populations, developing strategies for outreach (specifically a list of front-line health care workers, the elderly, and those with pre-existing conditions), reestablishing disrupted essential care services,

	development of strategies and plans to expand general immunization services to zero-dose communities (often clustered in urban slums, remote rural and conflict affected zones), support to ensure infection prevention and control measures, procurement of supplies (e.g., hand hygiene products, disinfectants, etc.), development and implementation of protocols in place (i.e., physical distancing), ensuring continuity of essential health services including country schedule of vaccines for children that may have been disrupted because of COVID-19 and any catch-up efforts
Monitoring and evaluation	Evaluating and assessing the implementation of the COVID-19 vaccine delivery across DMCs to identify gaps, inform strategic changes, and enable sharing of best practices
Knowledge management	Coordinating interdisciplinary knowledge management, including (i) developing a regional information portal containing the development status of vaccines, regulatory approvals, supply availabilities, and other information as needed; (ii) supporting a regional task force for equitable vaccine access; and (iii) sharing knowledge and best practices from across the region

Source: Asian Development Bank.

THEORY OF CHANGE, MONITORING, AND EVALUATION

1. The figure presents the theory of change for the Asia Pacific Vaccine Access Facility (APVAX).



2. **Design and monitoring frameworks for countries.** APVAX's results monitoring and evaluation (M&E) system will be structured to strike a balance between enabling timely, flexible, and country-tailored support and the need for accountability. Each country project will have its own design and monitoring framework (DMF), aligned with APVAX's theory of change. Each project will have at least one of the facility's outcomes in its DMF as the project outcome or project impact, depending on the project's scope. This will ensure country projects are aligned with APVAX's objectives. It will also provide an opportunity to compare and benchmark results across projects, where appropriate, which is beneficial for transferring knowledge and learning among developing member countries (DMCs). Projects that are broader in scope are expected to have the same outcome and impact statements as the facility. However, the country project outputs will differ based on individual country needs. Some country projects may have a narrower focus (e.g., activities focused solely on expanding cold chain systems), which needs to match their DMF outcome to be suitably ambitious by measuring only the results directly attributable to the project's outputs (e.g., performance of the immunization supply chain improved). Such a project would include one of the facility's outcomes as its DMF impact statement (e.g., priority populations safely and effectively vaccinated against the coronavirus disease [COVID-19] without compromising routine immunization services or other health services).

3. Because of the fluidity of emergency situations, such as the COVID-19 pandemic, the imperative to respond rapidly, and the frequent absence of baseline data in this context, realistic yet ambitious targets cannot always be specified accurately at the project approval stage. To monitor progress and report results in accordance with Asian Development Bank (ADB) policies, country project DMFs will include meaningful performance indicators that are based on specific country contexts and capabilities. Additional indicators may be identified, as relevant, during implementation and used to monitor progress and evaluate project effectiveness as comprehensively as possible after project completion.

4. **Country project monitoring.** Project performance monitoring will follow the standard processes for investment projects as defined in ADB's project administration instructions. This includes monitoring and managing risks and critical assumptions (including monitoring for unintended negative consequences), reassessing the executing and implementing agencies' capacity to mitigate these risks, and devising an action plan to avoid or address them if they arise. Enhanced supervision and monitoring will be important to ensuring the effectiveness of ADB-financed projects and overall country programming under urgent and uncertain conditions.

5. Country and regional M&E systems are the backbone of an effective and efficient immunization system, and of M&E of the APVAX and projects. M&E activities related to country projects will be the responsibility of executing agencies, with the participation of the relevant implementing agencies in each DMC. For individual countries, detailed information on the M&E capacity of the implementing agencies and their specific responsibilities for M&E under the project should be described in project documents. M&E capacity varies widely between and within DMCs, and capacity is expected to be lower overall because of the pandemic's heavy burden on institutions' human, financial, and technical resources. It will be important to build on systems and arrangements and to strengthen data collection and monitoring systems. The digital information systems needed to monitor effectiveness, pharmacovigilance, and delivery of the new COVID-19 vaccines are not in place. Global, regional, and country initiatives are underway to establish and strengthen COVID-19 incidence and vaccine coverage monitoring including pharmacovigilance—led globally by the World Health Organization and Gavi, the Vaccine Alliance—and social effects and community awareness—led by the United Nations Children's Fund (UNICEF). In collaboration with other development partners to foster harmonization and avoid duplication, ADB will invest in building M&E capacity based on where it has the comparative advantage among

other partners and distinct country needs informed by vaccine readiness assessments. This will be carried out through APVAX, complemented by additional technical assistance, and contribute to the following: (i) strengthening existing immunization and public health information and monitoring systems; (ii) developing or adapting global tools to national contexts (e.g., vaccination cards and/or certificates, facility-based nominal registers and/or tally sheets, and paper and/or electronic vaccination reports) and analytical tools to monitor progress, effectiveness, and coverage among different at-risk categories, including by introducing and adapting and/or using and scaling up existing digital solutions and approaches for monitoring the vaccine and the public's acceptance of it; and (iii) supporting the setup of global and regional digital health public goods (e.g., unique patient identification, data privacy and security policies, digital health governance, interoperability) because they might also be included in revised international health regulations.

