Upcoming ACT-Accelerator Events

Dr Usman Mushtaq
Key upcoming events:

- 23 Apr  **ACT-A 1-Year Event**
- 24-30 April **World Immunization Week**
- 5 May **Facilitation Council Technical Pre-Brief**
- 12 May **6th ACT-A Council (HSC; Vx production)**
- 21 May **ACT-A @ Global Health Summit**
- 24 May – 1 June **World Health Assembly**
ACT-A 1-Year Event - 23 Apr, 15:00-16:30 CEST

Objectives:

- Amplify public & political awareness of ACT-A progress, challenges & needs
- Promote ongoing ACT-A Financing Appeal of Norway & South Africa

Proposed Run of Show

Head of State segment

- From Vision to Reality: ACT-A progress – DG & Co-Founders
- ACT-A Appeal: Challenges & needs - Council Co-Chairs South Africa and Norway

Principals segment

- Media Q&A with ACT-A Principals

Delegations can follow the livestream and submit questions [HERE](#)
6th ACT-A FACILITATION COUNCIL

PRE-BRIEF, 5 MAY 12.30-14.00 CEST

DRAFT AGENDA

1. Health Systems Connector

2. Look ahead to the 6th Council

Delegations can register HERE

6th COUNCIL, 12 MAY 12.30-15.00 CEST

DRAFT AGENDA

   Interactive panel discussion with countries & council members

2. Scale up of vaccine manufacturing
   Interaction with COVAX Task Force on expanding vaccine production

Proceeding will be livestreamed for all Member States on the ACT Accelerator site
Overview of COVID-19 Vaccine Rollout

Dr. Soumya Swaminathan
944 m doses of COVID-19 vaccine have been administered\(^1\) in 205 countries, areas, territories \& economies\(^2\)

15 economies have not yet started vaccination

1. Source: Bloomberg. 77% in top 10 countries (largely high income and/or vaccine-producing countries); 2. Source of this list of 220 countries, areas, territories \& economies: 218 economies listed by World Bank + WHO Member states Cook Islands + Niue


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 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.
Of WHO’s 194 Member States, 179 have started COVID-19 vaccination
at least 1 additional MS received vaccine & can start in the coming days

WHO Member States
N= 194

AFRO
N= 47

AMRO
N= 35

EMRO
N=21

EURO
N= 53

SEARO
N= 11

WPRO
N=27

1 Burkina Faso, Burundi, Central African Republic, Chad, Eritrea, Madagascar, United Republic of Tanzania
2 Cuba, Haiti
3 Democratic People’s Republic of Korea
4 Kiribati, Samoa, Vanuatu, Cook Islands, Niue

Source: WHO COVID-19 dashboard, COVAX, Our World in Data; press reports
COVAX has now shipped 40.8M doses to 117 participants
incl. 59 LMIC/LICs; 35 participants started their first campaigns thanks to COVAX doses

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.

*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 the 11 COVID-19 vaccines now in use, AstraZeneca & Pfizer products are the most prevalent

<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>56</td>
</tr>
<tr>
<td>Pfizer BioNTech - Comirnaty</td>
<td>56</td>
</tr>
<tr>
<td>Beijing CNBG - BBIBP-CorV / Wuhan CNBG - Inactivated (Sinopharm)</td>
<td>57</td>
</tr>
<tr>
<td>Moderna - mRNA-1273</td>
<td>56</td>
</tr>
<tr>
<td>Gamaleya - Sputnik V</td>
<td>46</td>
</tr>
<tr>
<td>Sinovac - CoronaVac</td>
<td>28</td>
</tr>
<tr>
<td>Janssen - Ad26.COV 2.5</td>
<td>24</td>
</tr>
<tr>
<td>Bharat - Covaxin</td>
<td>9</td>
</tr>
<tr>
<td>Novavax - Covavax</td>
<td>5</td>
</tr>
<tr>
<td>SRCVB - EpiVacCorona</td>
<td>2</td>
</tr>
</tbody>
</table>

45 economies are using 1 vaccine; 160 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
COVAX supply through AZ/SK Bio & Pfizer is improving; but SII risk for deliveries is increasing...

