COVAX Facility
Information session with industry
August 12, 2020
Welcome & objectives of the meeting
Objectives

1. Provide update on the COVAX Facility and operational aspects

2. Provide an opportunity to discuss and clarify key issues relevant to industry
Agenda & housekeeping
## Agenda

<table>
<thead>
<tr>
<th>Topic</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Welcome &amp; Objectives of the meeting</td>
<td>Derrick Sim (Gavi)</td>
</tr>
<tr>
<td>Agenda &amp; housekeeping</td>
<td>Derrick Sim (Gavi)</td>
</tr>
<tr>
<td>Facility &amp; Gavi COVAX AMC overview</td>
<td>Derrick Sim (Gavi)</td>
</tr>
<tr>
<td>Allocation, policy, regulatory, safety &amp; monitoring</td>
<td>Claudia Nannei &amp; Carmen Rodriguez (WHO)</td>
</tr>
<tr>
<td>Overview of economies participation &amp; agreements with Facility</td>
<td>Santiago Cornejo (Gavi)</td>
</tr>
<tr>
<td>COVAX Facility governance</td>
<td>Wilson Mok (Gavi)</td>
</tr>
<tr>
<td>Liability and Indemnification</td>
<td>Anthony Brown (Gavi)</td>
</tr>
<tr>
<td>Procurement update</td>
<td>Yalda Momeni &amp; Gian Gandhi – (UNICEF SD)</td>
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<tr>
<td>Participant Q&amp;A</td>
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</table>
Housekeeping

We have a full house today, so we kindly ask you to...

• Please click the ‘raise your hand’ button if you would like to speak. We ask participants to share questions/comments verbally during the Q&A as much as possible.

• Please state your name and where you are from before sharing a comment or question.

• Please make time bound interventions. Given the time constraints, we will proceed directly to the content and not have opening statements.

• Please respect Chatham House Rules – none of the comments raised on the line should be attributed.

• Share any further input offline to covax@gavi.org.
Facility & Gavi COVAX AMC overview
The COVAX Facility serves all participants.

The COVAX AMC is an instrument for ODA-eligible participants.

For ODA-eligible participants,

The COVAX AMC

ODA supported

For all participants,

The COVAX Facility
The Gavi COVAX AMC

• A financing instrument for the procurement of vaccines
• Works to ensure that no economy is left without access to a future COVID-19 vaccine
• Administered by Gavi
• Initially funds procurement through the Facility
• Draws upon the lessons of the pneumococcal AMC

Funding raised (to date): nearly $600 Mn

1. Agreements with manufacturers would be unified across full scope of economies participating in the Facility, but ODA funding will only be used to support LIEs, LMIEs and IDA-eligible UMIEs.
2. Financing for procurement incremental to contribution.
The ‘COVAX AMC Group’: Eligibility

- The ‘**COVAX AMC Group**’: The scope of economies eligible for support through the AMC

- This definition of scope focuses Gavi support on the **poorest economies in the world** today, uses **recognised World Bank definitions**, and it is **completely transparent**

- **92 economies eligible for COVAX AMC:**
  - All low-income economies and lower middle-income economies
  - World Bank classification (i.e. economies with a GNI per capita <US$ 4,000) based on either 2018 or 2019 GNI data, and
  - Other IDA-eligible economies
Additional vaccine support will be provided to the AMC group and tailored to individual health systems

<table>
<thead>
<tr>
<th>Vaccine Access (COVAX Facility)</th>
<th>HIEs and UMIEs</th>
<th>LIEs, LMIEs and IDA-eligible UMIEs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Participants expected to fully self-finance their participation in the global Facility</td>
<td>• Financial support for vaccine procurement and access through the COVAX AMC</td>
</tr>
<tr>
<td>Procurement mechanisms</td>
<td>• TBD – leverage existing procurement mechanisms</td>
<td>• Support from the Alliance through UNICEF and utilising PAHO Revolving Fund</td>
</tr>
<tr>
<td>Delivery</td>
<td>• No support provided</td>
<td>• Support through alternative means, incl. existing Gavi mechanisms – Cash grant (Ops) and CCEOP – Technical assistance</td>
</tr>
</tbody>
</table>

- **Level and extent of support** (e.g. co-financing, delivery, etc.) provided to the COVAX AMC Group to be determined by the Board at the end of September
- **Support may be differentiated within the group.** All options explored will aim to ensure that participants do not face any significant barriers to accessing a COVID-19 vaccine
# Timeline of COVAX AMC policy decisions

