Dialogue with civil society: ACT-A and COVID-19 vaccines

9 March 2021
Housekeeping

- Please use mute and turn video off while not speaking to preserve livestream quality
- We will have time for Q&A after the initial presentation
- To ask for the floor, please indicate your name and organization in the chat
Agenda

1. Welcome and introductions
   COVAX  10 mins

2. Updates from civil society representatives
   CSOs  10 mins

3. COVID-19 vaccine data and first introductions
   WHO  20 mins

4. Updates on the vaccine pipeline
   CEPI  10 mins

5. COVAX Facility update and supply forecast
   Gavi  10 mins

6. Q&A/Discussion
   All  30 mins
Update from civil society representatives

CSO representatives
**Civil Society Representation in COVAX**

- Following a nomination process (coordinated by the lead agencies and led by civil society in October 2020), representatives were nominated to 10 working groups across COVAX.
- Co-chairs of CSO Coordination: Mike Podmore, STOP AIDS and Lisa Hilmi, CORE Group, representing GAVI CSO

<table>
<thead>
<tr>
<th>Working Group</th>
<th>Name</th>
<th>Affiliated CBO/ NGO</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCM</td>
<td>Mesfin Teklu Tessema</td>
<td>IRC</td>
<td>US/Ethiopia</td>
</tr>
<tr>
<td>Access/Allocation</td>
<td>Karrar Karrar</td>
<td>Save the Children</td>
<td>UK</td>
</tr>
<tr>
<td>Vaccine Strategy</td>
<td>Jane Barratt</td>
<td>International Federation on Aging</td>
<td>Canada</td>
</tr>
<tr>
<td>Technical Review Group</td>
<td>Rebecca Grais</td>
<td>MSF</td>
<td>France</td>
</tr>
<tr>
<td>Country Readiness &amp; Delivery (Coordination Group)</td>
<td>Katy Clark</td>
<td>American Red Cross</td>
<td>Switzerland</td>
</tr>
<tr>
<td>Country Readiness &amp; Delivery (Communication, Advocacy, Training)</td>
<td>Carla Toko</td>
<td>Village Reach</td>
<td>Democratic Republic of the Congo</td>
</tr>
<tr>
<td>Country Readiness &amp; Delivery (Demand)</td>
<td>Robert Kanwagi</td>
<td>World Vision</td>
<td>Kenya</td>
</tr>
<tr>
<td>Manufacturing SWAT</td>
<td>Alain Alsalhani</td>
<td>MSF</td>
<td>France/Syria</td>
</tr>
<tr>
<td>Enabling Science SWAT</td>
<td>Sheetal Sharma</td>
<td>Safari Doctors</td>
<td>Kenya</td>
</tr>
<tr>
<td>Clinical Development and Operations SWAT</td>
<td>Farah Qamar</td>
<td>Aga Khan Foundation</td>
<td>Pakistan</td>
</tr>
</tbody>
</table>
Civil Society Coordination in COVAX and across ACT-A

- **Regular methods of communication:**
  - Listserv and bi-weekly calls for COVAX representatives (co-facilitated by Platform for ACT-A Civil Society and Community Representatives & Gavi CSO Constituency)
  - Broader ACT-A calls for all civil society representatives (coordinated by the Platform for ACT-A Civil Society and Community Representatives)

- **Recent steps for improved coordination:**
  - Call(s) between civil society representatives and the COVAX lead agencies
  - Letter sent to all lead agencies in ACT-A

- **Next steps:**
  - Broader consultation with civil society and communities, particularly at the national and regional level
  - Monthly Covax-CS Dialogue calls co-created and hosted by COVAX lead agencies and COVAX CS reps
COVAX CS Representatives: Key Priorities

- **Equity** → Allocation (global & sub-national), vaccine nationalism, Humanitarian Buffer
- **Operationalizing COVAX**: delivery funding, reaching the most vulnerable, including migrants, IDPs, asylum seekers
- **Vaccine supply constraints**: Increase global manufacturing capacity, dose sharing
- **Transparency and accountability**
COVID-19 vaccine data and first introductions

Kate O’Brien, WHO
COVID-19 vaccines: overview of key numbers (data at 8 March)

• **90 days** since first countries started vaccinating\(^1\), **71 days** since all EU countries received vaccines, and **7 days** since first use of COVAX doses\(^2\)

• **304 million vaccine doses** have been administered:
  - 78% of these doses have been administered in 10 countries
  - At least 9 different vaccines (3 platforms) have been administered\(^3\)

• Campaigns **have started in 124 economies:**
  - incl. 65 HICs, 33 UMICs, 23 LMICs and 3 LICs
  - The vaccines used by the highest number of economies are: Pfizer-BioNTech (67 economies using it), followed by Oxford/AZ (58), Moderna (30), Gamaleya (20) and Sinopharm (16)

