

Introductory Presentation



SAGE extra-ordinary meeting, 21 January 2021

Dr Hanna Nohynek, SAGE Member, Chair Working Group on COVID-19 Vaccination

Agenda

Time	Session	Lead
12:00	Opening	Director General, WHO
12:05	Welcome	A Cravioto, K O'Brien
12:10	Introduction, session objectives & overview	H Nohynek
12:20	Vaccine safety and efficacy data (mRNA1273)	Moderna representatives
12:50	Questions	All
13:20	<i>Break</i>	
13:30	Assessment of evidence	SAGE working group
14:00	Questions	All
14:15	Draft recommendations	H Nohynek
14:35	Discussion	All
15:30	Closure	

Key documents for guiding country decision-making on COVID-19 vaccination



WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination

14 September 2020



WHO SAGE ROADMAP FOR PRIORITIZING USES OF COVID-19 VACCINES IN THE CONTEXT OF LIMITED SUPPLY

An approach to inform planning and subsequent recommendations based upon epidemiologic setting and vaccine supply scenarios

*Version 1
20 October 2020*



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

Interim guidance
8 January 2021



Our World
in Data

- Availability for ONE of following: key workers/ clinically vulnerable groups / elderly groups
- Availability for TWO of following: key workers/ clinically vulnerable groups / elderly groups
- Availability for ALL of following: key workers/ clinically vulnerable groups / elderly groups
- Availability for all three plus partial additional availability (select broad groups/ages)
- Universal availability



State of COVID-19 Vaccines: key numbers (data as of 20 January 2021)



- **44 days** since 1st countries started vaccinating¹ and **25 days** since all EU countries received vaccines



- **45 million vaccine doses** have been administered:
 - 95% of these doses have been administered in 10 countries
 - At least 7 different vaccines (3 platforms²) have been administered³
- Rollout **has started in 52 countries** (incl. 41 HICs; 9 UMICs; 1 LMIC⁴; 1 LIC⁵)

1. Dec. 8, 2020 in the UK (Pfizer)

2. mRNA, Viral vector, Inactivated

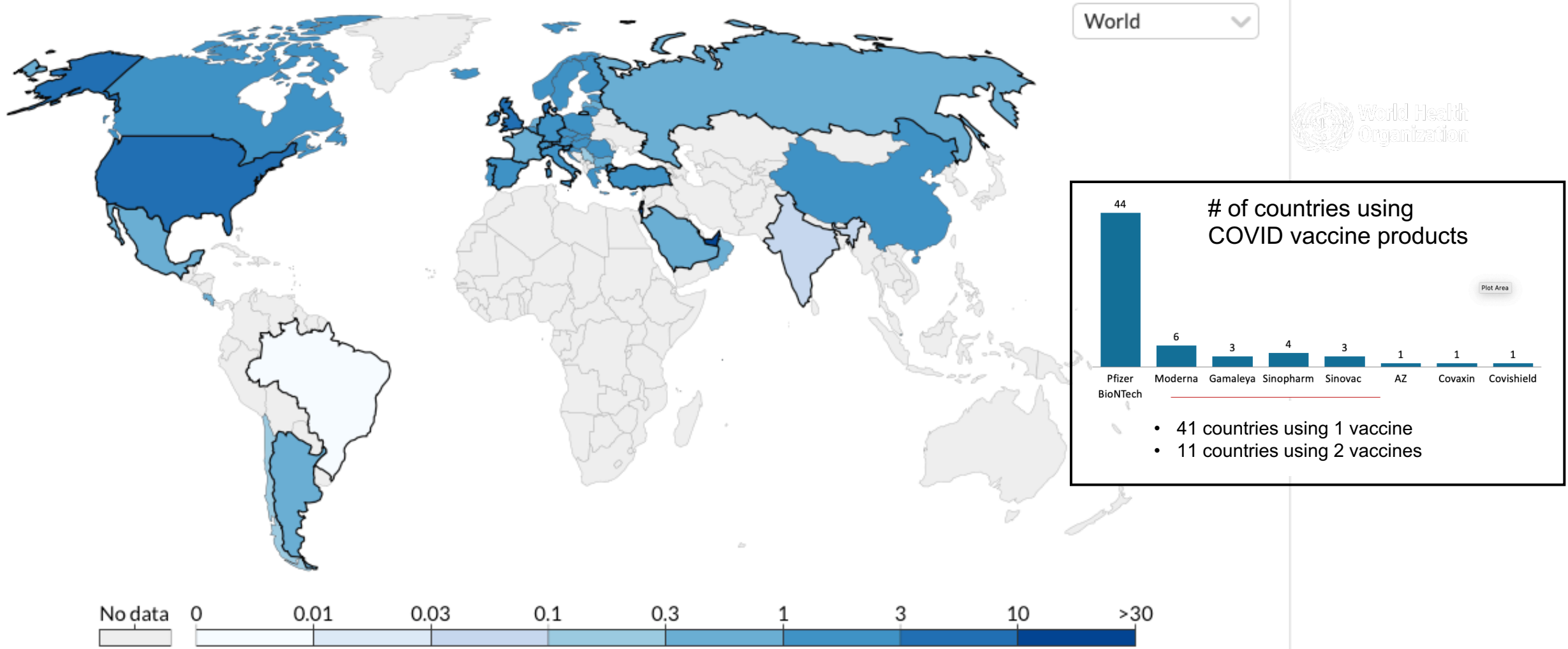
3. Pfizer, Moderna, Gamaleya, Sinovac, Sinopharm, AZ (Covishield in India) and Covaxin