6. Project performance management processes will need to be flexible to adjust projects, as needed, to changing circumstances and the regular emergence of new information. The use of rapid evaluation and assessment methodologies supported by real-time monitoring systems, in coordination with other development partners and in harmonization with country systems, will be essential to good project management. A midterm review will examine the progress toward desired outcomes, identify issues, and adjust the project design and DMF, as needed, to better track and manage progress, learn, and complete an evidence-based assessment of the outcomes at project completion.

COMPARISON OF EXISTING LENDING MODALITIES AND APPROPRIATENESS FOR VACCINE SUPPORT

1. The Asian Development Bank (ADB) introduced the multitranche financing facility (MFF) as a sovereign financing modality in 2005, and, after a 3-year pilot period, mainstreamed it into its operations in 2008.¹ MFFs have helped to establish a long-term presence of ADB in priority sectors for ADB and its clients, supporting a more constructive dialogue on policies, capacity issues, and the governance needed for sector policy reforms and institutional capacity development commensurate with the country's ability to adapt and change. Through large financing, MFFs provide critical mass, predictability, and continuity throughout programmatic engagement with ADB's long-term support.
2. MFF operations follow streamlined processing procedures. ADB's Board of Directors approves the overall facility framework and the financing envelope, and ADB Management approves the tranches. The funding is released gradually, as investment projects become ready. During the implementation of each tranche, the project team works with the executing agency from the borrowing developing member country (DMC) to ensure project implementation, monitoring, and reporting.
3. To use MFFs, DMCs are required to meet certain preconditions, including the development of a road map, strategic context, policy framework, investment program, and financing plan. Given the need to establish an ADB-wide facility and recognizing that the needs of individual DMCs will differ substantially, an MFF is not well suited to support vaccine access.
4. The emergency assistance loan (EAL), introduced under ADB's 2004 Disaster and Emergency Assistance Policy, also has some characteristics that could be applied to ADB support to enhance vaccine access, including streamlined project preparation and procurement flexibilities.² To meet the urgent needs that arise during a natural disaster or complex emergency, EALs allow for rapid preparation. For example, the requirement for a project concept paper is waived, interdepartmental reviews are replaced with a One ADB team approach, and Board circulation and consideration take place under a compressed timeline.
5. However, the EAL is designed primarily as a mechanism for supporting the rehabilitation and reconstruction of affected infrastructure and services following major disaster events. Although the EAL instrument has been able to integrate quick-disbursing components into several past operations, its use revealed several challenges. In particular, the wide range of allowable expenditures under the EAL coupled with limited procedures instead of financial reporting and auditing, safeguard due diligence, or physically verifying the completion of activities has led to implementation and performance reporting challenges.³
6. The lending terms and conditions for EALs are also relatively generous, in line with the humanitarian focus of their support, and are calculated in line with support for individual, one-off crises. A broad application of EAL terms and conditions under an ADB-wide facility would severely limit the ability of ADB to expand its financial support for DMCs.

¹ ADB. 2005. *Pilot Financing Instruments and Modalities*. Manila; and ADB. 2008. *Mainstreaming the Multitranche Financing Facility*. Manila.

² ADB. 2004. *Disaster and Emergency Assistance Policy*. Manila.

³ ADB. 2019. *Review of ADB's 2004 Disaster and Emergency Assistance Policy*. Manila.

QUESTIONS AND ANSWERS ON THE COVID-19 VACCINES GLOBAL ACCESS FACILITY

What is the COVID-19 Vaccines Global Access (COVAX) facility?

1. In response to the coronavirus disease (COVID-19) pandemic, the World Health Organization (WHO), the European Commission, the Government of France, and the Bill and Melinda Gates Foundation (BMGF) launched the Access to COVID-19 Tools Accelerator in April 2020.¹ COVAX is one of its three pillars. The purpose of COVAX—coordinated by Gavi, the Vaccine Alliance (GAVI), the Coalition for Epidemic Preparedness Innovations (CEPI), and WHO—is to ensure equitable access to COVID-19 vaccines by all participating members, which include developing and developed countries.² The GAVI secretariat coordinates COVAX activities, working closely with other partners. The United Nations Children’s Fund (UNICEF) and the Pan American Health Organization support COVAX procurement activities.³

How is COVAX expected to work?

