MS COVID BRIEFING

ACT Accelerator Update, COVID-19 Vaccination & Evolving Issues

10 JUNE 2021
ACT-A events & recent developments

Dr Bruce Aylward, Senior Advisor to the Director-General
4 major ACT-A/COVAX events of past 2 weeks emphasize equity for Vx, Dx, Tx, PPE

G20/EC Global Health Summit (21 May)

IMF “Proposal to end the Pandemic” (21 May & 1 Jun)

World Health Assembly incl. IPPPR (24 May – 1 Jun)

Gavi COVAX AMC Summit (2 June)
IMF ‘Proposal to End the Pandemic’

Vaccinate 40% in all countries by end-2021 & 60% by mid-2022
- immediate grant of $4bn to COVAX
- end trade & export barriers
- donate at least 1bn doses

Invest $50B to end pandemic in 12 months
- $35bn in grants (incl 22bn for ACT-A)
- $15bn from MDBs

Manage disease & risks in parallel
- widespread testing, Tx, PPE (invest $30 Bn)

Track & secure against downside risks
- invest at-risk to increase Vx production
- scale up genomic surveillance
I call on Member States to support a massive push to vaccinate at least 10% of every country by September, and a “drive to December” to vaccinate at least 30% by the end of the year.

Sprinting to our September goal means we must vaccinate 250 million more people in LMICs in just four months, with all health workers and the most at-risk groups as the first priority.

World Health Assembly: ‘Sprint to Sept’ & ‘Drive to Dec’

Director-General Dr Tedros Adhanom Ghebreyesus opening remarks, 24 May
AMC Summit announcements to COVAX (2 June)

- **US$ 2.4 Bn** (total $9.6 Bn for procurement & $775 Mn for delivery)
- Vx dose donations 54Mn
- **1.8bn doses for AMC countries**

$800 Mn USD

$50 Mn USD

$50 Mn USD

220 Mn CAD

100 Mn EUR

> 71 Mn EUR
June 9: US announces 500M dose donations ahead of G7

President Joe Biden announced on June 9 that the US will donate 500M doses of the Pfizer-BioNTech vaccine over the next 2 years:

- 200M doses will be distributed in 2021, shipments starting in Aug
- 300M in the first half of 2022

Donations will go through COVAX aimed at the to AMC92 countries.

Biden plans to announce further details as part of the G7 meeting.
Upcoming Key Events for ACT-Accelerator

G7 Summit 11-13 June

7th Facilitation Council July, date tbc

ACT-A Strategic Review July-Sept, tbc
Global vaccine roll-out & regulatory themes

Dr. Soumya Swaminathan, WHO Chief Scientist
Dr. Mariângela Simão, Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals
2.2 Bn doses of COVID-19 vaccine now administered in 215 countries, areas, territories & economies

Total doses administered per 100 population

Vaccination has not yet started in 5 countries

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.

1. Source of data: Bloomberg
2. Total of 220 countries, areas, territories & economies: 218 economies listed by World Bank + WHO Member states Cook Islands + Niue
Incl. 67 LMIC/LICs; 40 participants started their first campaigns thanks to COVAX doses

COVAX has now shipped 81.8M doses to 129 participants

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*Kosovo: All references to Kosovo should be understood to be in the context of the United Nations Security Council resolution 1244 (1999).

Source: COVAX, WHO COVID-19 dashboard, Our World in Data; Government websites; Press research
Of WHO’s 194 Member States, 189 have now started COVID-19 vaccination

1. Burundi, Eritrea, United Republic of Tanzania
2. Haiti
3. Democratic People’s Republic of Korea

Source: WHO COVID-19 dashboard, COVAX, Our World in Data; press reports
10 countries administered 77% of all doses