<table>
<thead>
<tr>
<th>Date</th>
<th>Milestone</th>
<th>Description</th>
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<tbody>
<tr>
<td>End July</td>
<td>Gavi Board meeting</td>
<td>Decision on the <strong>scope of eligibility</strong> for the COVAX AMC Group</td>
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<tr>
<td>End September</td>
<td>Gavi Board meeting</td>
<td>Decision on the <strong>level and extent of support</strong> to be provided to the COVAX AMC Group</td>
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</table>
Allocation, policy, regulatory, safety & monitoring
Three components inform the formulation of vaccination strategies

2: Strategic Advisory Group of Experts (SAGE)

Provides guidance and policy advice in the context of specific candidates, e.g. on vaccination strategies

1: Allocation Framework

Sets frame for overarching public health goals and priorities (candidate independent)

Participant

Responsible for final decision on policy, allocation and vaccination strategy

3: Regulatory, Safety & Monitoring

Provides guidance on regulatory issues, safety and monitoring both for candidate specific and system specific approaches
1: The two main goals of a vaccination program are inextricably linked

1. Improve individual and public health
2. Minimize societal and economic impact

To significantly reduce the impacts of COVID-19 in the safest, quickest and most effective way, it is not necessary to vaccinate the entire population
1: The global allocation framework secures fair, equitable and necessary access

**Initial view for Vaccine Allocation Mechanism**

<table>
<thead>
<tr>
<th>Goals</th>
<th>Reducing COVID-19 mortality &amp; protecting health systems will significantly improve the well-being of populations and reduce the impact on societies and economies</th>
</tr>
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<tbody>
<tr>
<td>Priorities</td>
<td>Those goals, in the context of scarce supply, leads to prioritization of specific population groups for vaccination. These could include health and social care workers, older adults, and others with high risk conditions. High risk settings are also a consideration. Specific policy recommendations from SAGE, based on product performance and safety evidence and with evolving data on transmission and disease will be made.</td>
</tr>
<tr>
<td>Timing</td>
<td>Given the ubiquitous nature of COVID-19, an initial allocation should be received by all as products become available. Eventually, timing would be based on a risk assessment of participants’ vulnerability and COVID-19 threat.</td>
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</tbody>
</table>
1: We have continued to develop the draft Allocation Framework and Allocation Mechanism for Vaccines

Goals

Protect public health and minimize societal and economic impact by reducing COVID-19 mortality

Priorities

Health and social care workers

All participants receive doses to cover 3% of their population.
This would be enough to cover all workers involved in health and social care work.

High-risk adults

All participants receive additional doses beyond the 3% to total 20% of their population (in tranches).
This could include the elderly, adults with comorbidities or others depending on locally relevant risk factors.

Further priority groups

Participants receive doses to cover more than 20% of their population.
This would cover additional priority populations.

Timing

Participants receive doses proportionally to their total population*

Timing is based on participants’ need, vulnerability and COVID-19 threat

A buffer will also be set aside for emergency deployment based on immediate needs

Note: The fundamental principle applies that all participants receive doses at the same rate to the extent possible, notwithstanding likely practical limitations to be further worked out (e.g. minimum delivery volumes)
2: Vx candidates use different technology platforms with implications for how they can be used

Different technologies ... ... with different characteristics

- Protein
- Nucleic Acid
- Viral vector
- Inactivated

Vaccine characteristics and study settings (e.g. trial population or regional setting) affect deployment:
  - Immunogenicity (e.g. sub-optimal effect on elderly populations)
  - Safety profile (e.g. women of childbearing age)
  - Ability to scale-up manufacturing
  - Cold chain requirement (e.g. -70°C)
  - …

One vaccine may be more suitable for a target group and/or a specific region than another.

Vaccines are unlikely to be interchangeable.