2. COVAX will manage a portfolio of potentially successful COVID-19 vaccines, strategically selected from those undergoing clinical trials. Through a series of push and pull mechanisms,⁴ COVAX aims to secure access to 2 billion doses of COVID-19 vaccines at competitive prices, while also supporting manufacturers in preparing for future demand if a vaccine in their portfolio receives regulatory approval.⁵ Once authorized and approved, vaccines will be provided to COVAX participants equitably, through various supply avenues (Figure A8.1). As of 1 December 2020, COVAX had signed memorandum of understandings and/or statements of intent with potential manufacturers to procure up to 700 million doses.⁶

¹ World Health Organization. 2020. *The Access to COVID-19 Tools (ACT) Accelerator*. Geneva. <https://www.who.int/initiatives/act-accelerator>

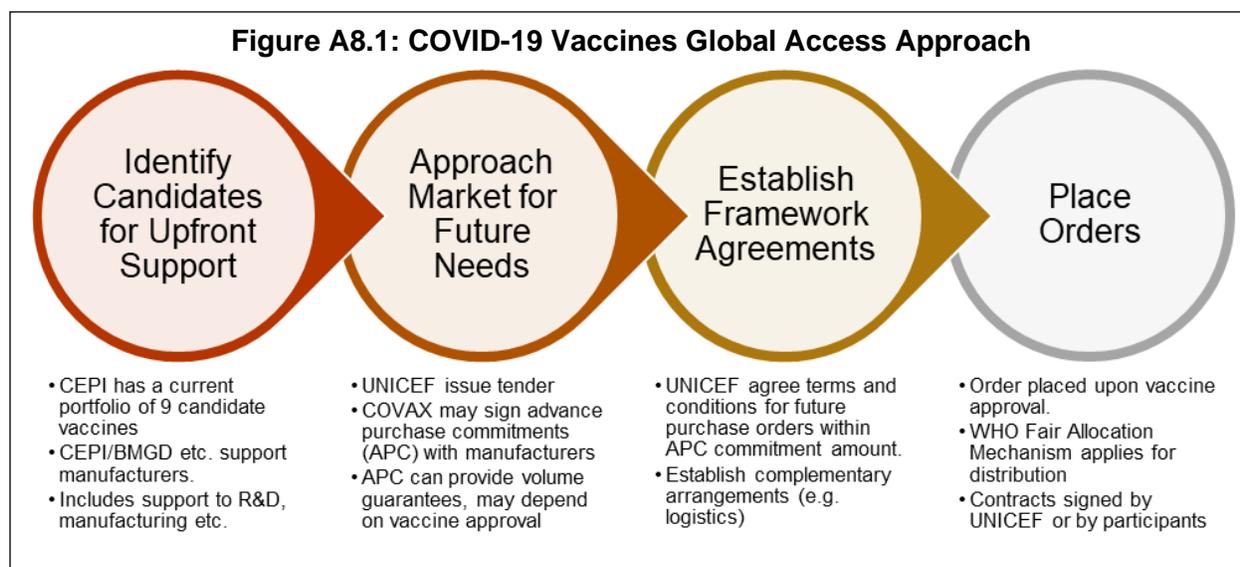
² Gavi, the Vaccine Alliance. 2020. *COVAX explained*. Geneva. <https://www.gavi.org/vaccineswork/covax-explained>

³ This refers only to UNICEF because of its role in providing support across Asia and the Pacific.

⁴ Push mechanisms support manufacturers by sharing up-front costs (e.g., research and development and building manufacturing capacity), while pull mechanisms provide strong guarantees on downstream demand (e.g., purchase guarantees) that may be contingent on vaccines being approved for use (e.g., WHO prequalification). CEPI and BMGF, among others, have used push mechanisms to support the development of a number of vaccines, while COVAX will use pull mechanisms by signing advance purchase commitments with selected suppliers. Used together successfully, these mechanisms can strongly influence the supply market.

⁵ CEPI, GAVI, and BMGF, among others, have supported manufacturers in accelerating vaccine development and scaling up manufacturing.

⁶ These include Astra Zeneca (300 million doses), Sanofi–GSK (200 million doses), and the Serum Institute of India (200 million doses) licensed from Astra Zeneca and Novavax.



APC = advance purchase commitment, BMGD = Bill and Melinda Gates Foundation, CEPI = Coalition for Epidemic Preparedness Innovations, COVAX = COVID-19 Vaccines Global Access, R&D = research and development, UNICEF = United Nations Children's Fund, WHO = World Health Organization.

Source: Asian Development Bank

How is COVAX structured?

