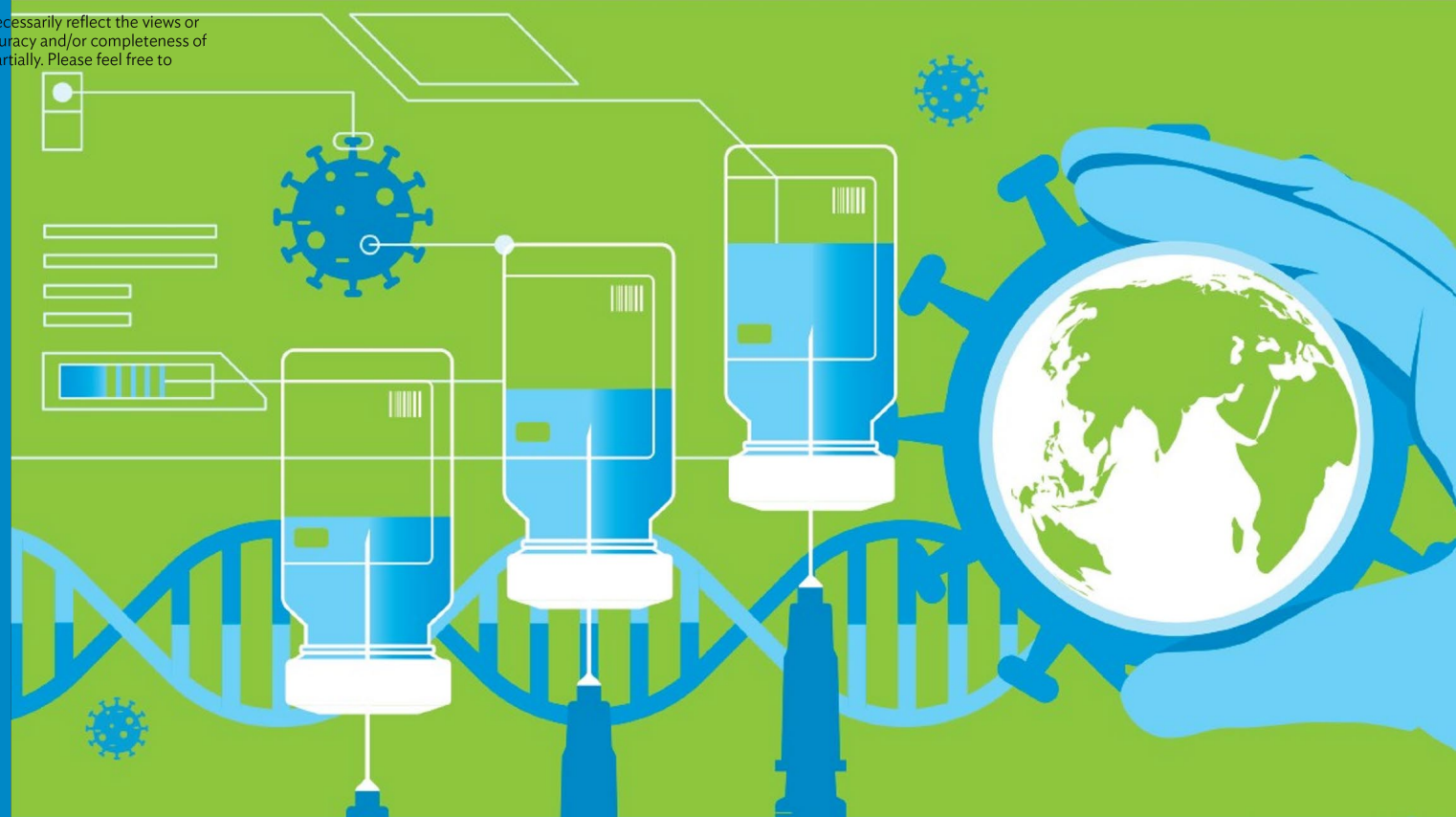


SESSION 4: BRIDGING FINANCING GAPS FOR PANDEMIC PREPAREDNESS



VACCINE REGULATION AND MANUFACTURING SUPPLY CHAINS

Patricia Rhee

Assistant General Counsel, Office of the General Counsel

Symposium on Multilateral Financing for Pandemic Preparedness and Response
11 July 2025, ADB Headquarters

ADB

APVAX Vaccine Eligibility Criteria

ADB adopted the followed criteria for identifying vaccines eligible for ADB financing:

Criterion 1: Vaccine has been selected for procurement through COVAX on behalf of its participating countries; **or**