- **AZ/SK Bio** aims to deliver balance of allocations in 2 shipments (late Apr & May)
- **Pfizer** aims to complete 1st wave in early May & start next 47 countries (14 m doses)
- **SII** COVAX deliveries uncertain in coming months & COVAX exploring contingencies (e.g. AZ/SK Bio June volumes)
### 6 urgent & ongoing initiatives to increase supply to COVAX

<table>
<thead>
<tr>
<th></th>
<th>Initiative</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>SII: working with Govt of India COVAX supply for coming months</td>
</tr>
<tr>
<td>2</td>
<td>AZ/SK Bio: accelerate release, rollout &amp; target territory</td>
</tr>
<tr>
<td>3</td>
<td>Expedite delivery of newly EUL’d products through COVAX (e.g. J&amp;J)</td>
</tr>
<tr>
<td>4</td>
<td>Pursue donations of vaccines that have WHO Emergency Use Listing (e.g. New Zealand, France)</td>
</tr>
<tr>
<td>5</td>
<td>Expedite EUL review of new products (e.g. Sinopharm, Sinovac, Gamaleya)</td>
</tr>
<tr>
<td>6</td>
<td>Expand global manufacturing capacity of COVID-19 vaccines</td>
</tr>
</tbody>
</table>
We must leverage this unique moment to build sustainable regional health security through expanding LMIC vaccine manufacturing capacity.

There is an urgent, near-term need to unlock additional COVID vaccine supply...

- Address bottlenecks of existing supply chain, in particular Fill/Finish
- Increase number of facilities producing COVID vaccines

...but a long-term solution is also critical to ensure equitable access to vaccines and ensure regional health security

- Currently a severe lack of manufacturing capacity in LMIC regions
- Regions with production capacity first in line to vaccinate population

On April 16, WHO issued a call for EOI to establish mRNA vaccine technology transfer hub; to be followed by other technologies: Link
The COVID Vaccine Capacity Taskforce was launched to address these challenges, with Pillar 3 focused on a long-term solution.

**Pillar 1**
Immediate response

**Unlocking bottlenecks**
- Implement immediate upstream supply chain solutions
- Create input supply visibility partnership
- Expand Fill/Finish match making mechanisms / partnerships

**Pillar 2**
Short-term response

**Bilateral Tech Transfer**
- Promote voluntary bilateral tech transfer to existing manufacturers
- Stimulate workforce development

**Pillar 3**
Longer-term

**Multilateral Tech Transfer and LMIC capacity expansion**
- Ensure Tech Transfer hubs and/or voluntary Tech Transfers
- Multilateral training and transfer to existing and new facilities (both COVID and routine vaccines)
- Support member states to establish sustainable regional health security
**Pillar 3 | Approach to establish hubs for tech transfer to LMICs**

Envisioning a global network of technology transfer hubs dedicated to LMIC uptake

Centralized hubs would facilitate multilateral tech transfer to many regionally distributed LMIC manufacturing sites

LMICs Recipients acquire technology to rapidly scale production of best candidate vaccines during pandemics

Recipient facilities would pursue sustainable business models between pandemics

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1. Manufacturers could voluntarily serve as centralized hubs if interested
Allocation & regulatory update
Dr Mariângela Simão
COVAX has announced 3\textsuperscript{rd} allocation round (14m doses Pfizer)\textsuperscript{1}