• **COVAX has shipped doses to 26 countries**\(^4\):
  - 4 LMICs & 1 LIC have started campaigns thanks to COVAX doses
  - In total, **15.6 M mn COVAX doses shipped**\(^4\)

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1. Dec. 8, 2020 in the UK (Pfizer)
2. March 1 in Ghana and Côte d'Ivoire
3. Pfizer, Moderna, Gamaleya, Sinovac, Sinopharm, SII, Bharat Biotech, AZ, Johnson & Johnson
4. On Jan 17, India received an additional 10 mn doses through COVAX from India-based supplier SII (excluded from this figure)

Source: WHO COVID-19 dashboard; Gavi; Bloomberg; Our World in data
78% of vaccine doses have been administered in 10 countries (data at 8 March)

<table>
<thead>
<tr>
<th>Top 10 countries in which Covid-19 vaccines have been administered,</th>
<th>% of total doses administered worldwide</th>
<th>Country population in % of the global population</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>90</td>
<td>30%</td>
</tr>
<tr>
<td>China</td>
<td>53</td>
<td>17%</td>
</tr>
<tr>
<td>UK</td>
<td>23</td>
<td>8%</td>
</tr>
<tr>
<td>India</td>
<td>21</td>
<td>7%</td>
</tr>
<tr>
<td>Brazil</td>
<td>10</td>
<td>3%</td>
</tr>
<tr>
<td>Turkey</td>
<td>10</td>
<td>3%</td>
</tr>
<tr>
<td>Israel</td>
<td>9</td>
<td>3%</td>
</tr>
<tr>
<td>Russia</td>
<td>8</td>
<td>2%</td>
</tr>
<tr>
<td>Germany</td>
<td>7</td>
<td>2%</td>
</tr>
<tr>
<td>UAE</td>
<td>6</td>
<td>2%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>78%</strong></td>
<td><strong>47%</strong></td>
</tr>
</tbody>
</table>

Source: Our World in data; Bloomberg
### Covid-19 vaccination rollout has started in 124 economies (data at 8 March)

Economies classified by income level | # of economies per income group | # economies where vaccination has started | % of income group where vaccination has started
--- | --- | --- | ---
High income economies (HICs) | 83 | 65 | 78%
Upper-middle income economies (UMICs) | 56 | 33 | 59%
Lower-middle income economies (LMICs) | 50 | 23 | 46%
Low income economies (LICs) | 29 | 3 | 10%
Total | 218 | 124 | 57%

**List of economies where vaccination has started**
- Andorra, Austria, Australia, Bahrain, Barbados, Belgium, Bermuda, Canada, Cayman Islands, Channel Islands, Chile, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Faroe Islands, Finland, France, Germany, Greece, Greenland, Gibraltar, Hungary, Hong Kong SAR, Iceland, Ireland, Isle of Man, Israel, Italy, Japan, Kuwait, Latvia, Liechtenstein, Lithuania, Luxembourg, Macao, Malta, Mauritius, Monaco, Netherlands, New Zealand, Norway, Oman, Panama, Poland, Portugal, Qatar, Romania, Saudi Arabia, San Marino, Seychelles, Singapore, Slovakia, Slovenia, South Korea, Spain, Sweden, Switzerland, Trinidad and Tobago, Turks and Caicos, UAE, UK, Uruguay, USA
- Afghanistan, Angola, Bangladesh, Bolivia, Cambodia, Côte d’Ivoire, El Salvador, Egypt, Ghana, Honduras, India, Kenya, Laos, Mongolia, Morocco, Myanmar, Nepal, Pakistan, Philippines, Senegal, Sri Lanka, Ukraine, Zimbabwe

**Status of Vx rollout per income group**
- > 50% of countries
- 25% < X ≤ 50%
- 10% < X ≤ 25%
- ≤ 10%

Green text: COVAX doses only

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1. World Bank classification (2021)

Source: World Bank; WHO COVID-19 dashboard; Our World in data; Bloomberg; Reuters
Accelerating the equitable rollout of COVID-19 vaccines is more important than ever

COVID-19 vaccine doses administered per 100 people, March 8, 2021

SOURCE: WHO COVID-19 Dashboard

Note: The designations employed and the presentation of these materials do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.
The wave of COVAX deliveries kicked off on February 24th

- **24 February**: The first batch of COVAX doses has arrived in Ghana (600,000 doses)
- **26 February**: South Korea receives 117,000 COVAX doses
- **26 February**: 504,000 doses have landed in Côte d’Ivoire
- **1 March**: Côte d’Ivoire and Ghana start their first COVID-19 COVAX vaccinations
- **2 March**: 3.94 million doses of COVAX vaccines arrive in Nigeria