4. India

5. Guinea

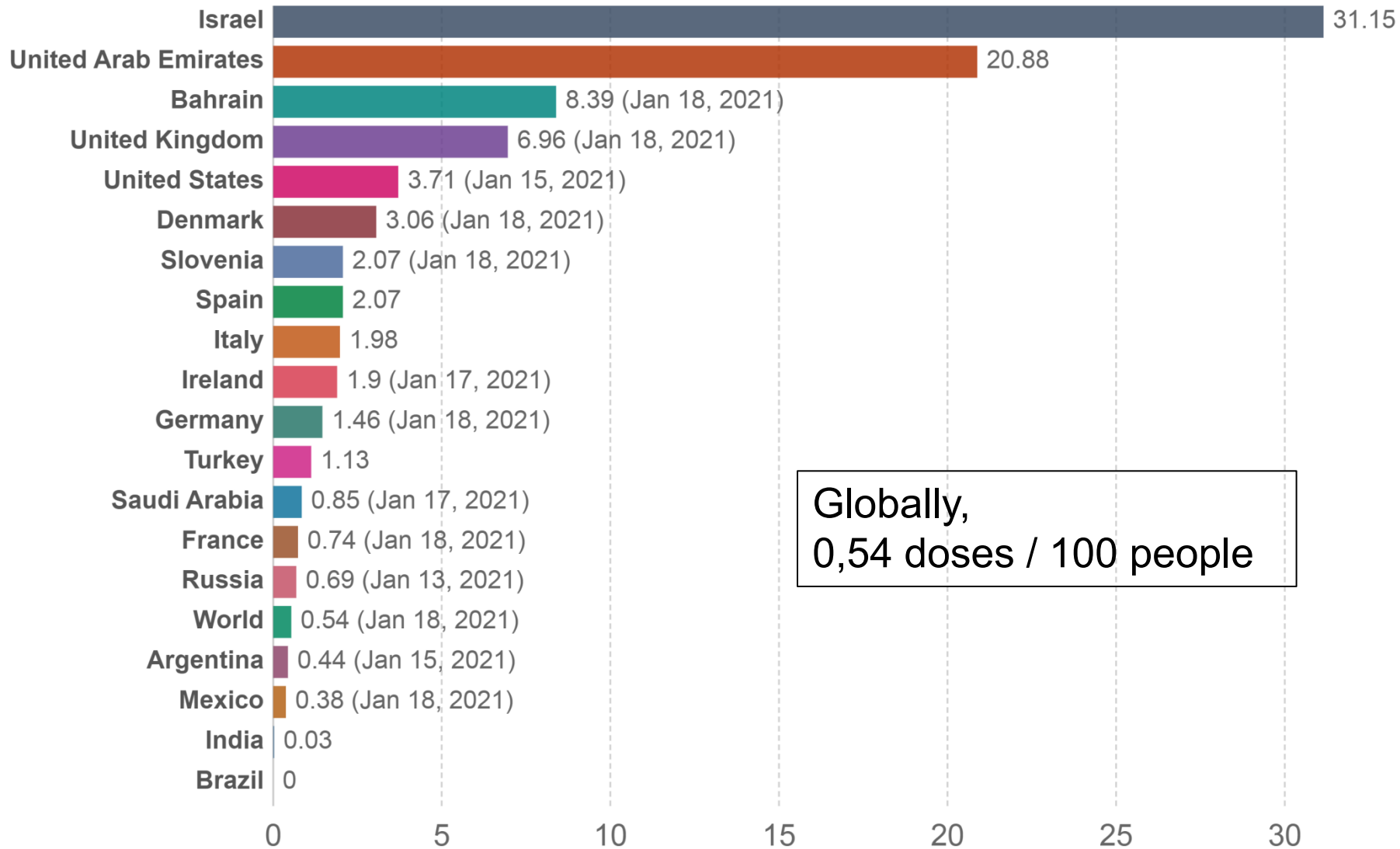
COVID-19 vaccine doses administered per 100 people, Jan 20, 2021