<table>
<thead>
<tr>
<th>Round #1</th>
<th>Round #2</th>
<th>Round #3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Announced</td>
<td>3 February</td>
<td>2 March</td>
</tr>
<tr>
<td>Period</td>
<td>February-March</td>
<td>January-May</td>
</tr>
<tr>
<td>Vaccine &amp; Number of doses</td>
<td>Pfizer 1.2M doses</td>
<td>SII &amp; AZ/SK Bio 237M doses</td>
</tr>
<tr>
<td>Number of participants</td>
<td>18 participants</td>
<td>142 participants: 60 SII; 82 AZ/SK Bio</td>
</tr>
</tbody>
</table>

\textsuperscript{1} Q3 allocation expected to be conducted by mid-May
Source: COVAX
## Regulatory timeline of key Vx candidates

### 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>AstraZeneca - Vaxzevria (AZ with EMA as authority of reference)</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>AstraZeneca – AZD1222 (AZ with EMA as authority of reference)</td>
<td>No FDA approval</td>
<td>Not applicable</td>
<td>1 COVAX node</td>
<td>Apr. 15, 2021, 1 COVAX node</td>
<td>EMA</td>
</tr>
<tr>
<td>AstraZeneca – AZD1222 (AZ South Korea w/ MFDS Korea as authority of record)</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Feb. 15, 2021 Emergency use</td>
<td>MFDS (Rep. Korea)</td>
</tr>
<tr>
<td>SII /AZ vaccine (Covishield) with DCGI India as authority of record</td>
<td>SII - Covishield</td>
<td>-</td>
<td>-</td>
<td>Feb. 15, 2021 Emergency use</td>
<td>DCGI (India)</td>
</tr>
<tr>
<td>Sinopharm / BIBP⁺</td>
<td>Beijing CNBG - BBIBP-CorV</td>
<td>No FDA approval</td>
<td>No EMA approval</td>
<td>April 2021 (Earliest)</td>
<td>NMPA</td>
</tr>
<tr>
<td>Sinovac - CoronaVac</td>
<td>No FDA approval</td>
<td></td>
<td></td>
<td>May 2021 (Earliest)</td>
<td>NMPA</td>
</tr>
<tr>
<td>Janssen – Ad26.COV 2.5</td>
<td>Feb. 27, 2021 Emergency Use</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gamaleya – Sputnik V</td>
<td></td>
<td></td>
<td></td>
<td>Rolling submission started - Add. data awaited</td>
<td>Russian NRA</td>
</tr>
<tr>
<td>CanSino – Ad5-nCOV</td>
<td></td>
<td></td>
<td></td>
<td>Rolling submission of data from April 2021</td>
<td>NMPA</td>
</tr>
<tr>
<td>Wuhan CNBG - Inactivated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Novavax – Covavax*</td>
<td></td>
<td></td>
<td></td>
<td>Novavax submitted EOI on 23 Feb</td>
<td>EMA</td>
</tr>
</tbody>
</table>

### Key messages

- **WHO EUL**: Pfizer BioNTech – Comirnaty, SII – Covishield, Janssen - Ad26.COV 2.5, AstraZeneca – Vaxzevria/AZD1222
- **AstraZeneca**: WHO EUL for selected European nodes with EMA as authority of record (1 COVAX node and non-COVAX for donations)
- Focus on assessment of Beijing CNBG - BBIBP-CorV, Sinovac - CoronaVac and Moderna - mRNA-1273
- Gamaleya: Additional data (NonCLIN, CLIN, CMC) required. Inspections in April, May and June 2021. EUL decision after inspections
- Novavax pre-submission meeting planned for May 7
- Bharat and CureVac / Bayer have submitted an EOI
- BioCubaPharma is in discussions to submit EOI

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* SII/Novavax needs to be specified

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

SAGE recommendations update
Dr Kate O’Brien
Rare safety related events have prompted regulatory and policy reviews of AstraZeneca vaccines: positive benefit-risk assessment