*SOURCE: GAVI*
In total, > 10 million COVAX doses have been delivered in just over a week

- More shipments to come in the coming days and weeks
- Planned shipments for the next 7 days are available on the UNICEF Vaccine market dashboard (see tab “Delivery”)
Countries that have received doses through COVAX (8 March)

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SOURCE: WHO COVID-19 dashboard, Our World in Data; Press Research
Deliveries of COVAX doses is a complex process – key bottlenecks at 8 Mar
Addressing the challenges to further accelerate roll-out of COVAX Facility vaccines require several actions from countries

1. Each country needs to submit for each product a signed I&L agreement and a Regulatory Authorization

2. Ensure timely export licenses for COVAX (ideally waivers)

3. Prepare in-country use of vaccines by costing\(^1\), securing resources and preparing / launching Vx campaigns

4. Encourage manufacturers to rapidly provide data for EUL/PQ & SAGE\(^2\)

5. All Member States allow manufacturers to prioritize COVAX commitments

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1. Using available tools such as the CVIC tool; 2. WHO PQ/EUL pipeline
There are three main variants of concern

**VOC 202012/01**  
(first identified in the UK)

**501Y.V2 or B.1.351**  
(first identified in South Africa)

**P.1**  
(first identified in Brazil)

Variants of concerns are defined by WHO by their transmission, disease severity or impact on Covid counter measures.

Evidence supports ongoing use of existing vaccines – with some concerns about B.1.351 vs. some vaccines (available data still limited).

COVID-19 Vaccine and SARS-CoV2 variants
Data are limited, early, and incomplete

### Availability of Evidence (9 March 2021)

<table>
<thead>
<tr>
<th></th>
<th>B 1.1.7 (original report SSA)</th>
<th>B 1.351 (original report AZ)</th>
<th>P 1 (original report Brazil)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Clinical</td>
<td>Lab</td>
<td>Clinical</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>✔️</td>
<td>pending</td>
<td>limited</td>
</tr>
<tr>
<td>J &amp; J</td>
<td></td>
<td></td>
<td>prelim</td>
</tr>
<tr>
<td>Moderna</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Novavax</td>
<td>prelim</td>
<td>prelim</td>
<td>pending</td>
</tr>
<tr>
<td>Pfizer</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Sinopharm</td>
<td></td>
<td>pending</td>
<td></td>
</tr>
<tr>
<td>Sinovac</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Evidence on protection against severe disease, hospitalization and deaths are especially limited
### Performance against B.1.351 or 501Y.V2 (variant first identified in South Africa)

<table>
<thead>
<tr>
<th>Reduction of neutralizing activity in laboratory assays</th>
<th>Clinical efficacy in South Africa</th>
<th>Clinical efficacy in global studies</th>
<th>Clinical efficacy criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>3x</td>
<td>-</td>
<td>95%</td>
<td>-</td>
</tr>
<tr>
<td>6x</td>
<td>-</td>
<td>94.1%</td>
<td>-</td>
</tr>
<tr>
<td>2.5-31x / eliminated(^3)</td>
<td>22% (NS)(^2)</td>
<td>62-90%</td>
<td>Mild &amp; moderate</td>
</tr>
<tr>
<td>pending</td>
<td>57%</td>
<td>72%</td>
<td>Moderate to severe</td>
</tr>
<tr>
<td>pending</td>
<td>49(^1) / 60(^2)</td>
<td>89%</td>
<td>Mild, moderate &amp; severe</td>
</tr>
<tr>
<td>1.6x</td>
<td>-</td>
<td>79 - 86%</td>
<td>-</td>
</tr>
<tr>
<td>-</td>
<td>-</td>
<td>50.4%</td>
<td>-</td>
</tr>
</tbody>
</table>

1. Including HIV positive subjects (6% of the study population); 2. Excluding HIV positive subjects; 3. previously infected placebo participants showed similar results.

Sources:
- South Africa: J&J; Novavax; Moderna; Pfizer 1 & Pfizer 2; AstraZeneca/Oxford; Sinopharm.

