ACT Accelerator: Near Term Priorities

MS COVID-19 Briefing
7 January 2021
Near term ACT-A Priorities

1. Refreshed & Prioritized **Strategy & Budget** (28 Jan briefing)

2. Operationalized **Allocation Mechanism** (14 Jan briefing)

3. Accelerated **Vaccine Rollout** (today)
The **refreshed ACT-A strategy & priorities** will be framed in terms of known and emerging risks to equitable access to Covid-19 tools

**2020**

- All countries fighting epidemic, accelerated development of tools for new disease
- Subset of HICs, UMICs & producers have early Vx supply & modest Dx/Tx gaps
- Rest of world has demand gaps for Dx & Tx, and lacks Vx supply

**2021**

- All countries have equitable access to COVID-19 tools
- Existing tools fail to control Covid-19 (e.g. due to variants)

**ACT-A priorities**

- Address AMC & UMIC Vx supply gaps
- Understand / generate Dx, dexa, PPE, O2 demand
- Address evolving supply gaps for Tx, Dx
- Intensify R&D to enhance tools and mitigate risks

**Potential ACT-A prioritization (2021)**
The **timeline for the Strategy & Budget refresh** is driven by a Council Finance Meeting (29 Jan) in advance of the 4th Council meeting.

**6 Jan**
1st Pillar meetings
Align on context, product & assumptions

**11/13 Jan**
2nd Pillar meetings
Strategic adjustments, critical “roadblocks”, prioritized budget

**Week of 18 Jan**
3rd Pillar meetings
Working version of refreshed strategy / budget

**29 Jan**
Council Co-Chair Finance Minister-led Meeting

**9 Feb**
4th Council meeting
Accelerating Vaccine Rollout
Priorities at 7 January 2021

MS COVID-19 Briefing
State of Vaccines (data at 6 January 2021)

COVID-19 vaccination doses administered per 100 people, Jan 6, 2021

Total number of vaccination doses administered per 100 people in the total population. This is counted as a single dose, and may not equal the total number of people vaccinated, depending on the specific dose regime (e.g. people receive multiple doses).

Source: Official data collated by Our World in Data. Dates refer to when the data was reported.
### State of Vaccines: campaigns have started in 42 countries
(data as of 6 January 2021)

<table>
<thead>
<tr>
<th>Country classification by income level(^1)</th>
<th># of countries per income group</th>
<th># of countries where vaccination has started</th>
<th>% of countries where vaccination has started</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIC</td>
<td>83</td>
<td>36</td>
<td>43%</td>
</tr>
<tr>
<td>UMIC</td>
<td>56</td>
<td>6</td>
<td>11%</td>
</tr>
<tr>
<td>LMIC</td>
<td>50</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>LIC</td>
<td>29</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Total</td>
<td>198</td>
<td>42</td>
<td>21%</td>
</tr>
</tbody>
</table>

#### List of countries where vaccination has started
- Austria, Bahrain, Belgium, Canada, Chile, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Kuwait, Latvia, Lithuania, Luxembourg, Malta, Norway, Oman, Poland, Portugal, Romania, Saudi Arabia, Slovakia, Slovenia, Spain, UAE, UK, USA
- Argentina, Bulgaria, China, Costa Rica, Mexico, Russia

---

1. World Bank classification (2021)
Source: World Bank; Our World in data
COVAX has negotiated to contract ~3 Bn doses (December 2020)

COVAX secured volume, in M doses (2021 and 2022)

- Committed doses
- Optional doses

2 B volume target

Volumes from signed deals
- AstraZeneca: 1,100
- J&J: 1,270
- Total: 2,370

Volumes from pre-deal agreements
- SANOFI: 500
- GLAXOSMITHKELLY: 200
- Total: 700

Secured volumes
- >1,000
- 1,970
- Total: 2,970

Other candidates
- 170

Total volume: 3,140

1. The COVAX Facility has secured right of first refusal on some candidates that received investments from the COVAX R&D portfolio (led by CEPI)

2. Single dose regimen; no adjustment to 2 dose regimen
The following Principles for Shared Doses aim to maximize their impact:

- Safe and effective
- Early availability
- Rapidly deployable
- Unearmarked
- Substantive quantity

COVAX is accelerating its work to supplement the Facility’s procured doses with donations. The Principles for Dose-Sharing now provide a way for high-income economies to make additional volumes from bilateral deals available primarily to AMC participants, for this purpose on an equitable basis.

The following Principles for Shared Doses aim to maximize their impact:

- Safe and effective
- Early availability
- Rapidly deployable
- Unearmarked
- Substantive quantity

Shared doses are ideally paid for by the dose-sharing country, including ancillary costs. The Facility ensures these doses are distributed equitably, effectively & transparently while supporting readiness in AMC economies.