AstraZeneca – Vaxzevria and SII - Covishield

**Regulatory authorities**

- **MHRA** issues new advice, considering possible link between COVID-19 vaccine AstraZeneca and extremely rare, unlikely to occur blood clotting events
- **EMA** confirm overall benefit-risk remains positive
- **MHRA**: “benefits of vaccination continue to outweigh any risks”
- **EMA**: Updates to product information leaflet sections 4.4 Special warnings and precautions for use & 4.8 Undesirable effects (very rare adverse event)
- **EMA’s** human medicines committee (CHMP) is conducting a further assessment using more data

**WHO Safety**

- **WHO GACVS** 16 April

**Key messages**

- Review of global data
- The **biological mechanism** for this syndrome of TTS is still being investigated
- A ‘**platform specific**’ mechanism related to the adenovirus-vectored vaccines is not certain but cannot be excluded

**Policy**

- Some countries have adjusted their policy use recommendations to specify age
- Some of them have reversed or adjusted these policies
- SAGE has updated interim recommendations based on GACVS statement and including other updates (22 April)
Rare safety related events have prompted regulatory and policy reviews of Janssen vaccines

Janssen – Ad26.COV 2.5

Overview of messages

• **US CDC & FDA have paused** use of Janssen vaccine in the US. Full safety assessment is ongoing

• “**EMA confirms overall benefit-risk remains positive**”

• **EMA: Updates to product information leaflet** sections 4.4 Special warnings and precautions for use & 4.8 Undesirable effects (very rare adverse event)

• **No other regulatory changes by EMA**

**Who Safety**

• **GACVS will continue to monitor & assess evolution of data from all countries**

**Policy**

• **Limited set of countries have paused roll-out** (e.g. South Africa)

• **Limited set of countries have adjusted their policy use** recommendations to specify age (e.g. Italy to over 60s)

• **WHO SAGE is monitoring and assessing evolution of data & regulatory decisions**
Disclaimer - Update of SAGE recommendations on AstraZeneca and SII vaccine products

As of 22/04 at 12:00 CET, the April 2021 update to the SAGE Interim Recommendations on AstraZeneca group of vaccines is **not yet finalized** and the listed revisions are still subject to change.

The updated document will be available online shortly at this location on the WHO website:

Update of SAGE policy recommendations on AstraZeneca and SII vaccine products (22 April)

### No substantial change in policy

- Overall recommendations remain the same
- Benefits of these vaccines largely outweigh the risks
- Latest data allowed more precision in recommendation language and characterization of risks

### Overview of changes

- ChAdOx1-S vaccine products are considered as **equivalent and interchangeable**
- More data on **efficacy of vaccines in 65+**
- **Opened multi-dose vaccine vials to be maintained at** 2°C to 8°C during the in-use period
- **Text on precautions now includes** Thrombosis with Thrombocytopenia Syndrome (TTS)
WHO COVID-19 Partners Platform
Dr Kate O’Brien
Member States can upload their resource needs on the WHO Partners’ Platform in the coming weeks

Context

- COVID-19 vaccination campaigns require significant financial resources for operational needs and vaccine purchase

- In order to contribute to the funding of these campaigns, donors need to have a clear view on resource needs of Member States

- From April 30th, Member States will have the opportunity to upload their resource needs on the WHO Partners’ Platform

- This platform can be used as a tool to have discussions with MoF, MoH, immunization partners, donors, and other stakeholders

Overview of the WHO Partners’ Platform

- The WHO Partners’ Platform is accessible via this link

- There will be two ways to upload resource needs:
  1. Upload the CVIC tool Excel spreadsheet
  2. Use a manual drop-down menu
4 reasons why uploading your needs on the Platform is important

1. **Prepare, plan and cost needs associated to your COVID-19 vaccination campaign** - WHO has released a new version 2.1 of the “COVID-19 vaccine introduction and deployment costing tool” (CVIC) tool, available [here](#).

2. **Help you identify the gaps between country plan needs and existing resources**

3. **Get access to transparent donor information to help mobilize resources globally**

4. **Use the Platform to inform discussions with MoF, MoH, immunization partners, donors, and other stakeholders**