**DATA AS OF FEB 2021**
Regulatory timeline of key Vx candidates

https://extranet.who.int/pqweb/key-resources/documents/status-covid-19-vaccines-within-who-eulpq-evaluation-process

<table>
<thead>
<tr>
<th>Vx candidates</th>
<th>FDA</th>
<th>MHRA</th>
<th>EMA</th>
<th>WHO EUL/PQ</th>
<th>Country reliance on PQ</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AZ with EMA as authority of reference</strong></td>
<td>April 2021</td>
<td>Dec. 30, 2020 Emergency Use</td>
<td>Jan. 29, 2021 Cond. Auth. (non-Covax)</td>
<td>Between March and April 21 (Covax sites)</td>
<td>Between April and July 21 onwards</td>
</tr>
<tr>
<td><strong>AZ South Korea w/ MFDS Korea as authority of record</strong></td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Feb. 15, 2021 Emergency Use</td>
<td>Since Feb</td>
</tr>
<tr>
<td><strong>SII /AZ vaccine (Covishield) with DCGI India as authority of record</strong></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Feb. 15, 2021 Emergency Use</td>
<td>Since Feb</td>
</tr>
<tr>
<td><strong>Sinovac</strong></td>
<td>Feb. 27, 2021 Emergency Use</td>
<td>-</td>
<td>-</td>
<td>March 2021</td>
<td>April 2021 onwards</td>
</tr>
<tr>
<td><strong>SinoPharm</strong></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Rolling submission started from Gamaleya. CMC data awaited</td>
<td>April 2021 onwards</td>
</tr>
<tr>
<td><strong>Gamaleya</strong></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Rolling submission of data from April 2021</td>
<td>April 2021 onwards</td>
</tr>
<tr>
<td><strong>Novavax</strong></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Novavax submitted EOI on 23 Feb</td>
<td>-</td>
</tr>
</tbody>
</table>

Key messages

- **Pfizer**: WHO EUL on Dec. 31st with EMA as authority of record; ongoing country reliance on PQ
- **AZ**: WHO EUL confirmed 15 Feb with MFDS (South Korea) as authority of record
- **SII/AZ**: WHO EUL confirmed on 15 Feb with DCGI (India) as authority of record
- Focus on assessment of J&J, SinoPharm and Moderna.
- Gamaleya: only partial submission. CMC data awaited. Sinovac: additional data awaited.

1. Conditional marketing authorization
2. According to the chief adviser for the U.S. COVID-19 vaccine program (Dec. 30, 2020; Source)
3. Temporary authorisation of supply of the vaccine in the emergency use setting (which is distinct from a marketing authorisation)
4. Wuhan Institute of Biological Products Co Ltd

COVAX delivered vaccine doses to low- and middle-income countries faster than the H1N1 vaccine deployment initiative in 2010 and aims at delivering 25 times more doses

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>Indicators</th>
<th>COVAX (March 2021)</th>
<th>H1N1 vaccine deployment initiative</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Breadth of participation</strong></td>
<td># of letter of intent</td>
<td>190</td>
<td>94</td>
<td>&gt;2x</td>
</tr>
<tr>
<td></td>
<td># of recipients of doses</td>
<td>To be determined</td>
<td>77</td>
<td>To be determined</td>
</tr>
<tr>
<td><strong>Funding</strong></td>
<td>Total pledges, in mn USD</td>
<td>5,900</td>
<td>56</td>
<td>&gt;100x</td>
</tr>
<tr>
<td><strong>Time to 1st dose</strong></td>
<td># of days after 1st vaccination in HICs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>First country</td>
<td>38 (India)</td>
<td>94</td>
<td></td>
</tr>
<tr>
<td></td>
<td>First country in Africa</td>
<td>78 (Ghana)</td>
<td>145</td>
<td></td>
</tr>
<tr>
<td></td>
<td>First 10 countries reached</td>
<td>Est. 90</td>
<td>149</td>
<td></td>
</tr>
<tr>
<td><strong>Vaccine doses</strong></td>
<td># of countries that received doses after</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 month¹</td>
<td>&gt;20</td>
<td>~4</td>
<td>4-5x</td>
</tr>
<tr>
<td></td>
<td>2 months</td>
<td>Est. 50</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 months</td>
<td>142</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cumulative doses delivered after... (in Mn)</td>
<td>1 month</td>
<td>15.6 (at 12 days)</td>
<td>&lt;1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 months</td>
<td>30+ (expected)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>12 months</td>
<td>Est. 2,000</td>
<td>78</td>
</tr>
</tbody>
</table>

2. Does not include the exceptional delivery of COVAX vaccines to India in January 2021 (10mn doses)

SOURCE: Report of the WHO Pandemic Influenza A (H1N1) Vaccine Deployment Initiative [link]; COVAX Facility supply forecast as of Jan 22, 2021 [link]
Overview of Covid-19 vaccination policies worldwide

COVID-19 Vaccination Policy, Mar 7, 2021
This metric records policies for vaccine delivery for different groups.
- Availability for ONE of following: key workers/clinically vulnerable groups/elderly groups
- Availability for TWO of following: key workers/clinically vulnerable groups/elderly groups
- Availability for ALL of following: key workers/clinically vulnerable groups/elderly groups
- Availability for all three plus partial additional availability (select broad groups/ages)
- Universal availability


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SOURCE: Our World in Data
Zoom on prioritized populations in countries that already received COVAX doses (data at March 8)

Out of 25 countries with an NDVP that have received COVAX doses¹...