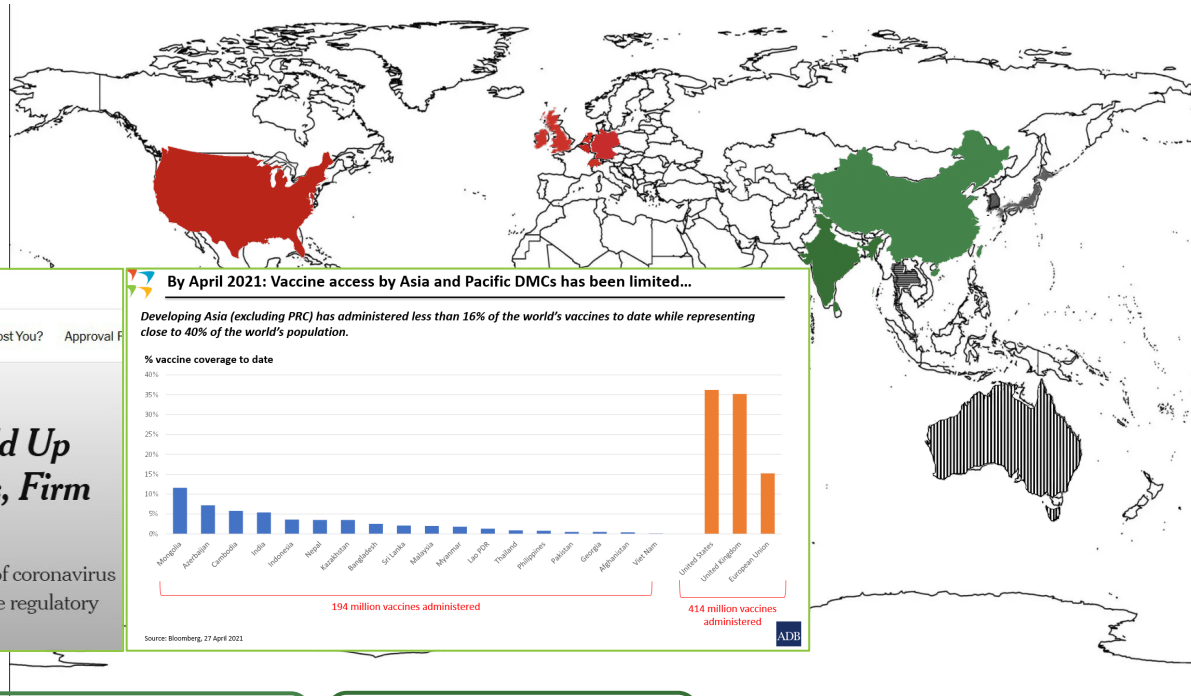
Criterion 2: Vaccine has received WHO PQ or EUL; **or**

Criterion 3: Vaccine has received regular or emergency licensure or authorization by an SRA^[1].

^[1] An SRA is any one of the SRAs identified by WHO for vaccines procured and/or supplied under the COVAX facility, as may be amended from time to time. In addition, an SRA's endorsement, or other functional equivalent of an SRA authorization, of (a) the vaccine's safety and efficacy; and (b) the good manufacturing practices of the manufacturer of such vaccine, shall constitute satisfaction of this criterion.

Each criterion is standalone. Only one of the three need to be satisfied in order for vaccines to be eligible for ADB financing.

TIMELINE OF COVID VACCINE REGULATORY APPROVALS, MANUFACTURING LOCATIONS, APVAX APPROVALS



The New York Times

100 Million Vaccine Doses Held Up Over Contamination Concerns, Firm Reveals

Executives from Emergent, which ruined millions of coronavirus vaccine doses, divulged to Congress the scope of the regulatory review of its troubled Baltimore plant.

AstraZeneca (UK MHRA)

Pfizer (US FDA)

Moderna (US FDA)

**J&J (US FDA)
AstraZeneca
Covishield (SII)
(WHO)**

J&J (WHO)

Moderna (WHO)

Sinopharm (WHO)

Sinovac (WHO)

Covaxin (WHO)

**Novavax
Covovax (SII)
(WHO)**

Dec 2020

ADB approves \$9 billion APVAX facility

Jan 2021

Feb 2021

Mar 2021



Apr 2021



May 2021



Jun 2021



Jul 2021



Aug 2021



Sep 2021



Oct 2021



Nov 2021



Dec 2021

Lessons Learned and Looking Ahead

Challenges are more complex than just bridging financing gaps. Real-world scenario planning that anticipates delays to vaccine approvals and bottlenecks in global manufacturing chains. Whole of value chain approach to achieve transformational and sustainable impact – this will take time.

1. **Expand Pathways for Regulatory Approval in Asia Pacific:** create multiple regulatory pathways for approval of vaccines, therapeutics and medical products by NRAs in the Asia Pacific region. Recent welcome developments from WHO with WLAs Levels 3 and 4: [list-of-nras-operating-at-ml3-and-ml4.pdf](#)
2. **Shore Up Vaccine Manufacturing in Asia Pacific:** invest in multiple touch points in manufacturing value chain including upstream R&D and critical inputs for manufacturing, discussions with WTO and WIPO on technology transfer and sharing intellectual property (waiver of TRIPS Agreement) including during future pandemics.
3. **Advance Commitments under “at risk procurement”:** implement advance purchase agreements which provide the manufacturer with some prepayment and a legally binding commitment to purchase conditional upon vaccine approval.