

Supporting Access to and Efficient Delivery of COVID-19 Vaccines in Southeast Asia¹

Introduction

SARS-CoV-2, the virus responsible for the coronavirus disease (COVID-19) pandemic, has infected over 18.3 million individuals and taken nearly 700,000 lives globally.² A total of 213 countries have been affected by COVID-19.³ Countries in Southeast Asia have not been spared, with 345,000 confirmed cases and over 8,900 deaths. Most countries continue to report increasing number of cases and deaths.⁴

Non-pharmaceutical interventions (such as mobility and travel restrictions, school closures, physical distancing, shielding of elderly and people with chronic health conditions, expanded testing to detect cases, contact tracing, and quarantine and isolation) have helped to prevent the spread of COVID-19. These measures, however, have significant adverse economic impacts and can only slow transmission, not prevent infection. Beyond the direct healthcare costs of the pandemic, the main economic consequences are due to policies aimed at flattening the curve.

Epidemiologists argue that suppression strategies will need to be maintained until vaccines and/or effective treatments become widely available.⁵ Eradication/elimination of COVID-19 is difficult to attain given the highly infectious nature of the virus and likely animal reservoir,⁶ but vaccination could help to control infection just as it does for many infectious diseases. One paper posits that 70% or more of a population would need to attain immunity (either through exposure and recovery or vaccination) to achieve sufficient herd immunity to stop transmission.⁷ Given that SARS-CoV-2 is airborne and highly transmissible, a vaccine is unlikely to be able to eradicate COVID-19 at this point in time⁸; however, it will be a major tool for reducing prevalence and allowing countries to re-open borders, businesses, schools, and economies.

Vaccine Development

As governments and health care systems struggle to maintain essential health services and provide care for those who have contracted the virus, unprecedented efforts are underway to quickly develop a vaccine to curb its spread. There are over 165 vaccine candidates in development, 27 of which are in clinical

¹ This background paper was prepared by PATH for the Tenth Policy Actions for COVID-19 Economic Recovery (PACER) Dialogue organized under the Asian Development Bank-supported BIMP-EAGA, IMT-GT and GMS Capacity Building Program (B-I-G Program) on Enhancing readiness for large-scale vaccine distribution amid COVID-19 on 19 August 19, 2020 via Microsoft Teams.

² <https://covid19.who.int>; <https://coronavirus.jhu.edu/>, accessed 4 August 2020.

³ https://www.worldometers.info/coronavirus/?utm_campaign=homeAdvegas1?, accessed 4 August 2020.

⁴ <https://covid19.who.int>; <https://coronavirus.jhu.edu/>, accessed 4 August 2020.

⁵ Walker, P, et al. (2020), "The Global Impact of COVID-19 and Strategies for Mitigation and Suppression," Imperial College COVID-19 Response Team, 26 March.

⁶ Geoffard, P-Y, and T Philipson (1996), "Disease Eradication: Private versus Public Vaccination", *American Economic Review* 87(1): 222-30.

⁷ JHU, <https://coronavirus.jhu.edu/from-our-experts/early-herd-immunity-against-covid-19-a-dangerous-misconception>, accessed 4 August 2020.

⁸ *Allergy*. 2020 Jul;75(7):1564-1581.

phases.⁹ Vaccine research and development timelines are moving at unprecedented speed and scale with one or more vaccines likely approved by early 2021.¹⁰

The candidate vaccines include non-replicating viral vector vaccines, RNA vaccines, inactivated COVID-19 virus vaccine, protein sub-unit vaccines, and DNA vaccines. Several vaccines are under development in Asia (Table 1).

Table 1. COVID-19 vaccine candidates originating in Asia and Asia Pacific

Candidate	Sponsor	Trial Phase	Institution	Funding	Country of Origin
CoronaVac	Sinovac	Phase 3	Sinovac	Sinovac R&D	China
inactivated vaccine	Wuhan Institute of Biological Products; Sinopharm	Phase 3	Henan Province	Ministry of Science & Technology, China	China
Adjuvant recombinant vaccine candidate	Anhui Zhifei Longcom Biopharma, Institute of Microbiological Chinese Academy of Sciences	Phase 2			China
Ad5-nCoV	CanSino Biologics	Phase 2	Tongji Hosp; Wuhan, China	CanSino Biologics	China
BBIBP-CorV	Beijing Institute of Biological Products; Sinopharm	Phase 1/2	Henan Province CDCP	Ministry of Science & Technology, China	China
GX-19	Genexine	Phase 1/2		Genexine	South Korea
ZyCoV-D	Zydus Cadila	Phase 1/2	Zydus Cadila		India
Covaxin	Bharat Biotech; National Institute of Virology	Phase 1			India
Molecular clamp vaccine	Commonwealth Serum Laboratories (CSL); University of Queensland	Phase 1		CEPI; CSL	United Kingdom, Australia
SCB-2019	GlaxoSmithKline, Sanofi Pasteur, Clover Biopharma, Dynavax, Xiamen Innovax	Phase 1	Linear Clinical Research (Australia)	Operation Warp Speed, Coalition for Epidemic Preparedness Innovation (CEPI)	United States/ European Union/ China/ Australia
mRNA-based vaccine	Chulalongkorn University Center Vaccine R&D	Preclinical			Thailand
mRNA-LNP vaccine	CanSino Biologics, Precision NanoSystems	Early research			China