... 25 prioritize health care workers

... 10 prioritize based on age in the first 3% of population²

1. At the time of writing, COVAX had shipped to 26 countries (excluding India). The figure shown here includes 25 countries due to no NDVP available for Republic of Korea; 2. 100% prioritize based on age in the first 20% of the prioritized population

Premiminary

SOURCE: NDVPs
WHO calls for urgent action to ramp up production of COVID-19 vaccines for all

“One of our main priorities now is to increase the ambition of COVAX to help all countries end the pandemic. This means urgent action to ramp up production.”

Dr Tedros Adhanom Ghebreyesus, DG of the WHO on March 5

WHO is working on 3 approaches:

1. **Connecting companies that produce vaccines with others that have excess capacity** to fill and finish them (e.g., partnership between Johnson & Johnson and Merck announced last week)

2. **Advocating bilateral technology transfers**, so that companies that own vaccine patents can license them to another company.

3. **Implementing a coordinated technology transfer** - whereby universities and manufacturers would license their vaccines and Knowhow to other companies through a global mechanism coordinated by WHO through Technology Transfer Hubs
How CSOs can continue helping COVAX

• Contribute to aspects of programme delivery, where feasible

• Support the vaccination of prioritized populations within countries

• Support acceptance and uptake of vaccination:
  - By supporting community leaders and their voices
  - By discussing the benefits and safety of vaccination with local communities
  - By promoting accurate information about vaccines
  - By advocating for fair and equitable access to vaccines
  - … and any other locally tailored assistance

• Help to raise funds for COVAX

… and other areas where CSOs and community representatives may support
Vaccine pipeline: latest developments

Kristine Rose, Richard Wilder
CEPI
Rapid progress in vaccine innovation

- Year in which pathogen was linked to disease
- Year in which US vaccine was licensed

**Data source:** Our World in Data
CEPI’s response to COVID–19

CEPI has moved quickly and collaboratively to rapidly develop vaccines against the COVID-19 virus.

We have so far invested ~1.2 USD Bn in the search for a COVID-19 vaccines, through **11 partnerships** where of 9 is still active.

Our ultimate goal is to develop vaccines against COVID-19 as quickly as possible, making **2bn** doses available by the end of 2021 through COVAX.
## COVAX R&D Wave 1 portfolio

<table>
<thead>
<tr>
<th>Location</th>
<th>Moderna</th>
<th>CureVac</th>
<th>Inovio</th>
<th>Novavax</th>
<th>Clover</th>
<th>Biological E</th>
<th>AZ/University of Oxford</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platform</td>
<td>mRNA (modified)</td>
<td>mRNA (unmodified)</td>
<td>DNA</td>
<td>Protein</td>
<td>Protein</td>
<td>Protein</td>
<td>Viral Vector</td>
</tr>
<tr>
<td>Current clinical phase</td>
<td>Phase III</td>
<td>Phase II/III</td>
<td>Phase III</td>
<td>Phase I</td>
<td>Phase I</td>
<td>Phase I</td>
<td>Phase III</td>
</tr>
<tr>
<td>Clinical trial sites</td>
<td>USA, JPN</td>
<td>DEU, BEL, PER, PAN, ARG, COL, DOM, FRA, MEX, NLD, ESP</td>
<td>USA, KOR, CHN</td>
<td>AUS, USA, MEX, PRI, ZAF, GBR</td>
<td>AUS, Phase II/III in multiple countries</td>
<td>IND</td>
<td>GBR, USA, BRA, ZAF, IND, BGD, RUS, TUR, PER, DEU, FRA, CZE, ITA, NLD, ESP</td>
</tr>
<tr>
<td>Expected 1st efficacy data</td>
<td>Nov-20</td>
<td>Q1 21</td>
<td>Q1 21</td>
<td>Jan-21 (UK)</td>
<td>Q2 21 (US)</td>
<td>Q3 21</td>
<td>Q3 21</td>
</tr>
<tr>
<td>Signed budget to date ($ M)</td>
<td>0.90</td>
<td>15.28</td>
<td>21.95</td>
<td>414.53</td>
<td>327.78</td>
<td>4.96</td>
<td>205.15</td>
</tr>
</tbody>
</table>

+ CEPI has also supported SK Bioscience and Hong Kong University COVID-19 vaccine candidate as part of 'Wave 2' investments
Manufacturing: What we need to do now