Total number of vaccination doses administered per 100 people in the total population. This is counted as a single dose, and may not equal the total number of people vaccinated, depending on the specific dose regime (e.g. people receive multiple doses).



COVID-19 vaccine doses administered per 100 people, Jan 19, 2021

Total number of vaccination doses administered per 100 people in the total population. This is counted as a single dose, and may not equal the total number of people vaccinated, depending on the specific dose regime (e.g. people receive multiple doses).



Pathway to vaccine use in a country

Pathway to vaccine use in a country

What needs to happen NOW

1. Regulatory authorization / import approval



1. EUL/PQ or SRA authorization & country authorization



2. Policy on use



2. SAGE¹ recommendation & country policies

3. Procurement mechanism



3. COVAX deals and Allocation & country legal components

4. Plan and execution of vaccine use



4. NDVP² & country implementation




1. Strategic Advisory Group of Experts on Immunization

2. National Deployment and Vaccination Plan

WHO PQ/EUL assessment timeline for COVID-19 Vaccines (1)



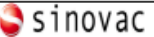



As of 20 January 2021. <https://extranet.who.int/pqweb/key-resources/documents/status-covid-19-vaccines-within-who-eulpq-evaluation-process>

Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process

	Manufacturer	Name of Vaccine	NRA of Record	Platform	EOI accepted	Pre-submission meeting held	Dossier accepted for review*	Status of assessment**	Anticipated decision date***
1.		BNT162b2/COMIRNATY (INN tozinameran)	EMA	Nucleoside modified mRNA	✓	✓	✓	Finalized	31/12/20
2.	Zhifei Longcom, China	Recombinant Novel Coronavirus Vaccine (CHO Cell)	NMPA	Recombinant protein subunit	Not accepted Product in Phase I/II				
3.	IMBCAMS, China	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)	NMPA	Inactivated	Not accepted, still under development				
4.		AZD1222	Core – EMA Non-COVAX	recombinant replication defective chimpanzee adenovirus expressing the SARS-CoV-2 S surface glycoprotein	✓	✓	✓	In progress Core data Non-Covax. Covax data to be reviewed as EMA post approval change	Earliest by EMA End of Jan-Feb 2021 (non-Covax) Additional nodes in March/ April for Covax
5.		AZD1222	MFDS KOREA	=	✓	✓	Tentative 18 and 29 Jan 2021 (CMC for SK Bio)	Core data (non-covax) in progress	Earliest 2 nd half Feb 2021

WHO PQ/EUL assessment timeline for COVID-19 Vaccines (2)

As of 20 January 2021. <https://extranet.who.int/pqweb/key-resources/documents/status-covid-19-vaccines-within-who-eulpq-evaluation-process>

Vaccines			Guidance Document						
	Manufacturer	Name of Vaccine	NRA of Record	Platform	EOI accepted	Pre-submission meeting held	Dossier accepted for review*	Status of assessment**	Anticipated decision date***
6.		Ad26.COV2.S	EMA	recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding the (SARS-CoV-2) Spike (S) protein	✓	✓	Rolling data to EMA – Dec, Feb, April (critical data), May ✓	Not yet started. Use abridged procedure relying on EMA	Earliest May – June 2021
7.		SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV)	NMPA	Inactivated, produced in Vero cells	✓	✓	End of Dec 2020	In progress	Earliest March
8.		SARS-CoV-2 Vaccine (Vero Cell), Inactivated	NMPA	Inactivated, produced in Vero cells	✓	✓	13 January 2021 (under screening)		Earliest March
9.		Sputnik V	Russian NRA	Human Adenovirus Vector-based Covid-19 vaccine	Additional information submitted – under assessment	✓	22 nd January discussion on content and format		
10.	Vector State Research Centre of Virology and Biotechnology	EpiVacCorona	Russian NRA	Peptide antigen	Letter received not EOI				
11.		Ad5-nCoV		Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)	Additional information requested	26 January 2021			
12.		mRNA-1273	EMA	mRNA-based vaccine encapsulated in lipid nanoparticle (LNP)	Expected in Feb 2021				Estimated end of Feb 2021