<table>
<thead>
<tr>
<th>Country</th>
<th>Doses Administered, M</th>
<th>Doses per 100 pop</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>763</td>
<td>55</td>
</tr>
<tr>
<td>United States</td>
<td>302</td>
<td>92</td>
</tr>
<tr>
<td>India</td>
<td>231</td>
<td>18</td>
</tr>
<tr>
<td>Brazil</td>
<td>71</td>
<td>35</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>68</td>
<td>102</td>
</tr>
<tr>
<td>Germany</td>
<td>54</td>
<td>68</td>
</tr>
<tr>
<td>France</td>
<td>40</td>
<td>63</td>
</tr>
<tr>
<td>Italy</td>
<td>38</td>
<td>67</td>
</tr>
<tr>
<td>Mexico</td>
<td>34</td>
<td>27</td>
</tr>
<tr>
<td>Russia</td>
<td>33</td>
<td>23</td>
</tr>
<tr>
<td><strong>Global Total</strong></td>
<td><strong>2.123</strong></td>
<td><strong>28</strong></td>
</tr>
</tbody>
</table>

Source: Bloomberg

61% of all doses were administered by top 3 countries
Upcoming COVAX Allocation Rounds: impt updates

Round 4: Jul/Aug AZ doses for SII participants waiting 2\textsuperscript{nd} doses (~16 m)

Round 5: J&J, Pfizer & remaining AZ supply for Q3 (total max. 66 m)

Allocation team assessing transition to Phase 2 strategy for subsequent rounds (i.e. coverage, mortality rates/trend, absorptive capacity)

Distribution of ‘additional doses’ between allocation rounds continues to be managed by SWAT & JAT (e.g. FR dose-sharing, re-distributions)
Countries now announced further sharing of 145+ m doses, most through COVAX, but timing still challenge (i.e. Q3 gap)

Doses to be shared (as of 10 June 2021), M doses

108+ million doses announced by Team Europe

+5% of all doses will be shared

White house announcement that 75% of 80M doses will go through COVAX in June and additional 200M Pfizer doses should go through COVAX by end 2021

NOTE: all figures are rounded
Source: Gavi
### COVAX Supply chain & Manufacturing Taskforce
#### Status update for the four workstreams

<table>
<thead>
<tr>
<th>Workstream and conveners</th>
<th>Status to date</th>
</tr>
</thead>
</table>
| Immediate COVAX Response (1-3 months)                                                        | • Initiated engagement with WTO and WCO and industry stakeholders to identify options for facilitation of customs and trade<br>• Launching "Input supply marketplace/Exchange"
|                                                                                         | CEPI                                                                                                                                           |
| Mid-Term COVAX Response (until 2022)                                                        | • Identified resourcing bottlenecks, reaching out to relevant training providers; developing intervention plan to facilitate critical workforce travels and immunization<br>• Developed proposal to improve Fill Finish matchmaking
|                                                                                         | CEPI                                                                                                                                           |
| New and expanded sustainable capacity in LMICs                                              | • Completed call for Expression of Interest for mRNA hub tech transfer with 50+ respondents and initiated due diligence process<br>• Issued concept note consulting key stakeholders and launching working groups with partners to support implementation
|                                                                                         | World Health Organization                                                                                                                      |
| Shared fact base / Task Force Coordination Office                                           | • Developed and shared ecosystem mapping<br>• Developing a common supply outlook for expected Vx supply in 2021-23
|                                                                                         | CEPI, Gavi, UNICEF                                                                                                                             |
Travel for Vx workforce

Key challenges around travel of Vx workforce

- Difficulties for technical support personnel to enter some countries to solve manufacturing glitches
  - E.g., need to be vaccinated, go through quarantine, long travel approval processes, differentials in paperwork required between regions
- Currently there exist little to no travel exemptions for Vx workforce
- Travel restrictions for Vx workforce can lead to disruptions of production and supply

Member states should look into all available options to facilitate the travel of Vx workforce
With the addition of Sinovac on 1 June, 8 vaccines have now received WHO EUL