To deliver 2 billion doses by the end of 2021, 2-3 successful programmes are needed to:

1. Produce early doses to support clinical studies
2. Scale up processes to industrial scale before clinical trials begin
3. Scale-out products in different countries to expand capacity
4. Stockpile vaccines in bulk in anticipation of dose level definition
5. Anticipate projects failing during clinical development
6. Repurpose facilities for successful products, if needed
CEPI is committed to enabling equitable access

CEPI’s partnerships are supporting scale-out to different geographical sites and provides the COVAX Facility with the right of first refusal to procure potentially up to 1bn doses in 2021:

➢ AstraZeneca UK Limited (AZ), manufacture in Europe and Asia
➢ BioE, manufacture in India
➢ Clover, manufacture in China + potential tech transfer
➢ Novavax, manufacture in Europe and Asia
➢ SK BioSciences, manufacture in South Korea

CEPI has signed agreements with Biofabri (Spain) and GC farma (Republic of Korea) to reserve drug product manufacturing capacity for up to 1bn doses of CEPI-supported candidates

CEPI has also signed agreements with Dynavax to secure adjuvant in support of CEPI-supported candidates.

Emergence of new COVID-19 variants with increased transmission rates

❖ **At least five new variants of concern are spreading rapidly**
  - By country of first identification: B.1.1.7 (United Kingdom); B.1.351 (South Africa); B.1.1.28.1 (Brazil); B.1.526 (U.S. – NY); B.1.427/B.1429 (US - CA)
  - Resulting in increased stress on healthcare systems and need for more stringent nonpharmaceutical interventions to maintain control
  - B.1.1.7 variant may result in more severe disease

❖ **Evidence suggests current vaccines may be highly effective in preventing death and hospitalization from all variants**

❖ **Some new variants can reduce effectiveness of vaccines and natural immunity’s protection against symptomatic disease**

❖ There is an urgent need to develop vaccines for new variants (at risk), so sufficient doses are ready before a decision to introduce new vaccines is taken.

Source: https://www.gisaid.org/hcov19-variants/
New variants are making future vaccine planning more complex

<table>
<thead>
<tr>
<th>Options</th>
<th>Details</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linear increase in coverage</td>
<td>• Focus on maximizing production, distribution and coverage of existing vaccines</td>
<td>• Viable option if one or more current vaccines is highly effective in preventing death and hospitalization from all variants</td>
</tr>
<tr>
<td></td>
<td>• Clinical trials to expand the use of current vaccines (i.e. broaden immune response, special populations)</td>
<td>• May not stop SARS-CoV-2 transmission long-term</td>
</tr>
<tr>
<td>Variant specific boosters &amp; reformulation</td>
<td>• Current vaccines may be reformulated to better address variants</td>
<td>• Reformulated vaccine could be given as 1st dose or as boosters to already vaccinated</td>
</tr>
<tr>
<td>Booster for waning immunity</td>
<td>• Regardless of protection against variants, boosters may be needed for durable protection against infection or severe disease</td>
<td>• Similar to influenza vaccines, SARS-CoV-2 vaccines may need to be reformulated regularly</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Similar to booster doses against tetanus</td>
</tr>
</tbody>
</table>
COVAX R&D strategies to address challenges of SARS-CoV-2 evolution

Short term

❖ Assessing new variants
  Agility project – partnership with GISAID, PHE and NIBSC to evaluate whether new variants compromise the effectiveness of current vaccines
  Expanding CEPI central laboratory network to include variant neutralization assays
  Refining animal models in CEPI Animal Model Network to assess vaccines designed to address variants

❖ Optimizing current vaccines
  Extending protection afforded by current vaccines (adjuvants; HPB)
  Clinical trials to support expanded use of current vaccines - ongoing call for proposals

❖ Developing new vaccines
  Goal: Strain change, if needed, in 100 days from decision to proceed
  Stepwise approach to funding developers to prepare, test, and manufacture vaccines against new strains
  Work with Regulators to determine a strain change mechanism

Medium term

❖ Fund candidates with additional antigen targets to be available by 2022 if needed
❖ Evaluate limitations in manufacturing capacity that pose a threat to delivery of vaccines for new variants; including raw materials

Long term

❖ Develop broadly protective beta coronavirus vaccines to better protect against existing and potential future coronavirus threats – Call for proposal by end of March
COVAX Facility update and supply forecast

Sanne Wendes
Overview

1. COVAX Facility Updates
   - Supply & Deals
   - Delivery & Shipment

2. COVAX Facility Design
   - Dose Sharing
   - Exchange
   - COVAX Buffer

3. Vaccine Candidate Decision Making

4. Country Readiness
COVAX Facility candidate-specific supply

2021 and 2022

PRELIMINARY

There are 7 vaccines in the COVAX portfolio:

1. AstraZeneca: ChAdOx1-S [recombinant] ("AZD1222")
2. Novavax: NVX-CoV2373
3. SII: Covishield ("AZD1222")
4. SII: Covovax ("NVX-CoV2373")
5. Pfizer: BNT162b2
7. Sanofi-GSK: Recombinant Protein

COVAX Available Supply, Mn doses, 2021 and 2022

<table>
<thead>
<tr>
<th>Candidate</th>
<th>Committed doses</th>
<th>Optional doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>2,010</td>
<td>500</td>
</tr>
<tr>
<td>B</td>
<td>3,209</td>
<td>125</td>
</tr>
<tr>
<td>C</td>
<td>3,209</td>
<td>120</td>
</tr>
<tr>
<td>D</td>
<td>550</td>
<td>170</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>3,209</strong></td>
<td><strong>120</strong></td>
</tr>
</tbody>
</table>

The deal with SII for a total of 1.1bn doses is COVAX's largest deal and currently represents >50% of secured doses from signed agreements.

1 "Committed doses" are doses that the COVAX Facility is required to purchase once a legally-binding agreement has been signed. "Optional doses" are doses that the COVAX Facility has the option to make a firm order commitment for in the future, but is not required to purchase.

2 Building on the recently announced memorandum of understanding with Novavax, negotiations on the final terms of the agreement and the distribution of volumes between Novavax and the Serum Institute of India are ongoing; updates will be published in due course.
COVAX Facility global supply forecast (AMC/SFP)

PRELIMINARY AND SUBJECT TO ASSUMPTIONS

COVAX Available Supply, Cumulative, Mn doses, 2021

<table>
<thead>
<tr>
<th>Month</th>
<th>AMC</th>
<th>SFP</th>
<th>Secured volumes from signed agreements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan</td>
<td>100%</td>
<td>100%</td>
<td>85%</td>
</tr>
<tr>
<td>Feb</td>
<td>85%</td>
<td>100%</td>
<td>145%</td>
</tr>
<tr>
<td>Mar</td>
<td>145%</td>
<td>100%</td>
<td>165%</td>
</tr>
<tr>
<td>Apr</td>
<td>165%</td>
<td>100%</td>
<td>255%</td>
</tr>
<tr>
<td>May</td>
<td>255%</td>
<td>100%</td>
<td>470%</td>
</tr>
<tr>
<td>Jun</td>
<td>470%</td>
<td>100%</td>
<td>1,180%</td>
</tr>
<tr>
<td>Jul</td>
<td>1,180%</td>
<td>80%</td>
<td>920%</td>
</tr>
<tr>
<td>Aug</td>
<td>920%</td>
<td>70%</td>
<td>690%</td>
</tr>
<tr>
<td>Sep</td>
<td>690%</td>
<td>70%</td>
<td>225%</td>
</tr>
<tr>
<td>Oct</td>
<td>225%</td>
<td>60%</td>
<td>1,800%</td>
</tr>
<tr>
<td>Nov</td>
<td>1,800%</td>
<td>60%</td>
<td>1,545%</td>
</tr>
<tr>
<td>Dec</td>
<td>1,545%</td>
<td>60%</td>
<td>1,905%</td>
</tr>
<tr>
<td>Early 2022</td>
<td>86%</td>
<td>10%</td>
<td>2,265%</td>
</tr>
</tbody>
</table>

1 Supply refers to volumes of vaccine available from the manufacturer. Timing of forecasts is based on anticipated release of doses from manufacturers. Volumes for expected single-dose regimen vaccine candidates doubled to ensure comparability across vaccine candidates. Volumes have been rounded to the nearest 5M, and so totals may not equal sum of segments.
2 Signed agreements include legally-binding agreements, memoranda of understanding, and statements of intent.

CAVEATS

Contracts: Some of the supply included in the projections are linked to deals that are already concluded and some are currently being negotiated. Terms are subject to change.

Candidate attrition: Some candidates are still in clinical development. If they do not achieve positive clinical trial outcomes (safety and efficacy) and regulatory approval, these volumes will not be procured by COVAX.

Regulatory approval: Supply timing will depend on regulatory success and timelines, including reviews of individual batches ("batch release").

Manufacturing: In many cases, manufacturing is yet to reach full scale. Manufacturing productivity will be influenced by multiple factors, which will in turn influence volume and timing of supply.

Delivery: Timing of delivery will depend on various factors, including local regulatory approval, country readiness, logistics, indemnification and liability in place, in-country distribution etc.

Funding availability: Total potential supply is shown; procurement of these doses will depend on COVAX AMC fundraising, AMC92 cost-sharing beyond donor-funded doses, and the final prices and volumes of doses allocated to AMC92.

