DAY 3

COVID-19

VACCINE INDUSTRY CONSULTATION 2023
COVID-19 vaccine deliveries – 2.1 billion doses shipped

COVAX*, AVAT and Others

COVAX: 1.97bn (822.3 million procured, 1.14 billion donated) Delivered to 146 countries

AVAT: 146.8 mil (139.5 million procured, 7.4 million donated) Delivered to 45 countries

Other: 30.9 million procured and donated Delivered to 20 countries

2023 overall deliveries: A total of 96 million (including 83.4 million doses for COVAX)

*COVAX APA includes Cost-Sharing. COVAX Donation includes HB and USG facilitated doses.
COVID-19 vaccine deliveries – products

Products from 8 manufacturers across 4 vaccine platforms
## COVAX to C19 transition

<table>
<thead>
<tr>
<th>COVAX</th>
<th>C19</th>
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<tbody>
<tr>
<td>COVAX delivered vaccine to 146 countries, incl. 92 LICs and MICs</td>
<td>C19 program for AMC91 for 24/25 approved by Gavi Board</td>
</tr>
<tr>
<td>COVAX is ending at the end of 2023</td>
<td>High-risk populations with periodic booster dose</td>
</tr>
<tr>
<td>The last deliveries for delivery by year end</td>
<td>GAVI54 and AMC37</td>
</tr>
<tr>
<td>Supply through COVAX APAs and donations</td>
<td>UNICEF tendered supply + small donations + COVAX doses</td>
</tr>
<tr>
<td>Procurement and shipping through UNICEF and PAHO</td>
<td>End to end supply management through UNICEF and PAHO</td>
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**DEMAND?**
DEMAND

• Demand remains uncertain as the program transitions

• Desk study indicates demand of 60-90 mds for AMC91 assuming 17% coverage in target population

• Gavi approvals in Wave 1 indicate higher coverage, but remains uncertain

• UNICEF forecast and Wave 2 applications

• UNICEF will monitor and work closely with suppliers

The scope of the tender includes LICs and LMICs (Gavi's AMC91) eligible for support under the C19 program, as well as other countries traditionally receiving vaccine through UNICEF.

As a result of the RFP, UNICEF and PAHO will award separate non-exclusive Long-Term Arrangement(s) (LTAs) for the procurement of the vaccines.

UNICEF will be conducting staged awards in September 2023 and January 2024 (tbc) following the Gavi Country Application Waves 1 and 2.

Complexities

Demand is hard to predict, with several factors impacting demand

Large and diverse Covid-19 vaccine supplier base

Upcoming SAGE recommendations will impact demand and supply portfolio

Evolving virus and vaccine composition – new strains
C19 Tender Objectives (short term 2024-2025)

- Ensure **timely access to quality assured COVID-19 vaccine**, respecting country product preference to the extent that supply security is not compromised.
- Secure **sustainable prices** that attract manufacturers and are deemed affordable to donors and countries.
- Ensure **manufacturers’ capacity to scale up** in case of a surge in demand.
- Maintain **vaccine security**, in the form of sustained and uninterrupted supply of affordable vaccines of assured quality, through strategic awards and a diversified supply base.
• EUL remains valid while products transition to full PQ. New products must go directly for PQ

• Permissive statement to use EUL'ed BA.4/5 for primary series use – EUL/PQ pending, but....

• Recommendation for vaccine composition – XBB strain vaccine

• XBB expected to be approved for 'immunized' people

• Updated WHO SAGE recommendations expected following SAGE meeting in September
SAGE – Updated Roadmap (March ‘23)

Major changes to WHO SAGE Roadmap on uses of COVID-19 vaccines in the context of Omicron and substantial population immunity:

- Moving to only **3 groups** mostly defined by clinical risk
- **Differential approach** to recommending primary series and additional boosters by priority-use group
  - **12-month interval** for an additional booster for individuals in the **high priority-use groups**
  - Additional booster dose **during pregnancy** if last dose was given more than 6 months ago.
  - Additional booster dose for **frontline health workers** 12 months after the last dose.
- Taking into account increasing **hybrid immunity**, and increasing infection-induced immunity globally
- **Compare COVID-19 vaccination with established metrics** for other vaccine-preventable diseases (e.g. cost/benefit), plus programmatic considerations and community acceptance
- Considering **post-COVID** conditions

### WHO Interim Recommendations* for the optimal use of COVID-19 vaccination: primary series and booster doses in the context of Omicron and high population-level immunity