8 vaccines listed

- Pfizer/BioNTech,
- AZ/SII
- AZ x 2 (SK/Bio; EU sites)
- J&J
- Moderna
- Sinopharm (BIBP only)
- Sinovac

Pending

Gamaleya – pending documentation; GcP inspections in April (with EMA); GMP inspections in 4 sites from May 10 to June 3 (2 with EMA)

SAGE Interim Policy Recommendations exist for all products with WHO EUL

IMPT: many donations will require further EULs due to non-COVAX production sites!
WHO validated Sinovac COVID-19 vaccine for emergency use and issued interim policy recommendations on 1 June

Emergency use listing

On June 1st, WHO validated the Sinovac-CoronaVac COVID-19 vaccine for emergency use, giving stakeholders assurance that it meets international standards for safety, efficacy and manufacturing.

Policy recommendations from WHO’s Strategic Advisory Group of Experts on Immunization (SAGE)

On the basis of available evidence, WHO recommends the vaccine for use in adults 18 years and older, in a 2-dose schedule with a spacing of two to four weeks.

Vaccine efficacy results showed that the vaccine prevented:

- Symptomatic disease in 51% of those vaccinated
- Severe COVID-19 and hospitalization in 100%

While limited adults over 60 were enrolled in clinical trials, WHO is not recommending an upper age limit for the vaccine given data collected during subsequent real-world use (efficacy and no heightened safety concerns)
WHO published a simplified naming scheme for variants with neutral language (Greek letters)

<table>
<thead>
<tr>
<th>New WHO name</th>
<th>Transmissibility</th>
<th>Immune evasiveness</th>
<th>Vaccine effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ancestral</td>
<td>...</td>
<td>...</td>
<td>✓</td>
</tr>
<tr>
<td>D614G</td>
<td>...</td>
<td>+</td>
<td>✓</td>
</tr>
<tr>
<td>B.1.1.7</td>
<td>Alpha</td>
<td>+++</td>
<td>✓</td>
</tr>
<tr>
<td>B.1.351</td>
<td>Beta</td>
<td>+</td>
<td>++++</td>
</tr>
<tr>
<td>P.1</td>
<td>Gamma</td>
<td>++</td>
<td>✓</td>
</tr>
<tr>
<td>B.1.429</td>
<td>Epsilon</td>
<td>+</td>
<td>✓</td>
</tr>
<tr>
<td>B.1.526</td>
<td>Iota</td>
<td>+</td>
<td>✓</td>
</tr>
<tr>
<td>B.1.617.2</td>
<td>Delta</td>
<td>++++(^1)</td>
<td>++(^3)</td>
</tr>
</tbody>
</table>

1. Relative transmissibility to B.1.1.7 yet to be fully defined
2. Effectiveness from real world evidence vs. severe illness, not all vaccines are effective vs. all variants and importance of 2-doses, especially for B.1.617.2 for which 1 dose of mRNA or AZ is only approx. 30% effective
3. May carry more immune escape than P.1, to be determined
Global vaccination strategy - progress to date

Dr. Kate O’ Brien, Director, Department of Immunization, Vaccines and Biologicals
Updating the Global Vaccination Strategy

Objective

1. Inform and motivate an equitable approach to COVID-19 vaccination as part of the pandemic control strategy

2. Confirm/update global goal for vaccination based on specified changes in the global context

Methodology

- Specify socio-economic and health goals and strategy along a continuum
- Estimate resource requirements to achieve each goal by country type:
  - Number of doses
  - Supply projections
  - Costing and financing
- Assess each goal by performing high-level feasibility analysis
- Evaluate against 3 future scenarios on epi, demand, supply, resources

Output & deliverables

WHO global COVID-19 vaccine strategy document endorsed by SAGE, including:

- Framework for goal-setting with the associated resource requirements per goal
- Most impactful uncertainties, i.e., factors that would influence achievement of goals
- High-level goal synthesis and updated global goal
Goal framework: Socio-economic goals and vaccination
2022 goals development

