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

<table>
<thead>
<tr>
<th></th>
<th>Phase I</th>
<th>Phase I/II</th>
<th>Phase IIa</th>
<th>Phase IIb / III and III</th>
<th>Registration/introduction</th>
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<tbody>
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<td>Viral vectors</td>
<td>Vaxart</td>
<td>Institut Pasteur</td>
<td>ReiThera GRAd-Cov2</td>
<td>AstraZeneca AZD1222</td>
<td>Janssen Ad26. COV2-S</td>
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<td>Gamaleya rAd5, rAd26</td>
<td>Cansino Ad5</td>
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<td>RNA</td>
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<td>Arcturus / Duke-NUS ARCT-021</td>
<td>CureVac CVnCoV</td>
<td>Pfizer / BioNTech / Fosun mRNA-BNT162</td>
<td>Moderna / NIAID mRNA-1273</td>
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<td>Inovio INO-4800</td>
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<td>Cadila 2019-nCov vaccine</td>
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<td>Vaxine</td>
<td>Clover</td>
<td>SpyBio / SII VLP</td>
<td>Kentucky BioProcessing</td>
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<td>Queensland</td>
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<td>Medicago VLP</td>
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<td>Sinovac Biotech</td>
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Board meeting
29-30 September 2020

CEPI COVID-19 Portfolio
To date - 47 Commitment Agreements received & Team Europe formally committed to join.

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
COVAX Facility Design and Funding Arrangements
COVAX Participants will mutually benefit from a large and shared vaccine portfolio

AMC donors

COVAX Facility (administered by Gavi)

Manufacturers

AMC funded economies (92 economies)

Self-Financing Participants (SFP) (~100 economies)

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)

AMC cash flows; AMC vaccine flows; SFP cash flows; SFP vaccine flows; Guarantee requirements

Board meeting
29-30 September 2020
Self-financing Participants have the option to select between two participation arrangements:

<table>
<thead>
<tr>
<th>Committed Purchase Arrangement</th>
<th>Optional Purchase Arrangement</th>
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<tbody>
<tr>
<td>• Lower down-payment</td>
<td>• Higher upfront payment</td>
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<tr>
<td>• Financial commitment /</td>
<td>• Options to decide on</td>
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<tr>
<td>guarantee to purchase doses</td>
<td>purchasing doses</td>
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<td></td>
<td>• Risk-sharing guarantee</td>
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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

Executive Office, Gavi

Managing Director, Office of the COVAX Facility

Design, policy, coordination and operationalisation

Deal-making and Vx portfolio management

Country engagement

Finance Operations

Resource Mobilisation (link to Gavi RM w dedicated FTE)

Facility resources deployed from the current Gavi Secretariat departments

<table>
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<tr>
<th>Department/Team</th>
<th>Department/Team</th>
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<tr>
<td>PEIS</td>
<td>EO</td>
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<tr>
<td>• KMTS</td>
<td>• Risk</td>
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<tr>
<td>• Comms</td>
<td>Audit &amp; Investigations</td>
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<tr>
<td>• Advocacy</td>
<td>Finance &amp; Ops</td>
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<tr>
<td>• Procurement</td>
<td>• Procurement</td>
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<td>Legal Counsel</td>
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<td>• Legal Counsel</td>
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<td>M&amp;E</td>
<td>M&amp;E COVAX</td>
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<td>• M&amp;E COVAX</td>
<td>Governance</td>
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<tr>
<td>Governance</td>
<td>• Facility governance</td>
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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
Operationalize design (set-up of Allocation mechanism, necessary infrastructure, processes, IT, org changes, Exchange)

Project Plan & Governance touchpoints for next 6 months

- **September**
  - AFC: Sep 15
  - MSDC: Sep 28
  - Board: Sep 29-30

- **October**
  - Sept 18: CAs signed
  - Sept 24-25: AMC 92 briefing
  - Oct 9: Upfront payments & Guarantees due
  - Oct. 12 (TBC): AMC 92 briefing

- **November**
  - November
  - Oct. 9: Upfront payments & Guarantees due
  - Oct. 12 (TBC): AMC 92 briefing

- **December**
  - December
  - AMC 92 briefing

- **January**
  - January

- **February**
  - February

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**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
  - Setting up a separate team with dedicated MD; developing a full operational plan; seeking secondments for qualified people ready to operate
3

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**
- 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

Ultra Cold Chain: -80°C
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.
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