Need for guidance and policy advice for specific vaccine candidates.
2: Strategic Advisory Group of Experts (SAGE) on Immunization: Introduction and setup

SAGE is the principal advisory group to WHO for vaccines, providing guidance and policy advice for specific vaccine candidates

1. Providing continuous review of the available evidence on the progress of specific vaccine candidate

2. Providing guidance for the development of prediction models to determine the optimal age groups and target populations for the introduction of a specific vaccine candidate

3. Preparing policy advice on the accelerated use of vaccine candidates, including recommendations for early allocation of vaccines when vaccine supply is still limited

4. Providing guidance to ensure equitable access to vaccination, and guidance on the safety of vaccines when safety data from wider population use become available

Sub-working groups

SAGE’s review, guidance and policy advice is informed by three sub-working groups:

- Vaccination goals & prioritization
- Evidence gathering on vaccines in clinical trials
- Vaccine impact modelling
Regulatory, safety & monitoring
## Features of PQ and EUL

<table>
<thead>
<tr>
<th>Prequalification (PQ)</th>
<th>Emergency Use Listing (EUL)</th>
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</thead>
<tbody>
<tr>
<td>Quality, safety and efficacy and PSPQ for international supply</td>
<td>Assessment of limited data for use during PHEs</td>
</tr>
<tr>
<td>CMC, clinical and programmatic assessment performed by WHO independent experts</td>
<td>Assessment performed by WHO independent experts in collaboration with Mature Regulatory Authorities (WLA)</td>
</tr>
<tr>
<td>Reliance on WHO Listed Authority (WLA) - abbreviated process under oversight of mature regulators (evaluation and oversight of programmatic aspects by WHO)</td>
<td>Reliance on WLA - abbreviated process under oversight of mature regulators (evaluation and oversight of programmatic aspects by WHO)</td>
</tr>
<tr>
<td>Pre-submission meetings encouraged</td>
<td>Pre-submission meetings encouraged</td>
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<tr>
<td>Post-PQ monitoring</td>
<td>EUL process similar for all product streams</td>
</tr>
<tr>
<td></td>
<td>Requirements differ (ex. for vaccines: programmatic suitability)</td>
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<tr>
<td></td>
<td>Post- deployment monitoring. RMP in dossier/collection in countries.</td>
</tr>
</tbody>
</table>
EUL procedure for vaccines

Pre emergency
1. Establishment of assessment platform
2. Eligibility and assessment of products
3. Roster of experts

Emergency
1. Roster of experts
2. WHO decision on EUL
3. Policy recommendations
4. Publication of review outcomes

Post deployment
1. Monitoring
2. Post EUL changes

Covid-19 Pandemic
Merge pre-emergency and emergency roster of experts
Facilitating access of COVID 19 vaccines (1/2)

**Roadmap**

<table>
<thead>
<tr>
<th>Pre-submission phase</th>
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<tbody>
<tr>
<td>• Mapping regulatory requirements for emergency use during PHE</td>
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<tr>
<td>• Interactions &amp; agreement with regulatory authorities</td>
</tr>
<tr>
<td>• Involvement of regulators of potential impacted countries in the EUL review to accelerate decision-making process</td>
</tr>
<tr>
<td>• Identifying priority countries may be complex due to changing COVID-19 situation: relevant epidemiological factors</td>
</tr>
<tr>
<td>• Exploring options through involvement of reference NRAs and regulatory networks in the EUL process</td>
</tr>
</tbody>
</table>
Facilitating access of COVID 19 vaccines (2/2)

- Assessment of available quality, safety and efficacy data.
- Sharing reports with all regulatory authorities for decision making process.
- Promotion of reliance principles in other countries based on facilitated pathways.
- WHO member states have the sovereignty for decision-making.

Discussion with Regional offices establishment of a mechanism for expedited approval in countries and monitoring performance of vaccines deployed to countries.
Think out of the box, Unite, Collaborate & Cooperate

• WHO is encouraging regulatory networks to consider joint reviews, fast track approvals of Clinical trials and when appropriate emergency authorisations

• Prepare a roadmap for each vaccine, which will include expected option and collaboration with country regulators to facilitate local authorisation for emergency use.

• Substantial achievements made by AVAREF to facilitate coordinated reviews and approvals for preventive, diagnostic and therapeutic interventions for COVID-19

• Regulatory updates meetings held with regions in America, Europe, Central Asia, East Mediterranean, South East Asia and with regulatory networks such as AVAREF, Southern African Development Community, African Medical Device Forum and more

Opportunities to use regulatory networks and reliance
Additional information EUL:

Procedure and Questions and Answers

https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/EUL_PQ_Vaccines/en/

Target product profile


Contact: Carmen Rodriguez Hernandez Team lead Vaccine PQ, RPQ

rodriguezhernandezc@who.int

EUL@who.int
Overview of economies participation – Agreements with the Facility
Clearly defined participation principles will support the ambitious undertaking of the Facility

| Global access | • Ensure everyone can secure access to safe and efficacious vaccine to protect health security globally  
| | • Open to all, no one is prevented from participating due to income |
| Impact orientation and transparency | • Single minded in its goal to ensure equitable access to COVID-19 vaccines  
| | • Coordinated strategy for vaccination as supply constrained in the short term |
| Solidarity and collective ownership | • Commitment of participants to collaborative global effort - everybody contributes so that everyone can benefit  
| | • Clear political and financial commitments - all participants asked to contribute based on their capacities |
| Complementarity with other funding | • End to end solution – complementary investments to drive rapid availability of supply at scale  
| | • Manufacturers requested to disclose third party funding for R&D or manufacturing, which will be considered in contractual conditions  
| | • Vaccines from any manufacturer considered including those not in the CEPI/ BMGF portfolio |
Status of expressions of interest

**HIC:** 41 EOIs, 0.5+ B people

**UMIC:** 39 EOIs, 1.0+ B people

**LIC/LMIC:** 92 AMC-eligible economies\(^1\), 3.8+ B people

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1. AMC-eligible economies are not required to submit an expression of interest; the final scope of AMC-eligible economies was determined by the Gavi Board at its meeting on 30 July
Overview of the participation agreements

Commitment Agreements

These will be participant-specific and will set out the specific financial commitment to be made by the participant to the Facility. Sections will be included on expected doses to be made available for procurement.

Principles of Participation

These principles will provide the basis on which self-financing participants join the Facility. The Principles will be attached to and referenced in the Commitment Agreements.
Proposed COVAX Facility governance

1. Pending Gavi board approval
Guiding principles behind the Facility’s Governance

PROPOSAL

Structural considerations

• Build on Gavi’s existing Board and Committees, with new governance bodies established to ensure appropriate oversight, to avoid unnecessarily expanding existing mechanisms (principle of ACT-Accelerator)

• Ensure an accountable and representative governance framework to all stakeholders

• Be in place for the entire lifespan of the Facility

Objectives

• Enable the Facility to enter into time and commercially sensitive transactions with varying terms, accounting for different manufacturer profiles and needs

• Anticipate potential needs to adapt and adjust the use of funds, given uncertainties (e.g., disease epidemiology)

• Ensure representation of all participants and provide sufficient visibility

The details of the governance arrangements, including terms of engagement with civil society and other non-funded/non-funding participants, are still being refined as the Facility is established
Self-financing participants form a ‘Shareholders Council’

PROPOSAL

Members/composition

- Representatives of all self-financing participants
- Could additionally include representatives of AMC Stakeholders Group and/or for observers e.g. CSOs, regional bodies

Meeting cadence

- Monthly - TBC

Role & Responsibility

- Provide strategic guidance to COVAX management on areas related to the status of vaccines under development
- Share information with the Secretariat and each other and receive access to regular updates from Secretariat (e.g. overview of the Facility’s processes on dose allocation)
- Representatives from Shareholders Council included on MSDC for review of COVAX-related agreements

Self-Financing Participants in collaboration with Facility would agree and establish the final terms of reference and operating procedures. Shareholders Council may establish a form of Steering Committee to liaise with the existing governance bodies to take key decisions
### Existing governance/advisory bodies of the COVAX Facility

**Gavi board**
- Portfolio

**MSDC**
- Market Sensitive Decisions Committee
- Allocation
- Financing
- Operations

**SAGE**
- Strategic Advisory Group of Experts

**RDMIC**
- R&D and Manufacturing Investment Committee

**CEPI**
Newly proposed governance/advisory bodies of the COVAX Facility

<table>
<thead>
<tr>
<th>Shareholders council</th>
<th>Independent allocation body</th>
<th>Independent product group</th>
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</thead>
<tbody>
<tr>
<td>Portfolio</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Allocation</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Financing</td>
<td>✓</td>
<td></td>
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<tr>
<td>Operations</td>
<td>✓</td>
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<tr>
<td>Role and composition of proposed governance bodies (1/2)</td>
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<td>PROPOSAL</td>
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<table>
<thead>
<tr>
<th>Affiliation</th>
<th>Composition</th>
<th>Role</th>
</tr>
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<tbody>
<tr>
<td>Gavi Board</td>
<td>• Gavi, WB, BMGF, UNICEF, WHO, Governments of developing countries (5), Governments of donor countries (5), CSO, IFPMA, DCVMN, independents, research institutes</td>
<td>• Oversee role of Gavi in the implementation of the Facility to ensure consistency with the mandate given to Gavi including full oversight of the Gavi COVAX AMC</td>
</tr>
<tr>
<td>MSDC</td>
<td>• Board (Vice) Chair, AFC Chair, PPC Chair, UNICEF, WB, Gavi, BMGF, Governments of developing countries (2), Governments of donor countries (3), CSO • TBC - Self-financing participants (3), COVAX AMC participant</td>
<td>• Review the business terms of the proposed COVAX volume guarantee agreements that the Facility would enter into with manufacturers</td>
</tr>
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</table>
### Role and composition of proposed governance bodies (2/2)

