COVAX Global Supply Forecast

December 14, 2021





World Health Organization





The COVAX Global Supply Forecast aims to provide an up-to-date overview of the supply of safe and effective vaccines to the COVAX Facility. Our goal is to offer economies participating in COVAX as much clarity as possible on when we expect the doses we have secured to start arriving. To this end, we provide both a global overview as well as specific regional forecasts. The latest edition of this forecast also includes a detailed overview and analysis of changes from the previous edition (September 2021).

There are many uncertainties affecting the supply of COVID-19 vaccines in 2021, not least around manufacturing capacity, export restrictions, regulatory approvals, funding availability, and the readiness of countries themselves to begin their national COVID-19 vaccination programmes.

In recognition of the fast-changing nature of COVAX's supply outlook, and of the need to balance uncertainty in global supply with predictability for its participants, COVAX is committed to regularly updating this forecast.



COVAX Supply Forecast

December 2021: Headlines

- After a year of setbacks brought on by export restrictions, vaccine hoarding and regulatory and manufacturing delays, COVAX supply has increased in the fourth quarter, in line with earlier projections.
- Under the most likely scenario, nearly 1.4 billion doses will be available to COVAX by the end of this year.
- Of these, almost 1.2 billion doses will be made available to economies participating in the <u>Gavi</u> <u>COVAX Advance Market Commitment</u> (AMC). This is equivalent to 20% population coverage on average, or 40% of the adult population on average in all 92 AMC economies bar India.
- All of these doses have been allocated and communicated to countries, and deliveries are underway. Read more on the steps between availability (Supply Forecast) and arrivals in country (Deliveries Dashboard)<u>here</u>.
- While the current 2021 Supply Forecast remains within the range set out in the previous forecast, published in September, COVAX continues to experience delays for its Advance Purchase Agreement (APA) doses from several manufacturers. This is being offset by earlier availability of some 2022 doses from Moderna, limited resumption of exports of SII-AstraZeneca ("Covishield"), and increased dose donations.
- Delays in gaining regulatory approval for two promising vaccine candidates from Novavax and Clover have also caused some supply to be shifted into 2022.

(cont. overleaf)

COVAX Supply Forecast

December 2021: Headlines

- With COVAX now broadly able to meet the demands of its participating economies, 2022 will be defined by two priorities:
- The first is to sustain **regular**, **predictable**, **high-quality supplies**: Not only have supplies been curtailed in 2021, the reduced amount of doses available have too often come at short notice. Without the certainty of regular, predictable, high quality supply, countries have been unable to make necessary investments in their capacity to absorb doses. In resource-limited environments, capacity cannot remain on "standby": long-term planning is essential to ensuring successful COVID-19 vaccine rollout alongside the delivery of routine immunisation and other critical health interventions. This requirement to plan longer-term has already led to some countries having to decline or defer doses until 2022.
- In order to highlight the importance of improving predictability of supply, COVAX alongside the African Union and Africa CDC published in November a <u>Joint Statement on Dose Donations</u> laying out minimum expected standards for all donated doses.
- The second priority is to help countries to boost absorptive capacity to achieve national objectives. For COVAX to deliver doses, countries must first accept them, therefore as more supply comes available it is of paramount importance that country readiness is optimized.
- In addition to working with donors and manufacturers to provide assurance of supply, COVAX works closely with countries to help improve preparedness and access the funding that is available from the World Bank and other multilateral lenders, COVAX, Gavi and other sources to enable delivery at scale.

COVAX Facility Available Supply Forecast

Ranged forecasts under low, most likely, and high scenarios

PRELIMINARY AND SUBJECT TO ASSUMPTIONS

COVAX Forecasted Available Supply for all Participants,

Cumulative, Committed and donated doses only, M doses, 2021 and 2022¹



1 Forecasts only include committed doses and confirmed dose donations; optional doses and doses under negotiation are not included. Timing of available supply is based on anticipated date of release by manufacturer, at which point doses become available for delivery. Timing of delivery to countries will be lagged due to need for local regulatory approvals, supply agreements, country readiness, export licenses, logistics, etc. Volumes for single -dose regimen candidates doubled to ensure comparability across vaccines. Volumes have been rounded to nearest 5M.