<table>
<thead>
<tr>
<th>Target population</th>
<th>Primary series and booster*</th>
<th>Additional booster doses</th>
<th>Remarks</th>
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</thead>
<tbody>
<tr>
<td><strong>HIGH priority-use groups</strong></td>
<td></td>
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<tr>
<td>Older adults1</td>
<td>Recommended</td>
<td>Recommended (12 months after previous dose)</td>
<td>Most efficient use of COVID-19 vaccines with greatest impact on reducing deaths.</td>
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<tr>
<td>Younger adults with significant comorbidities or severe obesity1</td>
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<tr>
<td>Subgroup of older adults: oldest adults1</td>
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<tr>
<td>Older adults with multiple significant comorbidities1</td>
<td></td>
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<tr>
<td>Adults, adolescents and children 0 months to 17 years with severe immunocompromising conditions2</td>
<td>Recommended as extended primary series2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnant adults and adolescents1</td>
<td>Recommended</td>
<td>Recommended (approximately 6 months after previous dose; optimal time interval should be discussed with the treating physician)</td>
<td></td>
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<tr>
<td>Frontline health workers</td>
<td>Recommended</td>
<td>Recommended (12 months after previous dose)</td>
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<tr>
<td><strong>MEDIUM priority-use groups</strong></td>
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<tr>
<td>Healthy younger adults2, children and adolescents aged 18 months to 17 years with severe obesity or comorbidities that put them at higher risk of severe COVID2</td>
<td>Recommended</td>
<td>Not routinely recommended*2</td>
<td>Benefit of additional boosters is marginal.</td>
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<tr>
<td><strong>LOW priority-use groups</strong></td>
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<tr>
<td>Healthy children and adolescents aged 0 months to 17 years3</td>
<td>Countries could consider based on disease burden, cost effectiveness, and other health or programmatic priorities and opportunity costs.</td>
<td>Not routinely recommended*2</td>
<td>Benefit and cost-effectiveness of vaccinating healthy children and adolescents is substantially lower compared to high and medium priority-use groups and compared to most other vaccine-preventable diseases in childhood.</td>
</tr>
</tbody>
</table>

*Denotes revised recommendations from the March 2023 update.

1. For use in high-income settings.
2. For use in medium-income settings.
3. For use in low-income settings.
Meeting will review evidence and policy recommendations; including tabling of:

- An update of the good practice statement in relation to variant-adapted vaccines; with proposed language for XBB monovalent products similar to language used for the bivalent products;
- A modest update of the roadmap, which:
  1. Further emphasizes the focus on the high priority use groups
  2. Further deprioritizes children and young adults
  3. Shifts to a "simplified posology" - moving away from ‘primary’ and ‘booster’ language
12 products hold EUL, with SAGE recommendation for primary/booster

Number of vaccine approvals, by type of approval

Data from UNICEF’s COVID-19 Market Dashboard.
Vaccine Pipeline

There are 61 vaccines that have been authorized by at least one national regulatory agency, and an additional 43 candidates in late-stage development: 14 candidates are currently in Phase II/III clinical trials, 26 in Phase III clinical trials, and 3 already under regulatory review.

No broad-spectrum vaccines are in late-stage development, nor do we expect any combination C19-Influenza vaccine to come to the market shortly.

Source: https://www.unicef.org/supply/covid-19-market-dashboard
Data from UNICEF’s COVID-19 Market Dashboard.
THANK YOU
In order to improve protection, in particular against symptomatic disease, new formulations of COVID-19 vaccines should aim to induce antibody responses that neutralize XBB descendent lineages.

- One approach recommended by TAG-CO-VAC is the use of a monovalent XBB.1 descendent lineage, such as XBB.1.5 as the vaccine antigen;
- Given the small genetic and antigenic differences from XBB.1.5, XBB.1.16 may be an alternative;
- Other formulations and/or platforms that achieve robust neutralizing antibody responses against XBB descendent lineages can also be considered.

While currently approved COVID-19 vaccines, including those based on the index virus, continue to provide protection against severe disease, the TAG-CO-VAC advises moving away from the inclusion of the index virus in future formulations of COVID-19 vaccines.

- The index virus and antigenically closely related variants no longer circulate in humans;
- the index virus antigen elicits undetectable or very low levels of neutralizing antibodies against currently circulating SARS-CoV-2 variants, including XBB descendent lineages;
- inclusion of the index virus in bi- or multivalent vaccines reduces the concentration of the new target antigen(s) as compared to monovalent vaccines, which may decrease the magnitude of the humoral immune response; and
- immune imprinting due to repeated exposure to the index virus may reduce immune responses to new target antigen(s).

In alignment with advice from TAG-CO-VAC; EMA & FDA recommendations on COVID-19 strain composition:

- EMA’s Emergency Task Force recommends updating vaccines to target XBB strains on 6th June
- FDA’s vaccine advisory group voted unanimously to recommend updating the current COVID-19 vaccine composition for fall to a monovalent vaccine based on an XBB variant on 16th June