World Health Organization

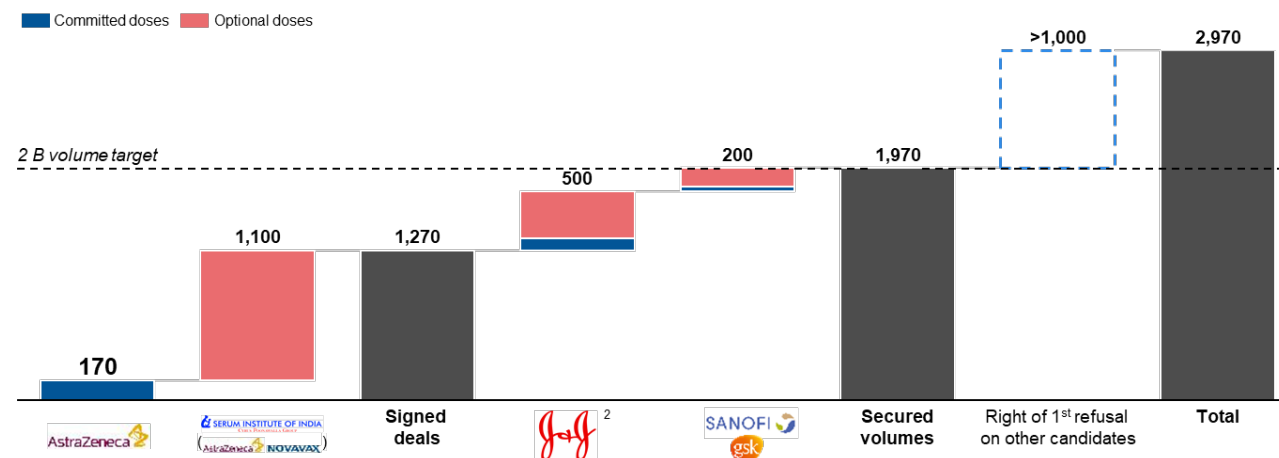


COVAX Facility is in a strong position to vaccinate, with the aim of initiating deliveries in February

COVAX Deals

- 2 billion doses
- 6 products
- 5 producers
- >1 B in options

COVAX secured volume, in M doses



COVAX Donations

- *Principles for sharing COVID-19 Vaccine Doses with COVAX*
- published 18 Dec 2020
- discussion ongoing with potential donors



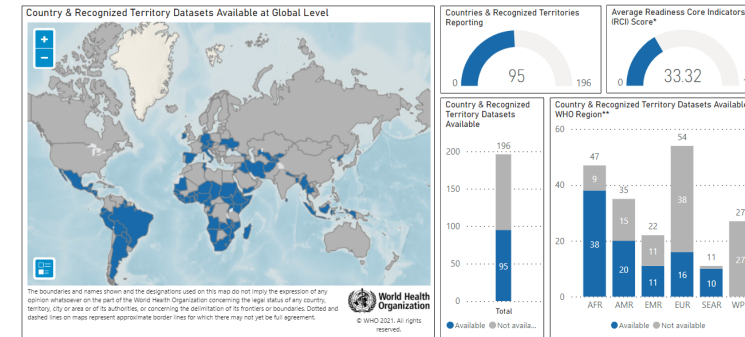
https://www.gavi.org/sites/default/files/covid/covax/COVAX_Principles-COVID-19-Vaccine-Doses-COVAX.pdf

COVAX Participant Countries are ready to begin administering COVID-19 vaccines



Country Readiness

- 88 of 92 AMC countries submitted Vaccine Request Form
- 124 country readiness assessments (incl. 64 AMC countries)



Regulatory Pathways for rapid in-country import & emergency use authorizations

Indemnification & Liability

- *model indemnification language* established (8 January 2021)
- *no-fault compensation mechanism* developed (end-January 2021)