“COVAX welcomes commitments by potential dose-sharing countries and manufacturers to adopt these principles and to partner with COVAX to provide additional doses for equitable distribution.”
COVID-19 Vaccines - outlook for equitable access thru COVAX

Medium term (3-6 months) - consolidate

- 2 billion doses
- Deals & pre-Deals: AZ, SII/AZ, SII/Novavax, J&J, Sanofi/GSK, +
- Regulatory pathways; Indemnification framework; Compensation mech
- Country readiness (100:100 initiative)

![Checkmark]

Near term (1-3 months) – accelerate

- Regulatory (see next slides)
- Deals: Pfizer discussion ongoing
- Donations Framework; early endorsers: EC, France, Canada, Norway
- Early rollout-out activity (see next slides)
- Rapid staffing of Allocation Mechanism (see next slides)
Planning for a potential COVAX Facility early rollout activity (e.g. Pfizer vaccine)
Priority: planning for a potential ‘early rollout’ activity (i.e. with limited quantities of Pfizer vaccine)

Key objectives

Meaningful public health impact with limited doses (e.g. target centralized HCWs)

Ensure continuity for countries (e.g. subsequent deliveries of same vaccines, in meaningful volumes within a reasonable timeframe)

Gain critical learnings in 1st wave for full-scale up

Ensure no doses go idle, with timely delivery
COVAX Facility letter on potential early ‘early rollout’ activity issued to all participating countries/economies (6 January 2021)
For the 1\textsuperscript{st} early rollout activity (e.g. with the Pfizer vaccine), countries would need to...

- Express an interest in mRNA vaccines, plan to initiate vaccination before May 2021, and willingness to use more than 1 type of vaccine in the national response\(^1\)

- Agree to use standard labels\(^2\) and rely on WHO EUL or EUA\(^3\) to grant national regulatory authorization for the Pfizer vaccine in January 2021

- Have necessary indemnity & liability frameworks in place in January 2021 and agreement with Pfizer to indemnify it for product liability claims

Have the Minister of Health or other authorizing authority confirm in writing that:

- The above conditions for using the Pfizer vaccine can be fully met in January 2021

Essential elements of an early rollout plan are in place (incl. target group, vaccination strategy, sites, UCC, sufficient ancillary materials, training plan, safety monitoring & reporting process; plan to address financing)

---

1. through the Vaccine Request Form (VRF) for AMC participants, the VIF for self-financing participants, or a subsequent communication
2. Without additional inserts or a language other than Spanish, French, Arabic, English, Chinese or Russian
3. or equivalent by a Stringent Regulatory Authority
Identifying potential ‘early rollout countries’
(e.g. Pfizer activity)

Steps involving Countries/Economies          Date          Steps involving Regions

**Letter** sent out                           Jan 6          Regional engagement cross-agencies

Participants to **confirm interest** with verification that minimum criteria can be met (incl. AMC MoH or equivalent)

COVAX establishes a **short list of participants** that are **confirmed ready**

COVAX to **review country submissions and readiness** based on draft NDVP or first wave plan as well as VRF or VIF

**Dose allocation and a distribution plan** to be recommended by the COVAX **Interim Joint Allocation Taskforce** and/or **Interim Independent Allocation of Vaccine Group**.

**First wave country notification**          Jan 29

Jan 6-18

Regional engagement cross-agencies - general update (demand, supply) and cross-agency alignment
WHO interim recommendation for the use of mRNA BNT162b2 (Pfizer-BioNTech) (1/2)

- BNT162b2 (Pfizer vaccine) has been shown to have an *efficacy* of 95% against symptomatic SARS-CoV-2 infection.

- No data are available related to *impact on transmission* or viral shedding.

- Vaccination is recommended for persons aged 16 years and above.

- The *recommended schedule* is two doses given intramuscularly with an interval of 21–28 days between the doses.

- The need for *flexibility* in the schedule was acknowledged and current data support an extension up to 42 days (6 weeks).

- The same product should be used for both doses. There are no *studies on interchangeability* with other vaccines against COVID-19.
WHO interim recommendation for the use of mRNA BNT162b2 (Pfizer-BioNTech) (2/2): Vaccination of specific populations

- BNT162b2 is not a live vaccine, the mRNA does not enter the nucleus and is rapidly degraded. Animal studies show no toxicity to the fetus, but no data on safety in pregnant women exist.

- SAGE recommends not to use BNT162b2 in pregnancy until more data are available, except where the benefit outweighs risks, such as health workers at high risk of exposure or women with significant comorbidities.

- Vaccination can be offered to breastfeeding women if part of risk group, and WHO does not recommend discontinuation of breastfeeding after vaccination.

