UPDATE on COVID-19 Vaccines Rollout

WHO Member States information Session

18 FEBRUARY 2021
Recent developments

1. WHO EUL for AstraZeneca vaccine

2. Interim SAGE recommendations for Oxford/AstraZeneca vaccine

3. Next steps for accelerated roll-out of COVAX Facility vaccines
State of Vaccines: key numbers (data at 18 February 2021)

- **74 days** since first countries started vaccinating¹ and **52 days** since all EU countries received vaccines

- **187 million vaccine doses** have been administered:
  - ~83% of these doses have been administered in 10 countries
  - At least 8 different vaccines (3 platforms) have been administered²

- Campaigns **have started in 84 economies**:
  - incl. 55 HICs, 17 UMICs, 11 LMIC and 1 LIC
  - Pfizer-BioNTech vaccine is by far the most used vaccine (59 economies using it), followed by Oxford/AZ (40 economies), Moderna (27 economies), Sinopharm (10 economies) and Gamaleya (10 economies)

1. Dec. 8, 2020 in the UK (Pfizer)
2. Pfizer, Moderna, Gamaleya, Sinovac, Sinopharm, SII, Bharat Biotech, AZ

Source: Our World in data; Bloomberg
WHO Emergency Use Listing (EUL) – indicative review timelines

31st December: Pfizer/BioNTech

15th February: AZ/Serum Institute of India
AZ/SK Bio, Korea

End Feb: Moderna

March: Sinopharm BIBP
Sinovac

March/April: J&J*

In discussion: Gamaleya
Novavax

* Abridged procedure - EMA

https://extranet.who.int/pqweb/key-resources/documents/status-covid-19-vaccines-within-who-eulpq-evaluation-process
https://extranet.who.int/pqweb/sites/default/files/documents/Product-Eligibility_COVAX-Facility_Dec2020_0.pdf
WHO SAGE interim recommendation for the use of AZD1222

• AZD1222 has been shown to have an **efficacy of 63.1%** \(^1\) against symptomatic SARS-CoV-2 infection (3-23 wk dosing interval).

• Vaccination is recommended for persons aged **18 years and above**.

• The **recommended schedule** is two doses given intramuscularly with an interval of **8 – 12 weeks** between the doses.

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

• The same product should be used for both doses. There are no studies on **interchangeability** with other vaccines against COVID-19.

• Countries are recommended to use the WHO **Prioritization Roadmap** and the WHO **Values Framework** as guidance for their prioritization of target groups.

---

1. (95% CI 51.8; 71.7)
Countries, territories and areas reporting SARS-CoV-2 variant VOC 202012/01 as of 16 February 2021

Countries, territories and areas reporting SARS-CoV-2 variant 501Y.V2 as of 16 February 2021
COVID-19 Vaccine and SARS-CoV2 variants  
*Data are limited, early, and incomplete*

**Availability of Evidence (10 Feb 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>Clinical</td>
<td>Clinical</td>
<td>Clinical</td>
<td>Clinical</td>
</tr>
<tr>
<td>Lab</td>
<td>pending</td>
<td>limited</td>
<td>pending</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>✔</td>
<td>limited</td>
<td>pending</td>
</tr>
<tr>
<td>J &amp; J</td>
<td>prelim</td>
<td>prelim</td>
<td>pending</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>prelim</td>
<td></td>
</tr>
</tbody>
</table>

Evidence on protection against severe disease, hospitalization and deaths are especially limited
### COVID Vaccines and the B.1.351 virus 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>-</td>
<td>-</td>
<td>91.6%</td>
<td>-</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)</td>
<td>89%</td>
<td>Mild, moderate &amp; severe</td>
</tr>
<tr>
<td>Sinopharm</td>
<td>1.6x</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. Sources global: 1. The Lancet on AZ/Oxford, The Lancet on Sputnik V, Bloomberg on Sinovac, Bloomberg on Sinopharm, Novavax website, J&J website.
Considerations of AstraZeneca Vaccine and SARS-CoV2 variants

- Slightly reduced vaccine effectiveness of AZD1222 against B1.1.1.7 in the United Kingdom and limited reduction in neutralizing antibody (Preliminary analyses)

- B.1.351 virus variant:
  - Phase 1/2a trial in South Africa indicate marked reduction in vaccine effectiveness against mild and moderate disease based on a small sample size and substantial loss of neutralizing antibody activity (Preliminary analyses)
  - Indirect evidence is compatible with protection against severe COVID-19, however this remains to be demonstrated in ongoing clinical trials and post-implementation evaluations. (Preliminary analyses)

- WHO currently recommends the use of AZD1222 vaccine according to the Prioritization Roadmap even if variants are present in a country.