3. There are two separate entry points for countries who want to participate in COVAX: the self-financing component of the facility⁷ and the advance market commitment (AMC) mechanism.⁸ Participants of the self-financing component have two options when joining the facility, a committed purchase arrangement or an optional purchase arrangement. Participants may request access to vaccines sufficient to cover between 10% and 50% of their population. Unlike participants in the committed purchase arrangement, participants in the optional purchase arrangement will be able to choose the type of vaccine they receive. As of 24 November 2020, 89 countries had signed commitments to join COVAX.⁹

4. Access to the COVAX AMC mechanism is only open to 92 lower and middle-income countries,¹⁰ of which 29 are ADB developing member countries (DMCs).¹¹ The AMC mechanism is predominantly funded by contributions from sovereign and nonsovereign donors and has funding targets of \$2 billion in 2020 and at least a further \$5 billion in 2021. Countries who have access to the AMC mechanism may be required to provide a contribution in order to receive 20% of the of their vaccine needs, albeit the precise amount and mechanism for payment have not yet

⁷ World Health Organization. 2020. *COVAX Facility Explainer*. Geneva. <https://www.who.int/docs/default-source/coronaviruse/covax-facility-explainer.pdf>

⁸ Gavi, the Vaccine Alliance. 2020. *The Gavi COVAX AMC Explained*. Geneva. <https://www.gavi.org/vaccineswork/gavi-covax-amc-explained>

⁹ Gavi, the Vaccine Alliance. 2020. *Commitment agreements*. Geneva. <https://www.gavi.org/news/document-library/covax-list-participating-economies>

¹⁰ Gavi, the Vaccine Alliance. 2020. *92 low- and middle-income economies eligible to get access to COVID-19 vaccines through Gavi COVAX AMC*. Geneva. <https://www.gavi.org/news/media-room/92-low-middle-income-economies-eligible-access-covid-19-vaccines-gavi-covax-amc>

¹¹ Afghanistan, Bangladesh, Bhutan, Cambodia, Federated States of Micronesia, Fiji, India, Indonesia, Kiribati, Kyrgyz Republic, Lao People's Democratic Republic, Maldives, Marshall Islands, Mongolia, Myanmar, Nepal, Pakistan, Papua New Guinea, Philippines, Samoa, Solomon Islands, Sri Lanka, Tajikistan, Timor-Leste, Tonga, Tuvalu, Uzbekistan, Vanuatu, Viet Nam.

been confirmed.¹² As of 17 November 2020, \$2.1 billion had been pledged to the AMC mechanism.¹³

5. The self-financing countries (ADB DMCs include Armenia, Azerbaijan, Cook Islands, Georgia, Kazakhstan, Nauru, Niue, Palau, People's Republic of China, Malaysia, Thailand, Turkmenistan) can also access COVAX to purchase vaccine doses procured at negotiated prices. They have the choice of signing a committed purchase arrangement or an optional arrangement with COVAX.

6. The provision of vaccines will follow an allocation mechanism developed by WHO.¹⁴ The primary aim is to provide each participating country with 20% of its vaccine needs (an initial allocation of 3% to vaccinate health and social care workers and a subsequent 17% to protect vulnerable population categories). Once all participants have received their initial allocation, the needs of countries that requested to receive vaccines for up to 50% of their population will be addressed.

7. A COVAX exchange will be established to permit participants to trade allocations of vaccines in circumstances where they do not wish to utilize their allocation (e.g., when they have excess supply or when they do not wish to accept a specific vaccine type). Details on how the COVAX exchange will function are not yet available.

8. The currently available costs of participating in COVAX is presented in Table A8.1.

		Committed Purchase Arrangement per Dose	Optional Purchase Arrangement per Dose	AMC per Dose
1	Up-front payment	\$1.60	\$3.10	
2	Financial or risk guarantee	\$8.95	\$0.40	
3	Financial contribution			\$1.60–\$2.00 ^c
	Total cost to participant	1 + 2 + balance of offered vaccine cost^a	1 + 2 + balance of selected vaccine cost^b	3

AMC = advance market commitment, DMC = developing member country.

^a Participants may elect not to receive a vaccine only if it costs double the commitment already entered into (e.g., \$21.10). In this event, the participant could elect to wait until a vaccine is available that is within this limit.

^b Participants will have the opportunity to choose which vaccine they receive at two different times during the process.

^c The remainder of the purchase cost is covered through donations to the AMC mechanism.

Source: Asian Development Bank.

What will COVAX define as acceptable vaccines?