- Vaccination can be offered to people living with HIV in accordance to the prioritization roadmap
Expediting Regulatory Review of COVID-19 Vaccines/Products
Priority: expediting regulatory review of key products (data at 7 Jan)

Stringent Regulatory Authority & WHO approvals

- Pfizer: multiple SRAs & WHO (30 Dec)
- Moderna: US, CAN; EMA (week of 4 Jan); WHO (TBD)
- AZ/Oxford: UK; (EMA, FDA, WHO decision Feb/Mar)

National Regulatory Authority (NRA) approvals

- SII/AZ: India (WHO decision Jan/Feb)
- Bharat Biotech: India (‘clinical trial use’)  
- Sputnik: Russia, Argentina; (WHO in discussion)
- Sinopharm: China, UAE, Bahrain; (WHO inspection Jan/Feb)
- Sinovac: TBD; (WHO site inspection Jan/Feb)
WHO PQ/EUL Updates for COVID-19 Vaccines

PQ/EUL update on COVID-19 vaccines

Status of applications/assessments

List of SRAs from which approval will be acceptable, under exceptional circumstances, for product eligibility under the COVAX Facility
https://extranet.who.int/pqweb/sites/default/files/documents/Product-Eligibility_COVAX-Facility_Dec2020_0.pdf

EUL Pfizer report

PQ/EUL update on Immunization Equipment

• Two brands of 0.3 ml AD syringes were PQed 31 December 2020

• ultra-low shipment supplement to WHO shipping guidelines to be published in Q1 2021

• WHO specifications for ULT freezers and associated power requirements, end January 2021
### WHO PQ/EUL assessment timeline for COVID-19 Vaccines
(details at 7 January 2021)

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Name of Vaccine</th>
<th>NRA of Record</th>
<th>Platform</th>
<th>EOI accepted</th>
<th>Pre-submission meeting held</th>
<th>Dossier accepted for review*</th>
<th>Status of assessment**</th>
<th>Anticipated decision date***</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.</strong> Pfizer Biontech</td>
<td>BNT162b2/COMIRNATY</td>
<td>EMA</td>
<td>Nucleoside modified mNRA</td>
<td>☑️</td>
<td>☑️</td>
<td>☑️</td>
<td>Finalized</td>
<td>31/12/20</td>
</tr>
<tr>
<td><strong>2.</strong> Zhifei Longcom, China</td>
<td>Recombinant Novel Coronavirus Vaccine (CHO Cell)</td>
<td>NMPA</td>
<td>Recombinant protein subunit</td>
<td>Not accepted</td>
<td>Product in Phase I/II</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3.</strong> IMBCAMS, China</td>
<td>SARS-CoV-2 Vaccine, Inactivated (Vero Cell)</td>
<td>NMPA</td>
<td>Inactivated</td>
<td>Not accepted, still under development</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>4.</strong> AstraZeneca</td>
<td>AZD1222</td>
<td>Core – EMA Non-COVAX</td>
<td>recombinant replication defective chimpanzee adenovirus expressing the SARS-CoV-2 surface glycoprotein</td>
<td>☑️</td>
<td>☑️</td>
<td>☑️</td>
<td>In progress</td>
<td>Non-Covax. Covax data to be reviewed as EMA post approval change</td>
</tr>
<tr>
<td><strong>5.</strong> SK Bio</td>
<td>AZD1222</td>
<td>MFDS KOREA</td>
<td>=</td>
<td>☑️</td>
<td>☑️</td>
<td>Tentative 18 and 29 Jan 2021 (CMC for SK Bio)</td>
<td>Core data (non-covax) in progress</td>
<td>Earliest end of Feb 2021</td>
</tr>
<tr>
<td><strong>6.</strong> Janssen</td>
<td>Ad26.COV2.S</td>
<td>EMA</td>
<td>recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding the (SARS-CoV-2) Spike (S) protein</td>
<td></td>
<td></td>
<td></td>
<td>Rolling data to EMA – Dec, Feb, April (critical data), May</td>
<td>Not yet started. Use an abridged procedure relying on EMA</td>
</tr>
</tbody>
</table>
## WHO PQ/EUL assessment timeline for COVID-19 Vaccines (cont’d)