2 Scenarios are based on best available information from manufacturers and analysis from Gavi and UNICEF on the impact and likelihood of potential mitigation efforts. 3 Coverage refers to proportion of total population in AMC91 Participants that could be fully vaccinated with available volumes, assuming India receives 20% of AMC-funded volumes

THREE BIGGEST DRIVERS OF UNCERTAINTY FOR COVAX SUPPLY

- Timing and extent to which export controls in India are eased. While vaccine have started being exported from India, the exact volumes and phasing of volumes for COVAX is still under discussion.
- Manufacturers prioritizing supply from global manufacturing networks to COVAX, so COVAX can access doses that it has already secured and paid for under its existing APAs.
- **Timely regulatory approval** of candidates that COVAX has signed deals with, including those being developed by Novavax, SII-Novavax, and Clover.

Key changes from September 2021 supply forecast update

- Since the last COVAX supply forecast, published in Sept 2021, overall projected supply in the most likely scenario remains relatively stable. The evolving supply landscape and COVAX portfolio management decisions have led to a slight reduction of ~40M in anticipated volumes available for supply in 2021 under the most likely scenario.
- The specific factors driving these changes are:
 - (+) **Dose donations**: Additional doses committed from donors including <u>new doses from Team Europe</u>.

(+) <u>SII-AstraZeneca</u>: The easing of export restrictions will lead to the resumption of supply to COVAX, although exact volumes remain under discussion.

(+) <u>Moderna</u>: Negotiations with manufacturer have <u>enabled 20M doses to be accelerated</u> from Q1 2022 to Q4 2021; COVAX's <u>first queue-swap</u> with Switzerland has enabled 1M doses to be accelerated into Q4 2021.

(-) <u>J&J</u>: While production at J&J's Emergent facility (which is assigned to supply COVAX) has now restarted, the manufacturing ramp-up combined with the backlog of orders for other bilateral customers has led to delayed timelines and lower volumes to be made available to COVAX in 2021.

(-) <u>Sinovac</u>: Delays in option exercise due to ensuring appropriate determination of country demand mean the availability of some volumes has slipped from Q4 2021 into early Q1 2022.

(-) <u>Sinopharm</u>: Issues with scale-up and release has led to supply delays.

(-) AstraZeneca: Technical issues at manufacturing sites assigned to supply COVAX have led to supply delays.

(-) <u>**Clover**</u>: Supply timelines account for potential risks related to regulatory timelines, as WHO Emergency Use Listing (EUL) or Stringent Regulatory Authority (SRA) approval is required for supply to COVAX participants.

(-) **Novavax**: Delays to original regulatory strategy have resulted in delays in expected supply to COVAX, as WHO EUL or SRA approval is required for supply to COVAX participants.

(-) **Options that were not exercised**: In line with country preferences and after satisfying requests made by self-financing and AMC participants, some options under contract have not been exercised.

• The graph on the next slide breaks down the impact of these changes in terms of volumes.

Overall forecast of available supply by end-2021 has remained relatively stable – with a ~40M reduction overall

Comparison of September most likely forecast vs. December most likely forecast M doses, total anticipated supply available by manufacturer in 2021¹



1 Forecasts are based on best available information from manufacturers and analysis from Gavi and UNICEF. Timing of available supply is based on anticipated date of release by manufacturer, at which point doses become available for delivery. Volumes have been rounded to nearest 5M.

2 Changes to how US support for the procurement of Pfizer/BioNTech dossisbeing documented means 80M dosshave been reclassified from the "Pfizer/BioNTech" category into the "Dose donation" category for 2021.

3 Actual volume is 100M doses, with volumes for J&J's single -dose vaccine doubled to ensure comparability across vaccines.

THE MAIN FACTORS LEADING TO DELAYS INCLUDE:

- Challenges with manufacturing scale-up in existing and new facilities means the speed of production has sometimes been slower-thanexpected. Resulting decreased capacity has led to decisions by manufacturers to deprioritize supply of volumes to COVAX.
- Delays to candidate development and regulatory timelines for Novavax and Clover means first doses are not expected to be available to COVAX until early 2022.
- Options that have not been exercised: COVAX's portfolio is being actively managed to respond to changes in the supply and demand landscape. Through the cost-sharing mechanism, all AMC Participants have been offered the opportunity to procure additional doses beyond their fully-subsidised allocations; after accounting for this demand, some remaining time-bound options were not exercised.

Total COVAX portfolio

Funded volumes, dose donations, and unfunded options / negotiations

PRELIMINARY AND SUBJECT TO ASSUMPTIONS

Total COVAX portfolio by vaccine, M doses



COVAX has access to 3bn+ extra doses across several vaccines through its options and negotiations We are currently seeking at least \$3.7bn in funding to procure at least 600mn of these doses to create the

Pandemic Vaccine Pool which will help AMC countries further mitigate demand and supply risks in 2022

With current funding and confirmed donations, COVAX has a portfolio of ~2.8bn doses that will be made available to AMC countries by mid-2022, with approx. ~300mn dose for SFPs

1 "Committed doses" are doses that the COVAX Facility is required to procure. "Optional doses" are doses that the COVAX Facility has the option to procure in the future, but is not required to purchase. Once optional doses are exercised, they become committed doses.