9. COVAX will require WHO prequalification of the vaccines that can be accessed via COVAX, or on an exceptional basis, at a minimum, an authorization from a stringent regulatory

¹² In September 2020, it was confirmed that AMC countries would be requested to contribute of between \$1.60 and \$2 per dose toward the cost of vaccines distributed through the AMC mechanism. ADB understands that this may not be applied on per dose basis, but rather used to defray the full cost of vaccines between the amount that are provided for free through the AMC mechanism and the 20% target.

¹³ Gavi, the Vaccine Alliance. 2020. *Key Outcomes: COVAX AMC*. Geneva. <https://www.gavi.org/sites/default/files/covid/covax/COVAX-AMC-Donors-Table.pdf>

¹⁴ World Health Organization. 2020. *Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility*. Geneva. <https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility>

authority.¹⁵ If a participant agrees, COVAX may supply vaccines that do not meet the two above criteria but are authorized for emergency use by WHO.

How much is COVAX expected to cost?

10. Based on available reference data, the initial estimated cost for COVAX to succeed in meeting its targets through 2020 and 2021 is \$18.1 billion. This figure includes \$9.4 billion for research and development, \$5.5 billion for volume guarantees and procurement, and \$3.2 billion for delivery (transport, storage, and implementation costs).¹⁶

How will COVAX manage liability issues from vaccine-related adverse events?

11. Countries are concerned about the requirement to indemnify the manufacturer for the vaccines deployed in their country for claims that may arise from vaccine-related adverse events. GAVI has recognized that the unprecedented speed and scope of the deployment of these vaccines have made vaccine manufacturers reluctant to deliver COVID-19 vaccines if these risks are not addressed. GAVI is, therefore, negotiating a model indemnification agreement that will be incorporated into agreements with manufacturers and requiring all COVAX participating countries to indemnify the manufacturer for the vaccines deployed in their country. GAVI has reported it is working on mechanisms to reduce the financial exposure of countries participating in the AMC mechanism. This includes ongoing discussions with the Multilateral Investment Guarantee Agency to provide a guarantee to backstop indemnity obligations and a planned compensation mechanism to cover unexpected serious vaccine-related adverse events designed to disincentivize claims in court.

Procurement and COVAX

12. UNICEF will lead the procurement and supply of vaccines on behalf of COVAX while the Pan American Health Organization will fulfill the role in Latin America and the Caribbean. A rolling request for proposal was published on 11 November 2020 to confirm manufacturers' interest and receive more specific information on the future supply capabilities of manufacturers.

13. The request for proposal process is expected to have three parallel outcomes:

- (i) the establishment of advance purchase commitments between COVAX, represented by GAVI, and manufacturers for future approved vaccines;
- (ii) the establishment of time-bound long-term agreements¹⁷ between UNICEF and manufacturers establishing the structure for future contractual relationships under the COVAX AMC mechanism; and
- (iii) the establishment of basic terms and conditions for future direct contracts concluded between COVAX participants and manufacturers.

¹⁵ World Health Organization. 2020. *List of Stringent Regulatory Authorities (SRAs)*. Geneva. <https://www.who.int/medicines/regulation/sras/en/>

¹⁶ World Health Organization. 2020. *COVAX, the act-accelerator vaccines pillar*. Geneva. <https://www.who.int/docs/default-source/act/covax-pillar-background.pdf>

¹⁷ Long-term agreements are called framework agreements under ADB's Procurement Policy (2017, as amended from time to time).

14. Under the AMC mechanism, UNICEF will be responsible for the procurement and supply of vaccines to designated participant countries. It is expected that the mechanism will cover the cost and delivery of the vaccine.¹⁸

15. Self-financing participants will be provided with the details of quantities, costs, and basic terms for vaccines they have been allocated. The participants will then be responsible for finalizing vaccine supply agreements directly with manufacturers and arranging the associated delivery of the vaccines to their country. While the initial down payment under both committed and optional purchase options will be paid to COVAX, the balance of the vaccine cost will be paid directly to the manufacturer. Upon request, and for an agreed additional fee, UNICEF may act as the procurement agent and purchase and supply vaccines on behalf of a participant. These services will be offered outside COVAX, based on a bilateral agreement between the participant and UNICEF.

16. Under ADB-financed loans and grants, payments for the procurement and supply of vaccines through COVAX will include:

- (i) down payments to COVAX for committed and optional purchase arrangements,
- (ii) balance payments for vaccines to be disbursed directly to manufacturers,
- (iii) logistics costs and UNICEF fees (if engaged) to procure and deliver on behalf of participants, and
- (iv) contribution payments to COVAX (for the AMC mechanism only).

Financial management and COVAX

17. The funds flow and documentation process is subject to the agreement entered into by the country. Countries may participate in two approaches: the self-financing component of the COVAX facility and the AMC mechanism.