1. Indicative framework as other countries have achieved same goals with different combinations (e.g., China);
2. Maps to SPRP 2021 strategic goals of “Protecting the vulnerable” and “Reducing mortality and Morbidity from all causes”

Countries are setting socio economic goals of increasing aspiration, aiming to lift PHSM

To do so while avoiding high mortality from COVID-19 and protecting health workers, countries need to increase their vaccination targets
Goal framework: Health dimension
2022 goals development

Priority group vaccination targets defined according to SAGE Roadmap

- Low
- Medium
- High
- Very high

Countries may also wish to increase their health goal aspiration level, from mortality reduction and health system protection to reducing viral transmission, for instance to reduce emergence and transmission of VoCs.

1. Indicative framework as other countries have achieved same goals with different combinations (e.g., China);
2. Maps to SPRP 2021 “Suppress transmission” strategic goal;
3. Maps to SPRP 2021 strategic goals of “Protecting the vulnerable” and “Reducing mortality and Morbidity from all causes”
Goal framework

2022 goals development

1. Indicative framework as other countries have achieved same goals with different combinations (e.g., China);
2. Maps to SPRP 2021 “Suppress transmission” strategic goal;
3. Maps to SPRP 2021 strategic goals of “Protecting the vulnerable” and “Reducing mortality and Morbidity from all causes”

Goals (global and countries) to be revisited as the pandemic unfolds and new epi data/information becomes available

Ultimately, countries have a continuum of socio economic and health goals they can pursue (non-exhaustive). Each will require a different level of vaccination ambition, different by country type

The framework focuses on vaccination, however must be considered within the broader Strategic Preparedness Response Plan

9 JUNE 2021
Goal-synthesis and deliberation

A What are the resources required to get to different socio-economic and health goals (doses, supply, financing)?

B Given a specific goal, is it feasible for a given country type and in a given time frame?

C Where are countries currently heading in terms of goals?

D What is the potential impact of some countries moving faster than others?

E Should we set a global goal and what should it be?
Considerations for setting a global goal

Preliminary analysis shows that...

Goals

1. Countries setting ambitious but diverse goals
2. WHO has already indicated (SPRP 2021) a strategic objective to suppress transmission using vaccination among other tools
3. Additional institutions proposing time-bounded steps on the goal trajectory

Requirements to meet goal

4. Global supply may be adequate, however distribution across countries is an obstacle particularly in the short term and for LICs
5. System and financial constraints can affect achievement of country goals
6. Certain amounts of capital need to be mobilized that, even if available, might not be attractive for countries (due to debt, tradeoffs on other health priorities, etc.)
Step-wise approach to set the global goal

2. Refers to actual population coverage
3. The IMF targets apply to each country, i.e., 40% vaccinated for each and every country regardless of age distribution, which differs from our age-based global coverage proposal.

Goal description

- **Step 0**: Protecting health care worker and high risk populations
- **Step 1**: Reducing mortality puts countries on trajectory towards resumption of socio-economic activity
- **Step 2**: Targeting reducing disease burden advances countries towards full global recovery
- **Step 3**: Mitigating of future health risks (e.g., VoC) for full global recovery

Timeline

- EOY 2021
- H1 2022
- EOY 2022 – H1 2023

Global proposal

- 20% 50+ incl. HCW
- 40% (22%-50%) 30+ incl. HCW
- 60% (47%-64%) 12+ incl. HCW
- 70-80% 0+ incl. HCW

Disclaimer: these values are not country specific values but global totals (heterogenous across income strata as it will depend on age distribution)

Moving to full global recovery advances through several goal targets.

Global coverage is driven by an analysis of what is required to achieve certain Vx goal (target population, etc.)

