

COVAX FACILITY OPERATIONALISATION AND VACCINE PROGRAMME

BOARD MEETING

Aurélia Nguyen

29-30 September 2020, Virtual Meeting



Historic pandemic and historic response

The pandemic continues to grow

33 M known cases; 1 M known deaths

**The COVAX Facility is an
unparalleled multilateral
collaboration**

Unprecedented speed, magnitude and
potential impact on health and equity








World Health
Organization



C E P I

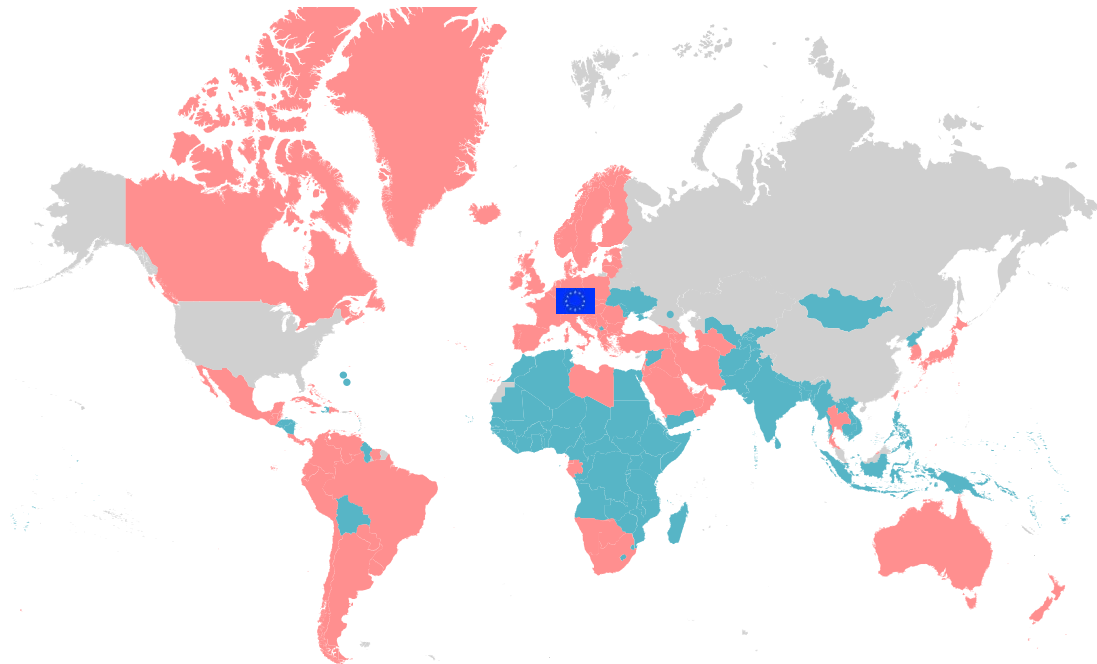
40 candidates are in clinical trial, with 10 currently in Phase IIb/III

		Phase I					Phase I/II		Phase IIa	Phase IIb / III and III		Registration/ introduction
	Viral vectors	Vaxart	Institut Pasteur★		ReiThera GRAd-Cov2					AstraZeneca AZD1222★	Janssen Ad26. COV2-S	
		Institute of biotech	Beijing Wantai Pharmacy			Gamaleya rAd5, rAd26				Cansino Ad5		
	RNA	Imperial College saRNA					Arcturus / Duke-NUS ARCT-021		CureVac CVnCoV★	Pfizer / BioNTech / Fosun mRNA-BNT162		
		Walvax Biotech mRNA								★ Moderna / NIAID mRNA-1273		
	DNA						Genexine GX-19	Inovio INO-4800★				
							Osaka /AnGes AG0301	Cadila 2019-nCov vaccine				
	Protein sub-unit	Medigen	Tuebingen	Vaxine	Clover★	Queens land★	SpyBio / SII VLP	Kentucky BioProcessing	Anhui Zhifei Recombinant	Novavax NVX-CoV2373★		
		COVAXX	Sichuan	Medicago VLP	Finlay	FBRI	Sanofi / GSK VLP					
	Inactivated						Bharat Biotech BBV152	Institute of Medical Biology, CAMS		Wuhan Institute of Biological Products	Beijing Institute Sinopharm	
							RIBSP			Sinovac Biotech		