- Countries should conduct benefit-risk assessment according to the local epidemiological situation.

- These preliminary findings highlight the urgent need for a coordinated approach for surveillance and evaluation of variants and their potential impact on vaccine effectiveness.
COVID-19 Vaccine Introduction Toolbox

- repository for resources and training documents
- help countries in their preparation to rollout COVID-19 vaccines
- updated frequently to ensure the webpage is complete

The Toolbox slide deck will be sent to countries, including all the links to guidance, tools, training, …

For comments, questions, queries, and/or feedback, please contact COVID19vaccineresources@who.int
NEXT STEPS: 5 key action for COVAX AstraZeneca & Pfizer Rollout

Red = urgent action from countries needed

Regulatory & PQ\textsuperscript{1}
- Country regulatory authorization for Pfizer, AZ/SK Bio & AZ/SII (asap)
- Issue import licenses for vaccine shipments (as applicable)

Policy & Guidance
- Country plan for priority populations to match supply (SAGE Pfizer & AZ recs)

Preparedness & Readiness
- Execute indemnity & liability agreements (asap)
- Trainings and Simulations

Vaccine Volumes
- COVAX confirmation of volumes & allocation of Q1 doses (week 15 Feb)
- Full allocation mechanism for March-May doses by week of 22 Feb

Product deliveries
- COVAX Facility, Unicef & PAHO initiating Purchase Orders (from 18 Feb onwards!)

\textsuperscript{1} https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_01Feb2021.pdf
\textsuperscript{2} 94 NDPs (National Deployment & Vaccination Plans) completed with 83 of 87 from AMC countries (5 AMC countries opted out)
BACK-UP
Immediate next steps to ensure first roll-out

<table>
<thead>
<tr>
<th>February doses (early POs for SII)</th>
<th>Formal allocation</th>
<th>I&amp;L submitted</th>
<th>I&amp;L signed</th>
<th>Regulatory approval</th>
<th>Import licence</th>
<th>Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Jan 30</td>
<td>7/7</td>
<td>0/7</td>
<td>7/7</td>
<td>TBD</td>
<td>5/7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>First allocation (March doses and later)</th>
<th>Formal allocation</th>
<th>I&amp;L submitted</th>
<th>I&amp;L signed</th>
<th>Regulatory approval</th>
<th>Import licence</th>
<th>Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer (1st wave)</td>
<td>Jan 30</td>
<td>0/18</td>
<td>0/18</td>
<td>7/18</td>
<td>TBD</td>
<td>TBC</td>
</tr>
<tr>
<td>SII</td>
<td>Feb 23</td>
<td>18/53</td>
<td>0/53</td>
<td>3/53</td>
<td>TBD</td>
<td>1/53 (TBC)</td>
</tr>
<tr>
<td>AZ</td>
<td>Feb 23</td>
<td>14/85</td>
<td>1/85</td>
<td>1/85</td>
<td>TBD</td>
<td>TBC</td>
</tr>
</tbody>
</table>

Next steps for countries:
1) **Execute I&L agreements** (incl. legislative requirements as applicable)
2) **Provide proof of regulatory approval to COVAX Facility**
3) **Approve import license** (as applicable)

PRELIMINARY – TO BE CONFIRMED

UPATED: 17 Feb 2021 12pm
## NDVP submission and review data

Data as of 16 Feb

### Total NDVPs submitted for review through PP
- **101** Total NDVPs submitted for review through PP
- **86** AMC92 submitted
- **6** AMC92 not submitted

### NDVPs validated by MoH of those submitted
- **93** of NDVPs submitted have been validated by MoH
  - **92%**

### AMC 92 countries not submitted

<table>
<thead>
<tr>
<th>Country</th>
<th>Updates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burundi</td>
<td>Not decided on vaccine introduction</td>
</tr>
<tr>
<td>Central African Republic</td>
<td>Expected to submit NDVP later</td>
</tr>
<tr>
<td>Eritrea</td>
<td>No information available</td>
</tr>
<tr>
<td>Madagascar</td>
<td>Not decided on vaccine introduction</td>
</tr>
<tr>
<td>Marshall Islands</td>
<td>Not decided on vaccine introduction</td>
</tr>
<tr>
<td>Tanzania</td>
<td>Not decided on vaccine introduction</td>
</tr>
</tbody>
</table>

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city, 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.
### NDVP Standard Review Form (SRF) Minimal Requirements Outcome