**Shareholders Council**
- **Affiliation**: *NEW*
- **Composition**: Self-financing participant representatives
- **Role**:
  - Provide strategic guidance to COVAX management on areas related to the status of vaccines under development
  - Share information with the Secretariat and each other and receive access to regular updates from Secretariat

**RDMIC**
- **Affiliation**: Research & development & manufacturing investment committee
- **CEPI**
  - **Composition**: CEPI, Gavi, BMGF, (ex) industry R&D and manufacturing experts, public health expert
- **Role**:
  - Drive CEPI portfolio strategy & investment decisions aligned with overall COVAX strategic objectives
  - Decide CEPI investment allocation and requirements across the portfolio
  - Make project selection and investment decisions
# Role and composition of proposed advisory bodies

## SAGE
- **Affiliation**: Strategic Advisory Group of Experts
- **Composition**: 15 experts in the fields of epidemiology, public health, vaccinology, infectious diseases, drug regulation, immunization delivery, safety, etc.
- **Role**:
  - Advise WHO on overall global policies and strategies, incl. vaccines, research and development, delivery of immunization and its linkages with other health interventions

## IPG
- **Affiliation**: Independent product group
- **Composition**: 5-7 independent experts
- **Role**:
  - Provide independent advice to e.g., COVAX Facility members, Gavi, the MSDC and inform selection of vaccine candidates for Facility
  - Assess whether candidates have met criteria for eventual purchase
  - Review overall portfolio, consider updates in clinical development, manufacturing and supply

## Independent allocation body
- **Affiliation**: Independent allocation body
- **Composition**: To be defined – independent technical experts
- **Role**:
  - Review and analyze data/ documentation, provide technical input
  - Make allocation recommendations in accordance with final technical design, approved by Member States, of the WHO Allocation Framework
Liability and Indemnification
The global pandemic requires an aligned approach on issues relating to liability and indemnification for COVID-19 vaccines under COVAX

The global pandemic presents **unprecedented circumstances** in terms of the speed of development and the scale of use of COVID-19 vaccines

There is an **unknown risk of potential liability** arising from COVID-19 vaccines

**Mechanism to compensate** persons who have sustained unexpected SAEs following vaccination

There is a **high urgency to avoid a potential delay** to widespread vaccine delivery

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The Liability Task Force which sits within COVAX is looking at these issues. The Task Force will engage with multiple stakeholders involved and affected by these issues to understand the issues and identify potential solutions.
Procurement Update
Expression of Interest for supply of COVID-19 vaccines

Public version, 12 August 2020
Public briefing on the Covid-19 vaccine

➢ Provide a briefing to all interested stakeholders on the findings of the Expression of Interest (EOI) issued to Covid-19 vaccine developers and manufacturers

➢ Contribute to the understanding of the potential global vaccine supply and demand situation and vaccine characteristics

➢ Inform COVAX procurement timeline and facility design.
High level readout from Expression of Interest
Expression of Interest (EOI) overview

UNICEF issued an EOI on 15 June 2020 on behalf of COVAX to vaccine developers / manufacturers. Information provided and compiled as of 1 July 2020.

• EOI Objectives: Understand manufacturing plans and help inform design elements of COVAX and procurement approach

• Information requested:
  o Production volumes
  o Manufacturing platforms
  o Timing of availability
  o Product presentation
  o Pricing policy
  o Support needed (e.g. on licensure pathway, registration...)