To date - 47 Commitment Agreements received & Team Europe formally committed to join

COVAX

**192 economies are in scope of the Facility which
represents >70% of the world's population**



AMC

92 economies

3.9+ bn people

Self Financing Participants (SFPs)

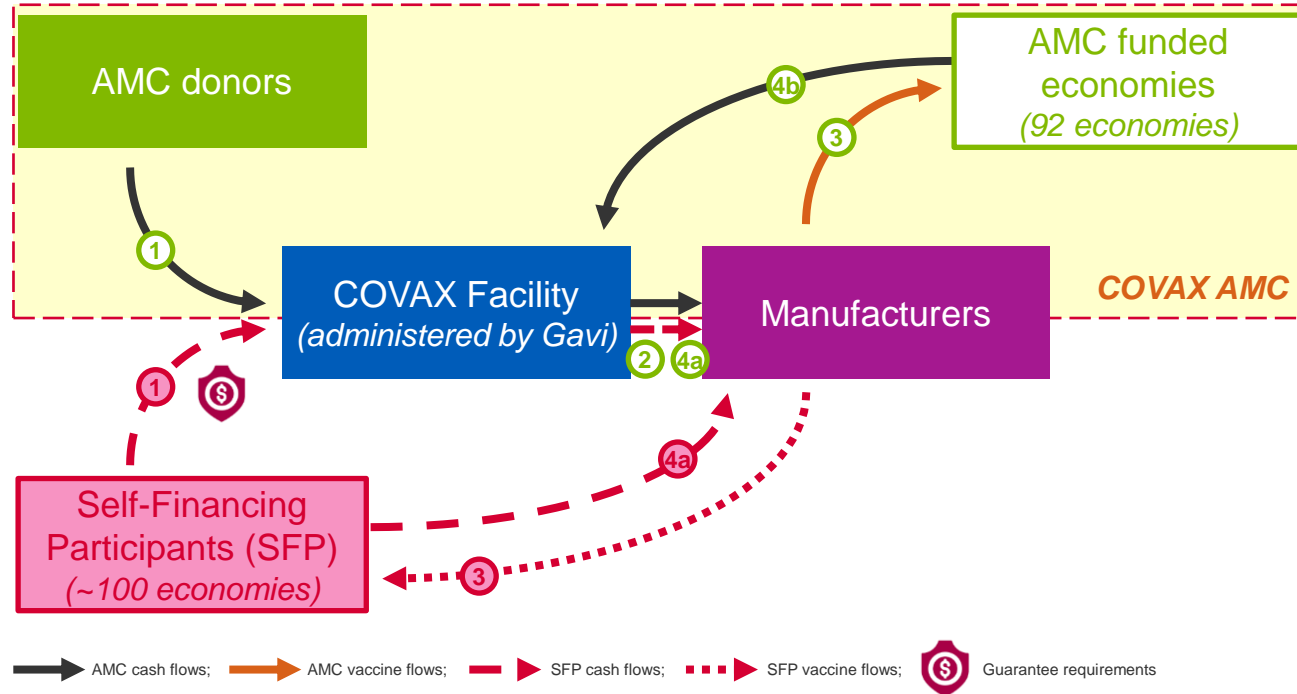
100 economies

1.7+ bn people

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COVAX Facility Design and Funding Arrangements

COVAX Participants will mutually benefit from a large and shared vaccine portfolio



Process flow

- ① AMC donors and SFP capitalise the COVAX Facility with upfront payments and financial guarantees
- ② Facility builds up vaccine portfolio by signing deals with manufacturers, which includes pre-approval costs
- ③ Approved vaccines are delivered as they become available
- ④a AMC and SFP make procurement payments to manufacturers
- ④b Cost-sharing vaccine payments by AMC92 (TBC)

Self-financing Participants have the option to select between two participation arrangements