18. The role assumed by the country, GAVI, and UNICEF regarding the procurement and payment of the vaccines may follow two possibilities: self-procurement and/or UNICEF-delegated procurement. Depending on the possibilities, the funds flow and documentation process will differ as follows:

- (i) **Self-procuring countries.** UNICEF will act as a procurement advisor. The DMC will provide an advance to COVAX that will (in principle) result in vaccines. When the vaccine is finalized (available and authorized in line with COVAX requirements), UNICEF will send a validation report to the DMC advising the price, quantity, and manufacturer. The DMC will sign a contract with the manufacturer and purchase the vaccines directly. The manufacturer will produce the vaccines and send them, together with the invoices to the DMC executing agency and/or implementing agency, which will then prepare the financial statements and have them audited and submitted to ADB. The funds flow and documentation flow can be found in Figure A8.2. The DMC will also need to authorize the vaccine with its national regulatory agency.
- (ii) **UNICEF-delegated procurement.** UNICEF will be the procurement agent. The DMC will provide the advance to COVAX and, when vaccines are finalized, disburse the balance of the funds to UNICEF, which will procure and arrange

¹⁸ Full details regarding COVAX covering logistics and associated services is yet to be confirmed. It is expected that delivery will consist of international transportation to an agreed entry port in a participant country.

delivery of the vaccines to the DMC. UNICEF will invoice the full amount to the DMC executing agency and/or implementing agency, which will prepare the financial statements and have them audited and submitted to ADB (Figure A8.3).

18. **Under the AMC mechanism.** Focused on low- and lower-middle income countries, participation is supported by official development assistance towards, for example, the initial financial contribution and subsequent vaccine procurement and vaccine delivery support. Funded countries (low-income countries and lower-middle income countries) are those whose financial commitments for participating in the facility are covered by official development assistance. UNICEF will procure and supply the vaccines to the DMC (Figure A8.4).

19. In all scenarios, the financial management capacity of the DMC executing agency and/or implementing agency needs to be assessed to confirm that robust systems exist for accounting, monitoring, reporting, controlling, and auditing to manage the funds and vaccine distribution and ensure the project objectives are attained.

20. Figures A8.2, A8.3, and A8.4 assume the scenario that the vaccine will materialize (i.e., become an ADB eligible expense). Where vaccines do not materialize, COVAX (i.e. GAVI) will provide an independent report stating the amount received, the criteria followed, the use of the funds, and the reasons for not achieving the objectives and outcomes.