<table>
<thead>
<tr>
<th>RRC outcome</th>
<th>AFR</th>
<th>AMR</th>
<th>EMR</th>
<th>EUR</th>
<th>SEAR</th>
<th>WPR</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved</td>
<td>35</td>
<td>5</td>
<td>4</td>
<td>10</td>
<td>8</td>
<td></td>
<td>62</td>
</tr>
<tr>
<td>Approved with minor revisions</td>
<td>5</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td></td>
<td></td>
<td>23</td>
</tr>
<tr>
<td>Major revisions/resubmission</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>35</td>
<td>10</td>
<td>11</td>
<td>6</td>
<td>10</td>
<td>14</td>
<td>86</td>
</tr>
</tbody>
</table>

**Data at 16 Feb 2021**

**Graph:**
- Approved
- Approved with minor revisions
- Major revisions/resubmission

<table>
<thead>
<tr>
<th>Region</th>
<th>Approved</th>
<th>Approved with minor revisions</th>
<th>Major revisions/resubmission</th>
</tr>
</thead>
<tbody>
<tr>
<td>WPR</td>
<td>8</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>SEAR</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EUR</td>
<td>4</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>EMR</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMR</td>
<td>35</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Additional priorities to assure rollout

<table>
<thead>
<tr>
<th>Area</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emerging hot topics</td>
<td><strong>Costing for vaccine delivery</strong>, e.g. budgets need to be fine-tuned or developed</td>
</tr>
<tr>
<td></td>
<td><strong>Securing resources to deliver vaccine</strong>, including govt resources, reprogramming of WB funds, other</td>
</tr>
<tr>
<td></td>
<td><strong>Microplanning</strong> for vaccine delivery</td>
</tr>
<tr>
<td></td>
<td><strong>Risk communications and vaccine acceptance</strong> and demand</td>
</tr>
<tr>
<td></td>
<td><strong>HR planning</strong>, e.g. explore task shifting and mobilize all needed HR resources</td>
</tr>
</tbody>
</table>
**Indemnity agreements**

**AMC92**

- **Model Indemnity Agreement** agreed with manufacturers and shared with AMC92

- A **compensation program** for AMC92 participants to cover serious adverse events arising from vaccines received through COVAX is being established

**SFPs**

- SFPs without bilateral deals will be provided with manufacturer-specific indemnity

**I&L support to AMC92 countries**

**O’Neill Institute for National and Global Health Law (at Georgetown Law)**

- Agreement with Gavi on 14 Jan 2021
- Support elements:
  - a **list of concrete legislation or executive actions of other countries**
  - a **concise checklist of principles** to have the necessary legislation
  - a **preliminary (and non-exclusive) list of consultants** that countries can choose to work with in drafting the required legislation

**Additional Support in Development**


OpenWHO COVID-19 Course Series: [https://openwho.org/covid-19](https://openwho.org/covid-19)
No-Fault Compensation Program

Details

The program is for AMC eligible economies to provide no-fault lump-sum compensation in full and final settlement of any claims to persons who suffer a SAE resulting in permanent impairment or death associated with the use or administration of a COVID-19 vaccine made available through the Facility.

Individuals will be able to apply for compensation under the Program even if the SAEs arise from vaccines administered before the Program is fully operational.

Next Steps

- Identify if any legislative action is needed to enable I&L agreements
- Implement such legislative action

Once the Compensation Program has been established, AMC92 countries will need to:

- Make “How to Submit an Application” instructions (as provided by the Program’s independent claims administrator in due course) available to vaccine recipients, inform healthcare professionals and raise awareness in the country.

- Work with independent claims administrator to facilitate the submission and investigation of claims, as well as the exchange of safety information.

Further information will be made available once the Compensation Program is closer to launch.

Country Readiness and Delivery webpage: https://www.who.int/initiatives/act-accelerator/covax/covid-19-vaccine-country-readiness-and-delivery
OpenWHO COVID-19 Course Series: https://openwho.org/covid-19
SAGE policy recommendations (to date, 18 Feb 2021) - Products with WHO/EUL or SRA

**WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccines**  
14 Sep 2020

**WHO SAGE Roadmap for Prioritizing Uses Of COVID-19 Vaccines In The Context Of Limited Supply**  
13 Nov 2020

Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing  
5 Jan 2021

Interim recommendations for use of the Moderna mRNA-1273 vaccine against COVID-19  
25 Jan 2021

Interim recommendations for use of the AZD1222 (ChAdOx1-S (recombinant)) vaccine against COVID-19 developed by Oxford University and AstraZeneca  
8 Feb 2021

[Links to relevant documents]

https://www.who.int/publications/i/item/interim-recommendations-for-use-of-the-moderna-mrna-1273-vaccine-against-covid-19  