Allocation: These supply forecasts reflect a preliminary distribution of doses based on each participant’s share of available supply pro rata by demand and are to be treated as indicative. Final timing and volumes will be determined by the WHO Allocation Mechanism.
12.6mn Doses Have Been Delivered and Another 30.2m Ordered

Available [here](#). Note allocation total missing India, Syria and Buffer allocation numbers.
COVAX Exchange

Mechanism under development to:
provide participants with a platform through which to trade their allocated doses with each other

Through the Exchange, participants will be able to potentially improve upon their allocation

Product consistency: a participant trades to minimize the number of different vaccines and improve the performance of its vaccine programs.

Optimize preferences: a participant trades to increase access to a vaccine that it prefers.

(tbd) Temporal trade: a participant could trade current doses for future doses (to a time when they plan to expand their program)

Principles for the Exchange include:
• Mutual Benefit
• Fairness
• Speed
• Validity
• Financial Neutrality
• Simplicity
Dose sharing mechanism under development to bring additional doses to AMC Participants to supplement funded doses

Dose sharing via COVAX will help to:

- **Accelerate coverage**: Shared doses enable COVAX to reach high-risk populations faster
- **Deepen coverage**: Shared doses expand coverage rates for recipients
- **Promote equity**: Shared doses leverage allocation mechanism for distribution to advance equity goals
- **Ensure efficiency and maximize benefits to countries**: Streamlined processes and preferential terms for, e.g., indemnity and liability; access to no fault compensation scheme

All shared doses will meet COVAX standards for safety and effectiveness, and will be channeled through relevant COVAX processes.
Under development: A COVAX Buffer to act as last resort

Pending Gavi Board approval, 5% of COVAX Facility doses and COVAX AMC funding is proposed to:

1. Ensure access to COVID-19 vaccines for high-risk populations in humanitarian settings

   National plans are the first resort for covering all high-risk groups

   Humanitarian Buffer doses available only as a last resort

   if unavoidable gaps in vaccination plans

   Humanitarian Agencies to show demonstrable gap in coverage, competence and experience in delivering vaccination campaigns in humanitarian contexts, and ability to reach target populations

   e.g. non-government controlled territories

2. Provide a contingency provision to enable an emergency release of doses to meet public health needs where normal vaccine allocation timelines may not be sufficient

   • This mechanism is only considered relevant and appropriate once all COVAX Facility participants have been allocated an initial number of doses to ensure that all participating economies have established a basic, equal level of coverage
Indicative candidate pathway

Candidates identified

- Vaccine candidates identified through the UNICEF/PAHO RFP for supply up to end 2021
- (Early candidates identified through CEPI and direct COVAX Facility manufacturer engagement)

IPG advice

- IPG assesses vaccine against candidate and portfolio criteria
  ✓ If candidate recommended, COVAX facility seeks advice from PRG

PRG advice

- PRG reviews commercial terms of a deal, taking into consideration risk tolerance and broader market conditions

Negotiations

- Advance Purchase Agreement Negotiations

MSDC decision

- MSDC approves financially binding agreements with manufacturers

Inclusion in COVAX Facility portfolio

IPG: Independent Product Group
PRG: Procurement Reference Group
MSDC: Market-Sensitive Decisions Committee
Criteria of country readiness

**Step 1:** Countries are confirmed as COVAX participant (submission of vaccine request)

**Step 2:** Countries submit their NDVPs or equivalent to online Platform

**Step 3:** Countries plans are reviewed by Regional Review Committees

**Step 4:** Countries who meet minimum criteria are included in next allocation round and allocated doses

**Step 5:** Confirmation step: regulatory approval, import procedures, I&L agreements, plans match allocated vaccine products

**Step 6:** Shipment orders are confirmed, and doses shipped

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**Ongoing and throughout:** Countries work on preparing for vaccine, refining their NDVPs (including conducting pre-assessment checks), securing funding for vaccine delivery programme

<table>
<thead>
<tr>
<th>Total NDVPs submitted for review through PP</th>
<th>AMC92 submitted</th>
</tr>
</thead>
<tbody>
<tr>
<td>104</td>
<td>86</td>
</tr>
</tbody>
</table>
Discussion/Q&A

All
Thank you

FOR FURTHER INFORMATION...

COVAX Facility:
https://www.gavi.org/covax-facility  .... and https://www.gavi.org/vaccineswork

COVID-19 vaccines:

Country readiness and delivery:
https://www.who.int/initiatives/act-accelerator/covax/covid-19-vaccine-country-readiness-and-delivery

To sign up for our mailing list: CSO_COVAX@who.int