Timing of those targets depends on the supply, program absorptive capacity and financing

Source: https://www.washingtonpost.com/opinions/2021/05/31/why-we-are-calling-new-commitment-vaccine-equity-defeating-pandemic/
Timeline to complete Global vaccination work – including consultations

Please contact C-19vaxglobalstrategy@who.int for input, comments and questions
Backup
Of the 17 COVID-19 vaccines now in use, AstraZeneca & Pfizer products are used in the greatest number of countries

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Number of countries &amp; economies using the vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>AstraZeneca - Vaxzevria / SII - Covishield</td>
<td>86</td>
</tr>
<tr>
<td>Pfizer BioNTech - Comirnaty</td>
<td>113</td>
</tr>
<tr>
<td>Beijing CNBG - BBIBP-CorV (Sinopharm)</td>
<td>69</td>
</tr>
<tr>
<td>Moderna - mRNA-1273</td>
<td>61</td>
</tr>
<tr>
<td>Gamaleya - Gam-Covid-Vac (Sputnik V)</td>
<td>55</td>
</tr>
<tr>
<td>Janssen - Ad26.COV 2-S</td>
<td>50</td>
</tr>
<tr>
<td>Sinovac - CoronaVac</td>
<td>37</td>
</tr>
<tr>
<td>Bharat - Covaxin</td>
<td>10</td>
</tr>
<tr>
<td>Novavax - Covavax</td>
<td>5</td>
</tr>
<tr>
<td>Wuhan CNBG - Inactivated</td>
<td>5</td>
</tr>
<tr>
<td>CanSino - Convidecia</td>
<td>4</td>
</tr>
<tr>
<td>SRCVB - EpiVacCorona</td>
<td>2</td>
</tr>
<tr>
<td>Anhui ZL - Recombinant</td>
<td>2</td>
</tr>
<tr>
<td>Adbala</td>
<td>1</td>
</tr>
<tr>
<td>Soberana 02</td>
<td>1</td>
</tr>
</tbody>
</table>

29 economies are using 1 vaccine; 184 are using 2 or more vaccines

1. World Bank classification (2021) of 218 economies. Note: The term country, used interchangeably with economy, does not imply political independence but refers to any territory for which authorities report separate social or economic statistics.

Source: Our World in data, WHO, Government websites; Press research
HICs administered 67x more doses per person than LICs

Cumulative COVID-19 doses administered per 100 population

Switch to WHO data source

Ratio of HIC to LIC

0 doses in LICs

10,000x  200x  84x  69x  67x

SOURCE: Our World in Data (Dec-Mar 7); WHO Dashboard (Mar 12 onwards); source for income groups: World Bank. Using the latest available values for each week.
# Regulatory timeline of key vaccine candidates

**Link** to Status of COVID-19 Vaccines within WHO EUL-PQ evaluation process

## Estimated dates of approval / Emergency use

<table>
<thead>
<tr>
<th>Vx candidates</th>
<th>FDA</th>
<th>MHRA</th>
<th>EMA</th>
<th>WHO EUL/PQ</th>
<th>Regulatory authority of record</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AstraZeneca - Vaxzevria</strong></td>
<td>No FDA approval</td>
<td>Dec. 30, 2020 Emergency Use²</td>
<td>Jan. 29, 2021 Cond. Auth.¹ (non-Covax)</td>
<td>Apr. 15, 2021 (donations only)</td>
<td>EMA</td>
</tr>
<tr>
<td><strong>AstraZeneca – AZD1222</strong></td>
<td>No FDA approval</td>
<td>Not applicable</td>
<td>1 COVAX node</td>
<td>Feb. 15, 2021 Emergency use</td>
<td>MFDS (Rep. Korea)</td>
</tr>
<tr>
<td><strong>SII - Covishield</strong></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Feb. 15, 2021 Emergency use</td>
<td>DCGI (India)</td>
</tr>
<tr>
<td><strong>Beijing CNBG - BBIBP-CorV</strong></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Sinovac - CoronaVac</strong></td>
<td>No FDA approval</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Janssen – Ad26.COV 2-S</strong></td>
<td>Feb. 27, 2021 Emergency Use</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Gamaleya – Sputnik V</strong></td>
<td>-</td>
<td>-</td>
<td>-</td>
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<td>-</td>
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<tr>
<td><strong>CanSino – Ad5-nCOV</strong></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Sinopharm / WIBP</strong>³</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Novavax – Covavax</strong></td>
<td>-</td>
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<td>-</td>
</tr>
</tbody>
</table>