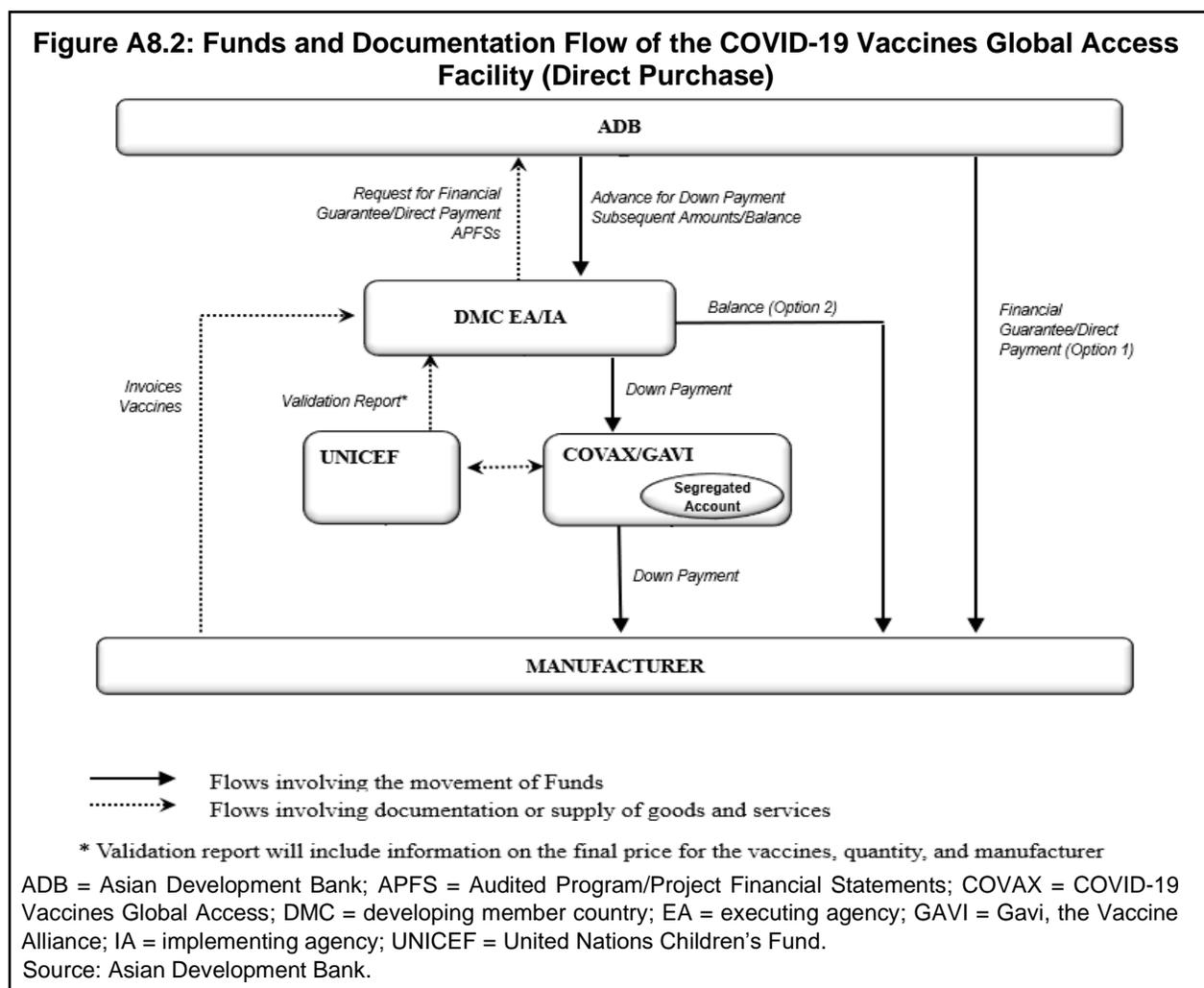
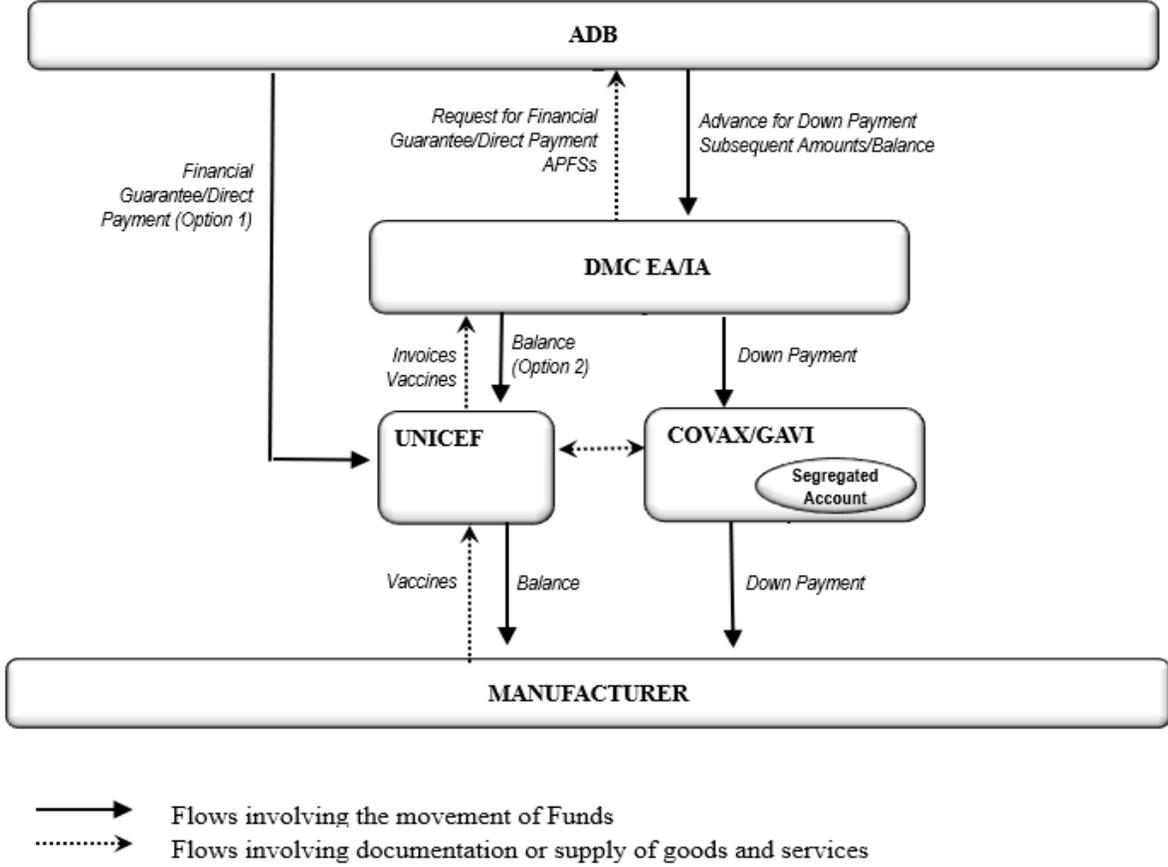
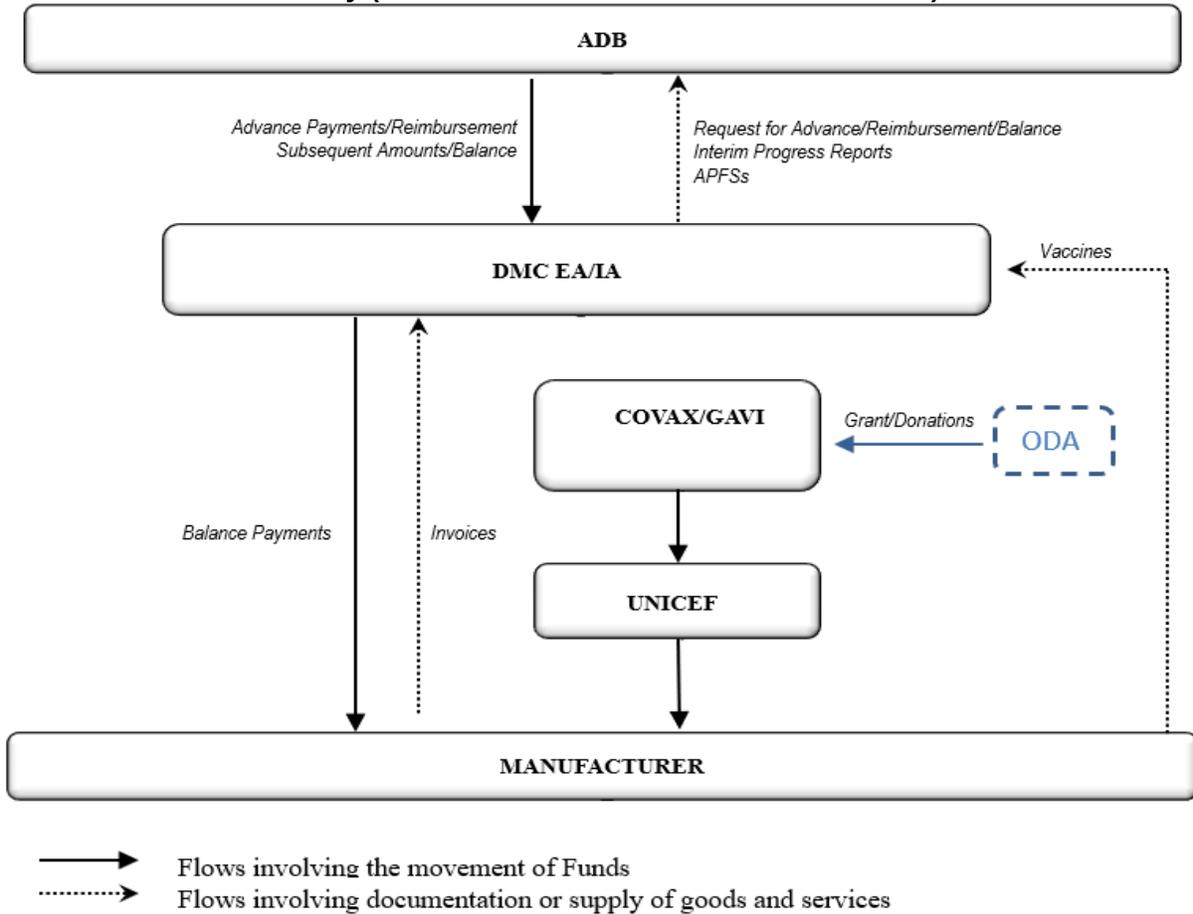


Figure A8.3: Funds and Documentation flow of the of the COVID-19 Vaccines Global Access Facility (UNICEF as Procurement Agent)



ADB = Asian Development Bank; APFS = Audited Program/Project Financial Statements; COVAX = COVID-19 Vaccines Global Access; DMC = developing member country; EA = executing agency; GAVI = Gavi, the Vaccine Alliance; IA = implementing agency; UNICEF = United Nations Children’s Fund.
Source: Asian Development Bank.

Figure A8.4: Funds and Documentation flow of the COVID-19 Vaccines Global Access Facility (under the Advance Market Commitment)



ADB = Asian Development Bank; AMC = advance market commitment; APFS = Audited Project Financial Statements; COVAX = COVID-19 Vaccines Global Access; DMC = developing member country; EA = executing agency; GAVI = Gavi, the Vaccine Alliance; IA = implementing agency; ODA = official development assistance; UNICEF = United Nations Children’s Fund.

Source: Asian Development Bank.