Ensuring Global Access to Vaccine

As a complement to domestic investments in vaccine development, manufacturing, and procurement, a global community of partners have established the Access to COVID-19 Tools Accelerator (ACT-A). ACT-A's high-level goal is to raise and coordinate the financing and policies needed to mobilize global access to new tools. Gavi, the Vaccine Alliance; the Coalition for Epidemic Preparedness Innovations (CEPI); and the World Health Organization (WHO) lead the vaccine pillar of ACT-A, referred to as the COVID-19 Global Vaccine Access (COVAX) with CEPI leading product development and manufacturing capacity efforts and Gavi leading on global financing, procurement, in collaboration with WHO on delivery of any successful vaccines.

⁹ NY Times, <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>, accessed 4 August 2020.

¹⁰ <https://www.livescience.com/coronavirus-covid-19-vaccine-timeline.html>, Accessed 13 May 2020.

At the center of the financing and procurement strategy is the COVAX Facility, launched at Gavi’s recent replenishment in June 2020. With a goal to secure enough vaccine to target priority populations globally, the COVAX Facility is working to pool purchase commitments from high-, middle-, and low-income countries and negotiate with companies for guaranteed doses.

More than 50 vaccine candidates are expected to enter clinical trials in 2020. Given the technical complexities of vaccine research and development, history suggests about seven vaccines may successfully make it to market.¹¹ As no one knows which of the vaccine candidates will work and for what populations, countries (even those like the United States and China hosting multiple suppliers) are offsetting risk by entering into multiple ‘advanced purchase commitments.’ The COVAX facility’s ability to negotiate multiple deals is enhanced both by the number of countries that sign on and the number of companies that have received R&D investments through CEPI since those deals will lock suppliers into contributing a percent of production supply to the COVAX Facility.

A total of 92 low- and middle-income countries will be able to access COVID-19 vaccines through Gavi’s COVAX Advance Market Commitment (AMC). Qualifying countries have a Gross National Income (GNI) per capita under US\$4,000 or are eligible for World Bank International Development Association (IDA) funding. Fundraising for COVAX is ongoing—with US\$600 million¹² raised against the goal of securing US\$2 billion by the end of 2020 to fund the cost of the vaccine and possibly immunization supplies for the pre-determined allocation amount. An additional \$3.4 billion will be required to procure 1 billion doses by the end of 2021.¹³ High- and upper-middle- income countries can opt into supply secured under the COVAX Facility via self-financing. Thus far, Republic of Korea, Armenia, and Palau have disclosed their joining the COVAX Facility as self-financing. Seven of the eleven Southeast Asian countries qualify for the Gavi AMC (Table 2).

Table 2. Southeast Asia and select Asia-Pacific countries’ COVID-19 vaccine finance strategy and epidemiology

Southeast Asia and select Asia-Pacific Countries	Vaccine Financing	WB Income Category	Total COVID-19 Cases¹⁴	Total COVID-19 Deaths¹⁴
<i>Australia</i>	Non-AMC Eligible	HIC	22127	352
<i>Brunei Darussalam</i>	Non-AMC Eligible	HIC	142	3
<i>Cambodia</i>	Gavi AMC	LMIC	268	0
<i>Fiji</i>	IDA eligible	UMIC	27	1
<i>Indonesia</i>	Gavi AMC	UMIC	130718	5903
<i>Lao PDR</i>	Gavi AMC	LMIC	20	0
<i>Malaysia</i>	Non-AMC Eligible	UMIC	9114	125
<i>Myanmar</i>	Gavi AMC	LMIC	361	6
<i>New Zealand</i>	Covax SF	HIC	1579	22
<i>Papua New Guinea</i>	Gavi AMC	LMIC	214	3
<i>Philippines</i>	Gavi AMC	LMIC	143749	2404

¹¹ McKinsey & Co., On pins and needles: Will COVID-19 vaccines ‘save the world’?, July 2020.

¹² WHO news release published on 15 July 2020 and accessed on 11 August 2020 from <https://www.who.int/news-room/detail/15-07-2020-more-than-150-countries-engaged-in-covid-19-vaccine-global-access-facility>

¹³ Gavi, <https://www.gavi.org/news/media-room/92-low-middle-income-economies-eligible-access-covid-19-vaccines-gavi-covax-amc>, 1 August 2020.

¹⁴ CSIS, <https://www.csis.org/programs/southeast-asia-program/southeast-asia-covid-19-tracker-0>, accessed 13 August 2020.