### Key messages

- **WHO EUL**: Pfizer BioNTech – Comirnaty, SII – Covishield, Janssen - Ad26.COV 2.5, AstraZeneca – Vaxzevria/AZD1222, Moderna mRNA-1273, Beijing CNBG - BBIBP-CorV, Sinovac-CoronaVac

- **AstraZeneca**: WHO EUL for European nodes (1 COVAX node and non-COVAX for donations)

- **Gamaleya - Gam-Covid-Vac**: Additional data (NonCLIN, CLIN, CMC) required. Inspections in April, May and June 2021.

- **Bharat and CureVac / Bayer** submitted EOI

- **BioCubaPharma** is in discussions to submit EOI

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1. Conditional marketing authorization
2. Temporary authorisation of supply of the vaccine in the emergency use setting (which is distinct from a marketing authorisation)
3. Wuhan Institute of Biological Products Co Ltd
4. Beijing Bio-Institute of Biological Products Co-Ltd

*SII/Novavax needs to be specified*

WS3: EOI process was initiated Mid April for mRNA tech, closed on May 31 - Due diligence process ongoing

AS OF 07JUNE2021

Call for EOI posted

EOIs submitted

Due diligence

Selection and implementation

EOI call for mRNA tech issued on April 16

Call closed on May 31, 50+ answers received

Top-down review
(Criteria-by-criteria assessment)

Final assessment to be led by WHO committee (PDVAC)

Today

Similar process to be run for recipients in order to initiate training

Subsequent EOIs for other techs to be issued as well (VV, Proteins)

AS OF 07JUNE2021

25+ Responses from potential tech donors and/or sites for hubs

25+ Responses from countries/ manufacturers more likely to be possible recipients

25+ Responses from countries/ manufacturers more likely to be possible recipients

Note: 5 recipients requalified as possible hubs on 09.06 following additional information received

Top-down review
(Criteria-by-criteria assessment)

Bottom-up due diligence
(Detailed questionnaire and government support letter)

AS OF 07JUNE2021

Potential tech donor only (based in China, UK, USA)

Potential tech donor & hub site (based in Belgium, India, South Africa, Thailand)

Potential hub site only (based in Argentina, Bangladesh, Chile, Colombia, India, Indonesia, Italy, Nigeria, Paraguay, Peru, Philippines, Senegal, South Korea, Venezuela)

Potential interest for establishing recipient site (based in Argentina, Brazil, China, Colombia, Cuba, Egypt, India, Indonesia, Kenya, Morocco, Nicaragua, Pakistan, Paraguay, Peru, Rwanda, South Africa, Thailand, Tunisia, Uganda, Uruguay, Vietnam)

Note: 5 recipients requalified as possible hubs on 09.06 following additional information received
Countries have been setting goals beyond 20% total pop: goals are clustered between 50-75% of total population range

Most countries are probably targeting **resumed socio-economic activity while reducing disease burden**. Some countries may be targeting reduced transmission

Variance in goals decreases with income level (HICs consistently ambitious)

HICs and UMICs have deals backing their goals

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1. Indicative framework as other countries have achieved same goals with different combinations (e.g., China); 2. Maps to SPRP 2021 "Suppress transmission" strategic goal; 3. Maps to SPRP 2021 strategic goals of “Protecting the vulnerable” and “Reducing mortality and Morbidity from all causes”