2 "Dose donations" estimated based upon donor commitments to share new doses bilaterally with COVAX. The transfer of COVAX al locations from SFPs to AMC Participants are already included in the volumes secured by COVAX from legally-binding agreements.

3 US support has allowed COVAX to secure one billion doses from Pfizer/BioNTech. Reflecting US funding above its original pledge, 700M of these are recorded as a donation.

4 COVAX has signed an APA with Janssen for 200M doses; negotiations for up to an additional 300M doses are ongoing as per the Memorandum of Understanding announced on 18 December 2020.

5 In these supply forecasts, volumes for J&J's single-dose vaccine have been doubled to ensure comparability with two-dose vaccines.

COVAX Facility global available supply forecast

By AMC-eligible and Self-Financing Participants

PRELIMINARY AND SUBJECT TO ASSUMPTIONS

COVAX Forecasted Available Supply for all Participants under Most Likely Scenario,

Cumulative, Committed doses and dose donations only, M doses, 2021 and 2022¹



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2 Final SFP volumes may be lower than forecasted due to opt-out and dose-sharing behavior. Volumes only account for current SFP demand based on Commitment Agreements. 3 "Dose donations" estimated based upon donor commitments to share new doses bilaterally with COVAX. The transfer of COVAX al locations from SFPs to AMC Participants are already included in the AMC Participant volumes.

CAVEATS

Candidate attrition: Some candidates are still in clinical development. If they do not achieve positive clinical trial outcomes (safety and efficacy) and regulatory approval, these volumes will not be procured by COVAX.

Regulatory approval: Supply timing will depend on regulatory success and timelines, including reviews of individual batches ("batch release").

Manufacturing: In many cases, manufacturing is yet to reach full scale. Manufacturing productivity will be influenced by multiple factors, which will in turn influence volume and timing of supply.

Delivery: Timing shown in graphs is based on anticipated date of release by manufacturers. Timing of delivery will depend on various factors, including local regulatory approval, country readiness, export licenses, logistics, indemnification and liability in place, in-country distribution etc.

Allocation: These supply forecasts reflect a preliminary distribution of doses based on each participant's share of available supply pro rata by demand and are to be treated as indicative. Final timing and volumes will be determined by the WHO Allocation Mechanism.

UPDATED ON 14 DEC 2021

COVAX Facility global available supply forecast

By WHO region

PRELIMINARY AND SUBJECT TO ASSUMPTIONS

COVAX Forecasted Available Supply for all Participants under Most Likely Scenario,

Cumulative, Committed doses and dose donations only, M doses, 2021 and 2022¹



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COVAX 10

COVAX Facility global available supply forecast

By contractual status

PRELIMINARY AND SUBJECT TO ASSUMPTIONS

COVAX Forecasted Available Supply for all Participants under Most Likely Scenario, Cumulative, M doses, 2021 and 2022¹



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2 "Dose donations" estimated based upon donor commitments to share new doses bilaterally with COVAX. The transfer of COVAX allocations from SFPs to AMC Participants are already included in the AMC Participant volumes.

UPDATED ON 14 DEC 2021

CAVEATS

Contracts: Some of the supply included in the projections are linked to deals that are already concluded and some are currently being negotiated. Terms are subject to change.

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Regulatory approval: Supply timing will depend on regulatory success and timelines, including reviews of individual batches ("batch release").

Manufacturing: In many cases, manufacturing is yet to reach full scale. Manufacturing productivity will be influenced by multiple factors, which will in turn influence volume and timing of supply.

Delivery: Timing shown in graphs is based on anticipated date of release by manufacturers. Timing of delivery will depend on various factors, including local regulatory approval, country readiness, export licenses, logistics, indemnification and liability in place, in-country distribution etc.

Funding availability: Total potential supply is shown; procurement of these doses will depend on COVAXAMC fundraising, AMC92 cost-sharing beyond donor-funded doses, and the final prices and volumes of doses allocated to AMC92.

Allocation: These supply forecasts reflect a preliminary distribution of doses based on each participant's share of available supply pro rata by demand and are to be treated as indicative. Final timing and volumes will be determined by the WHO Allocation Mechanism.

WHO region-specific supply forecasts

Coming soon