Committed Purchase Arrangement

- Lower down-payment
- Financial commitment / guarantee to purchase doses

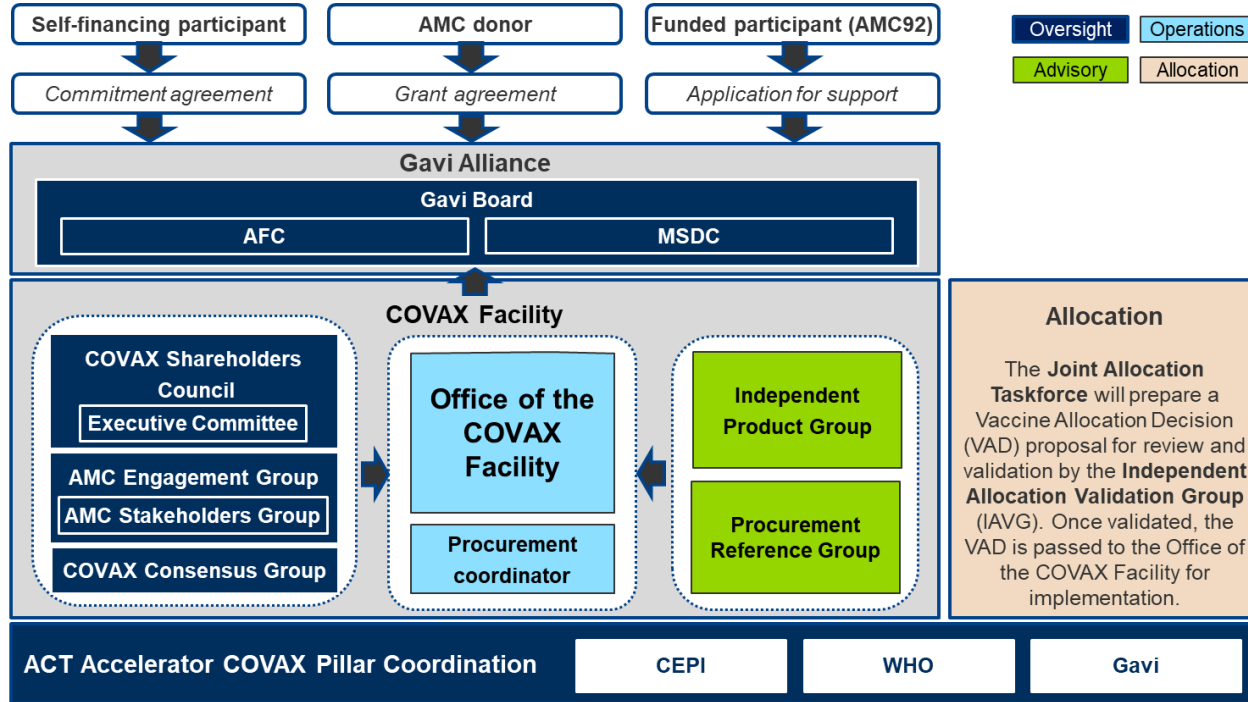
Optional Purchase Arrangement

- Higher upfront payment
- Options to decide on purchasing doses
- Risk-sharing guarantee

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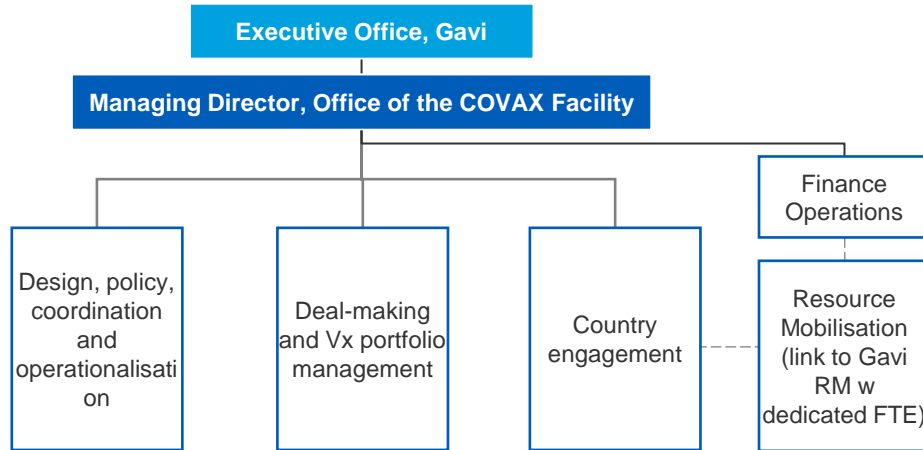
COVAX Facility Structure

Facility governance builds on the Gavi Board and its committees whilst ensuring representation



Proposed high level set-up of the Facility and interplay with current departments

COVAX Facility



Steady state FTEs through July 2021 and **additional FTEs** during surge phase through Feb 2021