• Confidential briefings of the consolidated feedback were provided to technical COVAX partners

• Public briefing being made available to all stakeholders
Contents of Public Briefing

• Background on EOI
• Respondents
• Indicated production volumes and timing, including in comparison with priority demand estimates
• Volumes by vaccine platform
• Product presentation
• Pricing policies
• Support needed by developers/manufacturers
• Key messages
Respondents to EOI

<table>
<thead>
<tr>
<th>Company/Institution</th>
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<tbody>
<tr>
<td>Anhui Zhifei Longcom Biopharmaceuticals</td>
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<tr>
<td>AstraZeneca</td>
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<tr>
<td>Aurobindo Pharma Ltd</td>
</tr>
<tr>
<td>Beijing Minhai Biotechnology Co.</td>
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<tr>
<td>Beijing Institute of Biological Products</td>
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<tr>
<td>Bharat Biotech International Limited</td>
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<td>Biological E Limited</td>
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<td>Chengdu Institute of Biological Products</td>
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<td>Chumakov</td>
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<td>FSUE</td>
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<td>GSK</td>
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<td>Indian Immunologicals Ltd</td>
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<td>Janssen</td>
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<td>Merck MSD</td>
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<td>NingBo RongAn Biological Medicine</td>
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<td>Novavax</td>
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<td>Panacea Biotec</td>
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<td>Pfizer</td>
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<td>Sanofi Pasteur</td>
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<td>Shionogi &amp; Co.</td>
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<td>Serum Institute of India</td>
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<td>SinoCellTech</td>
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<td>Sinovac</td>
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<td>SK Biopharmaceuticals</td>
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<td>StemRNA Therapeutics</td>
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<tr>
<td>Takeda</td>
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<tr>
<td>Walvax Biotechnology Co.</td>
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<tr>
<td>Wuhan Institute of Biological Products</td>
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</tbody>
</table>

- 10 with manufacturing in China
- 6 in India
- 3 in the USA
- 2 in each of Belgium, Russia, Japan
- 1 in each of France, S. Korea, Switzerland and the UK
How much vaccine is needed globally?

- Global vaccine demand depends on how long immunity lasts, the effectiveness of the vaccine & the number of doses per vaccine course (assumption is 2 doses per course)
- The ACT-A goal is to secure “2 billion doses by 2021”
- WHO is developing a framework to allocate Covid-19 vaccines. The current draft allocates as follows:
  - Every country receives doses for 3% of their population to reach health and social care workers with an immunisation course
  - Then, every country receives second allocation for up to 20% of their population to reach people over the age of 65 and people at higher risk of critical Covid-19 disease due to underlying conditions
  - Combined, these amounts exceed the 2 billion dose target for ACT if we assume they are needed prior to end 2021. The higher of the two volumes was used.
Global demand scenario

This UNICEF demand scenario uses the following global demand assumptions: 3% of population provided with COVID-19 vaccine by end 2020, 20% of population by end 2021; an annual vaccination of the full population* thereafter.

*Children under the age of 5 have been excluded due to lack of this age group being included in clinical trials thus far.
How many doses were indicated by manufactures globally?

Number of doses available, as indicated in EOI or publicly stated. Approximately 20% of aggregate total volumes comes from indications found in public sources.

Volumes from other >175 candidate vaccines not included.
Global supply volumes compared with global demand scenario

Number of doses available, as indicated in EOI or as publicly stated (NB: Data unqualified)

By end 2020: 1.3 billion
By June 2021: 1.8 billion
By end 2021: 7.4 billion
By end 2022: 13.5 billion
By end 2023: 14.1 billion

Global demand, inclusive of annual vaccination

By end 2020: 110 million
By end 2021: 5.4 billion
By end 2022: 15.8 billion
By end 2023: 15.8 billion
Projected annual manufacturing volumes from manufacturers with or without another WHO prequalified vaccine

- Qtys from mfrs with NO other WHO PQ vaccine
- Qtys from mfrs with other WHO PQ vaccine
Projected annual manufacturing quantities by location of manufacturing

- In 2020, 19% are from mfrs in China; 22% are from mfrs in India
- In 2023, 49% are from China; 22% from India
How far along in development are candidate vaccines?

Volume estimated by manufacturers with a candidate vaccine in Clinical vs. Preclinical development

<table>
<thead>
<tr>
<th>Year</th>
<th>Clinical vs Preclinical</th>
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<tbody>
<tr>
<td>End 2020</td>
<td>65%</td>
</tr>
<tr>
<td>1H 2021</td>
<td>36%</td>
</tr>
<tr>
<td>2H 2021</td>
<td>16%</td>
</tr>
<tr>
<td>End 2022</td>
<td>11%</td>
</tr>
<tr>
<td>End 2023</td>
<td>12%</td>
</tr>
</tbody>
</table>

End 2020

End 2021

End 2022

End 2023

Volume of doses (Billions)