<i>Singapore</i>	Non-AMC Eligible	HIC	55395	27
<i>Thailand</i>	Non-AMC Eligible	UMIC	3356	58
<i>Timor-Leste</i>	Gavi AMC	LMIC	25	0
<i>Vietnam</i>	Gavi AMC	LMIC	880	17
<i>Australia</i>	Non-AMC Eligible	HIC	22127	352

LIC = low-income country; LMIC = lower-middle-income country; UMIC = upper-middle-income country; HIC = high-income country; Covax SF = Covax Self-Financing; WB = World Bank

Several arrangements between groups of countries and companies have also been established to secure the supply of future COVID-19 vaccines. For example, beyond its bilateral deals with the United Kingdom and United States, Astra Zeneca/University of Oxford also reported commitment with the Inclusive Vaccine Alliance, organized by France, Germany, Italy, and Netherlands to secure of 400 million doses vaccine at €750 million for 27 European Union countries. Astra Zeneca also committed to supply 300 million doses to the COVAX Facility. Serum Institute of India, Pvt. Ltd. committed at least 300 million doses for designated populations in developing countries. The United States committed to providing \$10 billion to several vaccine developers and vial and syringe manufacturers under Operation Warp Speed. Other companies are securing financing from CEPI and their domestic governments to share the cost of expanding manufacturing capacity at risk before vaccine efficacy data are available.

Local Manufacturing

ACT-A is designed to work globally to secure sufficient vaccine supply at affordable prices. In addition, the acute and devastating impact of the virus has triggered social and political pressure on companies to lower prices or make licenses available for technology transfer of successful vaccines. The expected high demand for lower priced vaccines could stimulate local manufacturing, particularly in lower-middle income countries where pharmaceutical or biological manufacturing capacity is in place. In the absence of successful efforts to accelerate the distribution of licenses and expansion of manufacturing capacity, countries may invoke Article 31 of the TRIPS Agreement—forcing compulsory licensing to allow a local firm to produce a patented product for domestic and pre-specified export markets without the consent of the patent owner.¹⁵ Transferring chemistry, manufacturing, and compound know-how of biologics, however, is not trivial or inexpensive. Doing so is also time-intensive, often taking years. Ensuring that consistent process manufacturing standards and lot release guidelines are met, rigorous and timely pharmacovigilance is in place, and a strong regulatory authority can oversee production is critical for successfully producing a safe and efficacious vaccine. Often, importing vaccine may present a more cost-effective option and offset manufacturer and government liabilities, especially in the first few years of the pandemic.

Preparing for Vaccine Introduction

Safe and effective COVID-19 vaccine development, manufacturing, financing, and procurement need to be complimented by strengthening the capacity of countries to make informed decisions about prioritizing, introducing, and safely delivering COVID-19 vaccines. Action is needed now to prepare countries for COVID-19 vaccines. Delivering COVID-19 vaccines will require non-traditional immunization strategies and logistics to reach vulnerable populations. Low- and middle-income countries are likely to face significant resource, infrastructure, and personnel challenges. Country immunization programs may

¹⁵ In contrast to medicines, companies need to access not just the technology license but also the know-how that goes into the manufacturing processes.

require modifications to address the where, how, to whom, and by whom the vaccine is provided. Immunization programs for young children need to continue to focus on delivering vaccine to these populations. These programs are also unlikely to be effective in reaching populations most at risk of COVID-19 infection and new cadres of vaccinators may need to be recruited and trained. Advocacy and communications will be an integral part of the vaccine introduction and delivery process, from ensuring the population is kept up to date on criteria used to allocate vaccine doses within the country to reaching target populations not normally part of vaccination programs. Crisis communication plans should also be put in place. Transparency will be essential to mitigate the effects of misinformation and mistrust around vaccines. Additionally, mass campaigns that rely on large population gatherings may not be possible or appropriate due to physical distancing guidelines. As such, new delivery strategies will likely need to be designed and deployed. There is also uncertainty around current vaccine candidates and the product attributes that will be most appropriate for delivery in low-income contexts. Therefore, a transparent and criteria driven process will be needed that considers the latest guidance issued by WHO's Strategic Advisory Group of Experts (SAGE) and local epidemiologic and economic conditions.

We recognize that the Ministries of Health and Planning are working feverishly to control the pandemic, however, it is critical for countries to begin preparing for introduction of COVID-19 vaccine now to ensure safe, effective, and efficient delivery when vaccines are available. Given initial constrained supply of vaccine, policymakers will need to reflect on global recommendations based on epidemiology, target population deemed to be priority, and vaccine characteristics.

Critical near-term activities for countries in Southeast Asia to consider in developing overarching COVID-19 introduction plans and strategies may include: a) identification of national stakeholders and decision-makers involved in COVID-19 vaccine introduction and delivery, b) assessment of current vaccine delivery channels and administration capacity to inform a strategic vaccination plan, including innovative ways to deliver vaccines to selected target populations, and c) development of prioritization plans (e.g. identify target populations to receive COVID-19 vaccine [phased approach]), among others.