Funding now through pre-financing approved by the Board; thereafter via SFP fees and AMC



Facility resources deployed from the current Gavi Secretariat departments

Department/Team	Department/Team
PEIS	EO
<ul style="list-style-type: none"> KMTS Comms Advocacy 	<ul style="list-style-type: none"> Risk
Finance & Ops	Audit & Investigations
<ul style="list-style-type: none"> Procurement 	
Legal	
<ul style="list-style-type: none"> Legal Counsel 	
HR	
<ul style="list-style-type: none"> HRBP 	
M&E	
<ul style="list-style-type: none"> M&E COVAX 	
Governance	
<ul style="list-style-type: none"> Facility governance 	

Board meeting
29-30 September 2020

Project Plan & Governance touchpoints for next 6 months



Design & operationalisation

- Agree and codify design questions
- Operationalize design (set-up of Allocation mechanism, necessary infrastructure, processes, IT, org changes, Exchange)

Manufacturer deal-making & procurement

- Secure 10-15 manufacturer deals by end of December
- Setting up Procurement Coordinator, RFP Launch, set-up indemnification and liability mechanisms, establishment of supply agreements btw participants and manufacturers
- Purchase orders and vaccine delivery

Country engagement (SFP and AMC92)

- Securing SFP CAs, upfront payment/ guarantees
- SFP Participant relations (Shareholders Council meetings, updates on pipeline and candidate portfolio, etc.)
- AMC 92: Accelerate design
- Designing COVID-19 vaccine programme application process, defining delivery support, country readiness plan, help AMC92 countries submit applications etc.
- AMC92 engagement (AMC Engagement Group meetings, updates on pipeline and candidate portfolio, delivery preparedness etc.)

Financing

- Donor engagement and pledging (for US\$ 2 Bn AMC seed funding); getting signed legal donor agreements
- Design/secure financial instruments (insurance, etc.); Define COVAX co-financing policy; Assess financial guarantees submitted by SFPs; MDBs develop term sheets
- Implementation & management of select financial instruments

Detailed COVAX risk assessment underway

- **Failure to establish a successful Facility**

- **Entering into agreements rapidly is critical** to reserve sufficient/timely volumes
- Failure would cause inequitable access with continued impact on the **global economy and Gavi's core programmes**, and may affect Gavi's reputation
 - Need to balance risks of running the Facility with risks of inaction

- **Financial risk**

- **Liquidity gaps** (due to cash flow mismatches), **credit risk** (due to sovereign defaults) and **overcommitments** (due to lower attrition, opt-outs) creating **liabilities for Gavi**
 - Given low risk appetite, **only enter into deals with sufficient financial backing** to minimise risk on Gavi's balance sheet
 - However, there are **constraints** in financial backing given uncertain optional purchases and inability to take risk on SFP commitments; actively exploring solutions to enable deal-making:
 - Reduce risk in contracts where possible (e.g. mirroring optionality); secure SFP commitments with guarantees, insurance, financial instruments; cover liquidity gaps with loans and payment terms; use risk sharing guarantee and have pre-deal clarity on opt-outs; ensure successful AMC fundraising effort

- **Operational risk**

- Stretched people, new processes, increased transactions, many partnerships

- 12 ➤ Setting up a separate team with dedicated MD; developing a full operational plan; seeking secondments for qualified people ready to operate

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Gavi COVID-19 vaccine programme

The AMC seeks to mobilise MDB funds to support cost-sharing on vaccine doses and delivery

Context

- Co-financing to ensure sustainability and ownership is central to Gavi's model
- During the acute phase of the pandemic, given urgency, fiscal pressures, and country planning timelines, a **cost-sharing approach** is proposed instead of co-financing

Goals

- Foster **country ownership and solidarity** in the global fight against COVID-19
- **Mobilise additional resources** for the AMC

Cost-sharing approach (acute phase)

Vaccine doses

- Seek to **mobilise MDB financing** to support cost-sharing
- If this financing cannot be mobilised, **there will not be cost-sharing on doses**; more donor resources will be needed short-term to secure doses for countries

Vaccine delivery

- Gavi will allocate **initial targeted support**
- **Additional resources will need to be mobilised** for remaining costs; MDBs have expressed interest in supporting

Standard co-financing will be implemented longer-term if COVID-19 vaccines are routinised

The Secretariat requests **US\$150m** from core resources for critical country-level TA and CCE