- 0
- 2
- 4
- 6
- 8
- 10
- 12
- 14
- 16

0% 10% 20% 30% 40% 50% 60% 70%
Vaccine platform

In 2020/2021, volumes spread across platforms by 2022/2023, protein subunit candidates account for majority of volumes indicated
Vaccine platforms have different risks and pace

<table>
<thead>
<tr>
<th>PLATFORM</th>
<th>Indicated global volumes 2020-23</th>
<th>Manufacturers indicating platform and volumes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Virus:</strong> Weakened or inactivated. Often requires more safety testing. Majority of current vaccines (Vx).</td>
<td>5.7 billion 17%</td>
<td>Beijing Biom., Beijing Inst., Bharat1, Bharat2, Chum, NingBo, Panacea, Sinovac, Wuhan, Indian Imm.</td>
</tr>
<tr>
<td><strong>Viral vector:</strong> Modified. Safer. NB: While an rVSV (Ebola) is licensed, and is a replicating viral vector Vx, no non-replicating Vx has been licensed.</td>
<td>17 billion 49%</td>
<td>Anhui, BioE, FSUE, Novavax, Sanofi, SinoCellTech, Walvax1</td>
</tr>
<tr>
<td><strong>Nucleic acid:</strong> Easy to develop and manufacture, but no RNA or DNA Vx has been licensed.</td>
<td>4.2 billion 12%</td>
<td>Walvax3, StemiRNA, Pfizer</td>
</tr>
<tr>
<td><strong>Protein-based:</strong> Require adjuvants and multiple doses. Can be hard to manufacture.</td>
<td>7.4 billion 22%</td>
<td>Bharat3, Chengdu1, Chengdu2, Janssen, Merck, Shionogi, Walvax2, AstraZeneca, SII, Aurobindo</td>
</tr>
</tbody>
</table>
Risks and support identified by manufacturers
Regulatory pathway, country licensing, indemnity, clinical trials, COVAX design

- Streamlining / harmonizing regulatory processes at national and global level
- Accelerated PQ process (ref lessons learned from Ebola)
- Creation of an emergency use pathway
- Support to in-country registration

- Consultation with industry on mechanisms & processes
- Information on what type of support is available to manufacturers & when
- Communication & consultation with industry on demand, programmatic policy & approaches

![Graph showing other factors/support by indication received]

- Support for enrolment in phase 3 clinical trials (esp outside of China)
- Data sharing / cooperation between clinical trials
- Clarification on minimum level of acceptance for Phase III clinical trials
- More information and dialogue on product presentation
- Acceptance of universal packaging in English with country specific inserts in tertiary packaging

- Technical matchmaking (company) specific
- Push/pull funding for adjuvants, fill/finish capacity
- Adjuvant matchmaking
- Validation of country readiness
- Consultation with industry on CCE requirements
Feedback on COVAX pricing policy

Respondents indicate that they will want to have a tiered pricing approach, based on GNI.

Some commit to a single/flat price vaccine for all buyers during the pandemic phase, followed by tiered pricing.

Most indicate a need for some type of volume guarantee.

• Of the 28 respondents, 21% did not respond to pricing policy

• Of those that provided a response:
  • 50% suggested tiered price (11)
  • 41% suggested flat/single price followed by tiered price (9)
  • 9% suggested flat/single price (2)

1 respondent provided specific idea on tiering:
  • Single/flat price for LICs/Gavi countries
  • Single/flat price for MICs
  • Multiple prices for HICs

Nearly all indicated they did not have visibility on COGS from which to indicate a price. Many wanted more visibility on COVAX scope and design before able to give a price indication.
Vaccine specifications
[NB: Most information just indicative]

- All **liquid** except some **freeze-dried** products (Freeze dried can be more stable but require another manufacturing step; i.e. slower to scale; and more room for administration error)
- All indicated **intramuscular injection**, except one nasal atomisation
- Majority indicated **2-dose course**, a few indicated single dose, one indicated single dose with booster, one indicated 3-dose course
- Majority indicated vaccine would be provided in a **multi-dose vial**
  - Number of doses per via to be decided (8)
  - >50 doses per container (2)
  - A plan for vial size - 1, 2, 5 or 10 (6)
  - Pre-filled syringe (5)
- Most have target temperature requirement of stability between 2°C and 8°C.