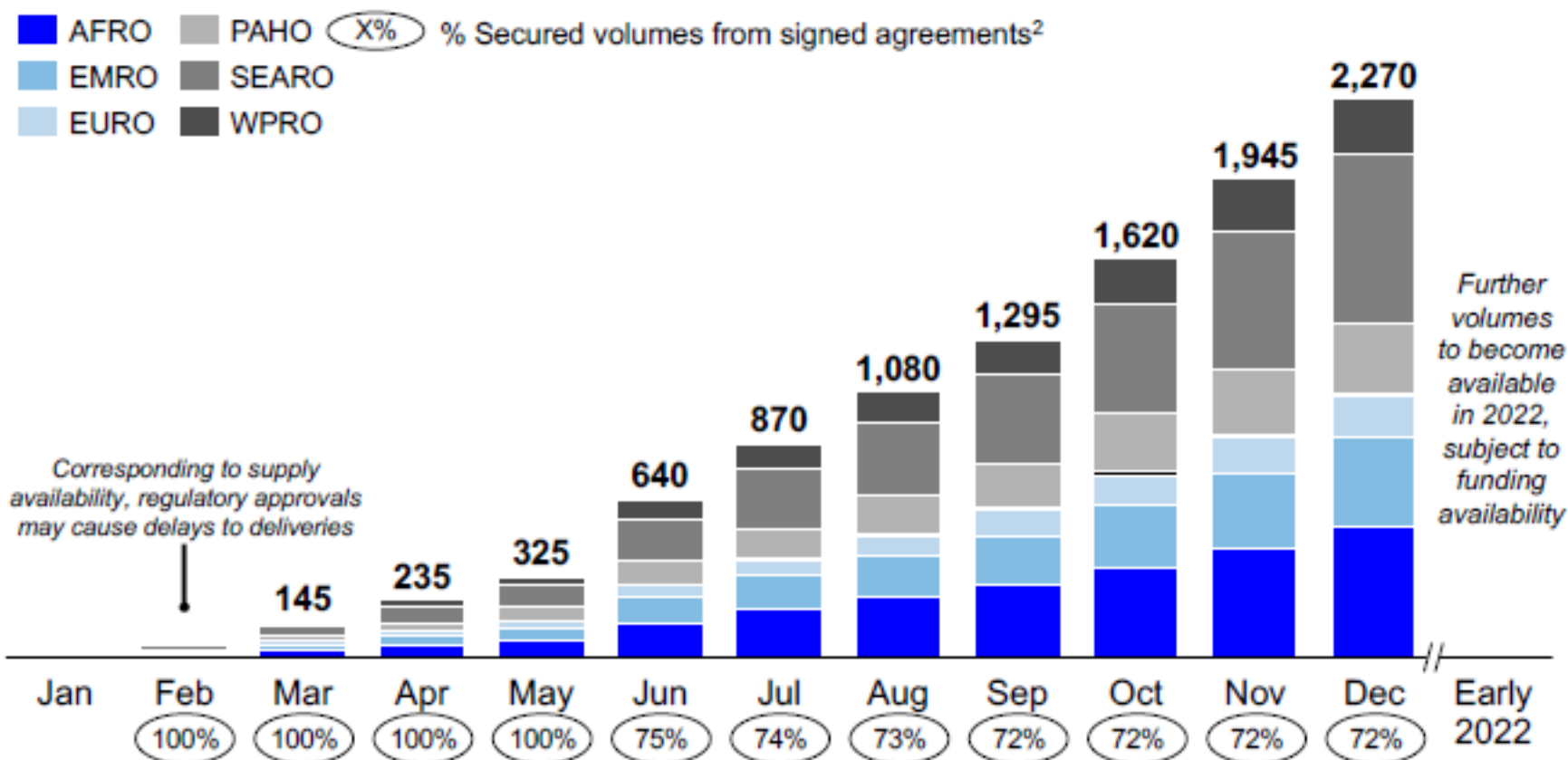


COVAX Facility global supply forecast by region

AS PER 2021-01-19

PRELIMINARY AND SUBJECT TO ASSUMPTIONS

COVAX Available Supply, Cumulative, Mn doses, 2021¹



¹ Supply refers to volumes of vaccine available from the manufacturer. Timing of forecasts is based on anticipated release of doses from manufacturers. Volumes for expected single-dose regimen vaccine candidates doubled to ensure comparability across vaccine candidates. Volumes have been rounded to the nearest 5M (except for those smaller than 5M).

² Signed agreements include legally-binding agreements, memoranda of understanding, and statements of intent.

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.

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 of delivery will depend on various factors, including local regulatory approval, country readiness, logistics, indemnification and liability in place, in-country distribution etc.

Funding availability: Total potential supply is shown; procurement of these doses will depend on COVAX AMC 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.