Bespoke country-level investments needed immediately to ensure timely delivery of vaccines



Cold chain equipment

- 4-6 mo. lead times to deploy CCE
- Enable economies to reach 20% of population with traditional cold chain (2-8C, -20C)
- Option to set aside funds for UCC solutions in a subset of economies



Technical Assistance

- Demand generation
- Supply chains
- Microplanning
- Data systems
- Monitoring & Surveillance

AMC92 economies cost-sharing ← MDBs



Total cost to deliver 1B doses to AMC92 in 2021 is ~US\$1.5B



Funding for the ACT-A investment case

Request for Board guidance: *Which economies should be in scope for US\$150m initial funding?*

The Secretariat is not recommending at-scale investment in Ultra Cold Chain (UCC) at this time

Secretariat not recommending UCC investment at this time...

- Current indications are that **only one vaccine in first phase may require UCC** up to the point of care;
 - All others indicated to have at least medium-term stability (up to 4mo) in traditional storage.
- **No UCC infrastructure in most AMC countries** – would cost ~6–15x more to build than typical cold chain
- **Time-limited need** – all vaccines aim to be stable outside UCC in long run

...and will continue to monitor risks and seek mitigation

- **Risk: If multiple vaccines or early volumes require UCC, it could delay launch**, due to 4-6 mo. lead time to procure, install and train HCWs
- Alliance exploring **3 mitigation strategies**:
 - Build capacity in subset of countries (e.g. those with existing UCC capacity);
 - Contract third-party logistics provider to provide UCC storage and/or distribution
 - Leverage UCC capacity in other sectors
- **Alliance will continue to monitor vaccine pipeline** and reconsider approach if it appears multiple vaccines will require UCC

Approach for India will seek to balance equity with constraints on overall doses and AMC funding



Context

- India has a **clear need** for AMC support
 - AMC-eligible, Gavi-eligible, and hardest hit Gavi country by the pandemic
 - 2nd highest number of cases globally
- As with current Gavi support to India, a **tailored approach** is required
- **Domestic manufacturing** and role as a global supplier of potential COVID-19 vaccines

Initial guidance is requested on parameters for an appropriate package of support

- Share of AMC doses
- AMC funding
- Delivery support

Return to Board in December for a decision on support for India

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Next steps

The Secretariat will revert to the Board with further details on the COVAX Facility and vaccine programme



Recommendation (1/4)

The Gavi Alliance Board is requested to:

- a) **Approve** the Terms of Reference of the COVAX Shareholders Council attached as Annex B to Doc 03;
- b) **Approve** the Terms of Reference of the COVAX AMC Engagement Group attached as Annex E to Doc 03;
- c) **Approve** the Terms of Reference of the COVAX AMC Stakeholders Group attached as Annex F to Doc 03;
- d) **Approve** the Terms of Reference of the COVAX Consensus Group attached as Annex G to Doc 03;

Recommendation (2/4)

- e) **Approve** the proposal for AMC92 economies to cost-share vaccines up to US\$ 1.60- US\$ 2 per dose, assuming a 2-dose regimen, towards the full cost of purchasing a dose of vaccine [bearing in mind that Gavi will exercise flexibility and work with economies on a case-by-case basis to adjust vaccine cost-sharing contributions as needed until end 2021, and with the expectation of additional cost-sharing on vaccine delivery, with targeted Gavi support (see decision point f) to supplement additional resources to be mobilised];

Recommendation (3/4)

With reference to the discussion on Doc 02 *Recalibrating programmatic priorities for Gavi 5.0 in light of COVID-19 and the successful replenishment: Financial implications*, at the Gavi Alliance Audit and Finance Committee meeting of 15 September 2020:

- f) **Approve** the allocation of US\$ 150 million from core resources [for initial funding] to prepare [*eligible economies subject to Board guidance*] to deliver COVID-19 vaccines, focusing on urgent technical assistance and cold chain needs;

Recommendation (4/4)

- g) **Request** the Gavi Secretariat to present to the Board in December 2020 the proposed approach for Gavi COVAX AMC support for India for COVID-19 vaccines and delivery;
- h) **Note** the proposed approach to not invest in UCC at this time, and the associated risks regarding access to COVID-19 vaccines; and
- i) **Note** the risks and mitigation measures outlined related to the COVAX Facility.

THANK YOU



Reach every child
www.gavi.org