➢ But stability data takes time ... so could expect minus (-60°C) **temperature requirement** and shorter shelf life during 2020-2021
COVAX EOI Volume Implications
(Demand vs. Supply Scenarios)
Scenario: Global Base case supply vs. Base case demand

UNICEF demand analysis
Aggregate Demand & Supply scenario analyses
(based on EOI responses and available demand estimates)

**Base Case**
- Supply volumes per EOI responses
- Demand per Global Forecast, inclusive of annual vaccination need

**Suppressed Supply assumptions**
- Aggregate volumes lowered by 30%
- 50% of aggregate volumes are delayed by 12 months
- Both suppressions looked at in combination

**Suppressed Demand assumptions**
- Coverage rates
  - Healthcare workers: 90% coverage
  - Essential workers: 80% coverage
  - Over 65 year olds: 80% coverage
  - Rest of population: 70% coverage
- Country readiness
  - 25% of demand in low resourced settings is delayed 12 months – *not included in global calculation*
- Vaccine presentation
  - Different presentations may have impact on wastage rate, more frequent deliveries, etc.
Scenario: Global Suppressed supply vs. Suppressed demand
UNICEF demand analysis
COVAX EOI Key Takeaways and Proposed Actions
Key Messages

➢ Overall, and despite the fact that production volumes were not indicated by some manufacturers, the aggregate supply situation could not be more optimistic with massive and accelerated scale up of COVID-19 vaccine production planned

➢ Unprecedented rapid pursuit for discovery and availability of a vaccine, reducing what would normally take 10+ years to potentially 1-3 years

➢ The global COVID-19 vaccine portfolio has a healthy mix of platforms, manufacturing locations and partnerships

➢ Quantities in 2020-2021 will be tight compared to aspirational demand. Careful dose allocation will be key to maximise impact (country readiness, basis for allocation, etc.)

➢ It could be reasonable to assume that a vaccine will be available for widespread global roll-out starting in late 2022; but also likely that annual vaccination or booster doses will be needed

➢ Potential high dependency on manufacturers that have never taken a vaccine through WHO PQ

➢ Manufacturers have signalled a need for support and clear pathways on what could be major bottlenecks to supply:
  — WHO emergency use listing (especially in the context of large array of platforms)
  — Country licensure and registration requirements
  — Liability and indemnification
Will a COVID-19 vaccine be a silver bullet?

- Indications of global vaccine production is positive.

- The impact of a vaccine depends on **how long immunity lasts** and **the effectiveness of the vaccine**

- Likely to be different vaccines with different efficacy, different durations of protection, different and presentations

- Short duration and modest effectiveness may imply **booster vaccination or annual vaccination**

- The development of an antiviral medicine remains important. Most therapeutic research is currently around monoclonal antibodies/plasma – which is hard to scale, especially in low resource countries.

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“We think that it will protect for about a year”
AstraZeneca CEO

“The durability of immunity [to common coronaviruses] that is protective, ranges from 3 to 6 months to almost always less than 1 year”
Director, NIH, A. Fauci

50% effective: the WHO and FDA minimum standard for COVID-19 Vx
COVAX Procurement Timeline and Next Steps
**Procurement Timeline and Next Steps**

### 3Q PREPARE, 6 weeks
- Demand scenario for procurement
- Partner & industry agreement on Term Sheet
- Industry consultation
- Industry on-boarding for new suppliers
- Procurers’ consortium / consultation
- COVAX Reference Group
- Partner consultation
- Country Indications
- Alignment with safety injection equipment

### 3Q PROCURE, 6 weeks
- Procurement process finalized and launched
  - E.g. in early phase, COVAX Facility enters into Advance Purchase Agreements with manufacturers.
  - UNICEF procurement process and engagement with manufacturers will be guided by these agreements.

### 4Q CONTRACT, 10 weeks
- Launch pooled procurement platform for all COVAX procurers
  - E.g. Framework agreements in place with manufacturers including base terms, and then updated with call options once commercial terms set
  - Clearing house for relevant intelligence sharing
  - Agreements in place to facilitate access by other procurers to contracted doses, etc.

### 2020-2021 DELIVER
- Draw-down on manufacture-specific call options within agreements
  - E.g. As a product meets the TPP, and WHO allocations are defined, call options is activated.
  - COVAX buyers trigger draw-down on quantities directly with manufacturers
  - Deliveries commence

**Procurement enablers:**
- COVAX country membership scope defined
- Membership will need to address licensing/pre-licensure, indemnification, vaccine injury compensation, level of commitment, etc.
- COVAX allocation/delivery trigger process outlined
- Country readiness, including pharmacovigilance systems, and cold chain
Thank You

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