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Name of Vaccine</th>
<th>NRA of Record</th>
<th>Platform</th>
<th>EOI accepted</th>
<th>Pre-submission meeting held</th>
<th>Dossier accepted for review</th>
<th>Status of assessment**</th>
<th>Anticipated decision date***</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sinopharm / BIBF²</td>
<td>SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV)</td>
<td>NMPA</td>
<td>Inactivated, produced in Vero cells</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
<td>End of Dec 2020</td>
</tr>
<tr>
<td>sinovac</td>
<td>SARS-CoV-2 Vaccine (Vero Cell), Inactivated</td>
<td>NMPA</td>
<td>Inactivated, produced in Vero cells</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
<td>Tentative early Jan 2021</td>
</tr>
<tr>
<td>Vector State Research Centre of Viralology and Biotechnology</td>
<td>EpiVacCorona</td>
<td>Russian NRA</td>
<td>Peptide antigen</td>
<td>Letter received not EOI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>康希诺生物 / CanSinoBC</td>
<td>Ad5-nCoV</td>
<td>Russian NRA</td>
<td>Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>moderna</td>
<td>mRNA-1273</td>
<td>EMA</td>
<td>mRNA-based vaccine encapsulated in lipid nanoparticle (LNP)</td>
<td>Expected in Jan 2021</td>
<td></td>
<td></td>
<td></td>
<td>Estimated end of Feb 2021</td>
</tr>
<tr>
<td>Serum Institute of India</td>
<td>Covishield (ChAdOx1_nCoV-19)</td>
<td>DCGI</td>
<td>Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.</td>
<td>EOI Under assessment</td>
<td>08 Jan 2021</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sinopharm / WIBF¹</td>
<td></td>
<td>NMPA</td>
<td>No pre-submission meeting yet</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOVAVAX</td>
<td></td>
<td>EMA</td>
<td>No pre-submission meeting yet</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Establishing the Independent Allocation Working Group (IAVG) for the COVAX Facility
**Context:** The IAVG contributes to the validation of Vaccine Allocation Decisions for COVAX Facility

**COVAX Facility**
- **Office of the COVAX Facility**
  Provides data relevant to the allocation
  Ensures Allocation Decision is implemented by COVAX Facility
- **WHO Allocation Unit**
  Provides data relevant to the allocation and prepares the allocation model for the JAT
- **Procurement agencies** *(UNICEF SD, PAHO RF)*
  Provides data relevant to the allocation
  Implement Vaccine Allocation decisions
- **Self-procuring countries**
  Implement Vaccine Allocation Decisions

**Allocation Mechanism**
- **JAT (Joint Allocation Taskforce)**
  Composed of staff from WHO and Gavi’s Office of the COVAX Facility
  Prepares Vaccine Allocation Decision (VAD) proposals for the IAVG based on allocation model
- **IAVG (Independent Allocation Vaccines Group)**
  Composed of independent Experts nominated by Gavi, CEPI and WHO and formally appointed by WHO
  Validates Vaccine Allocation Decisions based on JAT proposal, ensuring it is technically informed and free to conflict of interest (to be signed off by WHO DG/DDG)
Priority: establish the Independent Allocation of Vaccines Group (IAVG) to support the allocation of COVAX Facility Vaccines

**Role**
Validates Vaccine Allocation Decisions based on Joint Allocation Taskforce (JAT) proposal, ensuring it is technically informed and free to conflict of interest (to be signed off by WHO DG)

**Composition**
12 multidisciplinary members appointed by WHO with expertise in the following areas:

- Access to medicines and health products
- Global immunization (incl. program delivery) and/or infectious disease epidemiology
- Emergency public health response
- International health diplomacy, law and policy

Due consideration will be given to the principles of equitable geographical representation and gender balance

**Status**
- Open call launched on Dec 18
- Deadline for nominations on Jan 8th
- Members appointed by WHO in January

*Expressions of Interest* to be sent by **Friday Jan 8th** on IAVGnominations@gavi.org

Backup
State of Vaccines (data at 6 January)

COVID-19 vaccination doses administered, Jan 6, 2021

Total number of vaccination doses administered. This is counted as a single dose, and may not equal the total number of people vaccinated, depending on the specific dose regime (e.g. people receive multiple doses).

- **World**: 15.56 million
- **United States**: 5.31 million
- **China**: 4.5 million (Dec 31, 2020)
- **Israel**: 1.48 million (Jan 5, 2021)
- **United Kingdom**: 944,539 (Dec 27, 2020)
- **United Arab Emirates**: 826,301 (Jan 5, 2021)
- **Russia**: 800,000 (Jan 2, 2021)
- **Germany**: 367,331 (Jan 5, 2021)
- **Italy**: 307,182
- **Canada**: 163,418 (Jan 5, 2021)
- **Spain**: 139,339 (Jan 5, 2021)
- **Bahrain**: 68,472
- **Denmark**: 63,312 (Jan 5, 2021)
- **Argentina**: 52,195
- **Mexico**: 48,236 (Jan 5, 2021)
- **Croatia**: 13,798 (Jan 5, 2021)
- **Estonia**: 5,009
- **France**: 5,000 (Jan 5, 2021)

Source: Official data collated by Our World in Data. Dates refer to when the data was reported. OurWorldInData.org/covid-vaccinations • CC BY