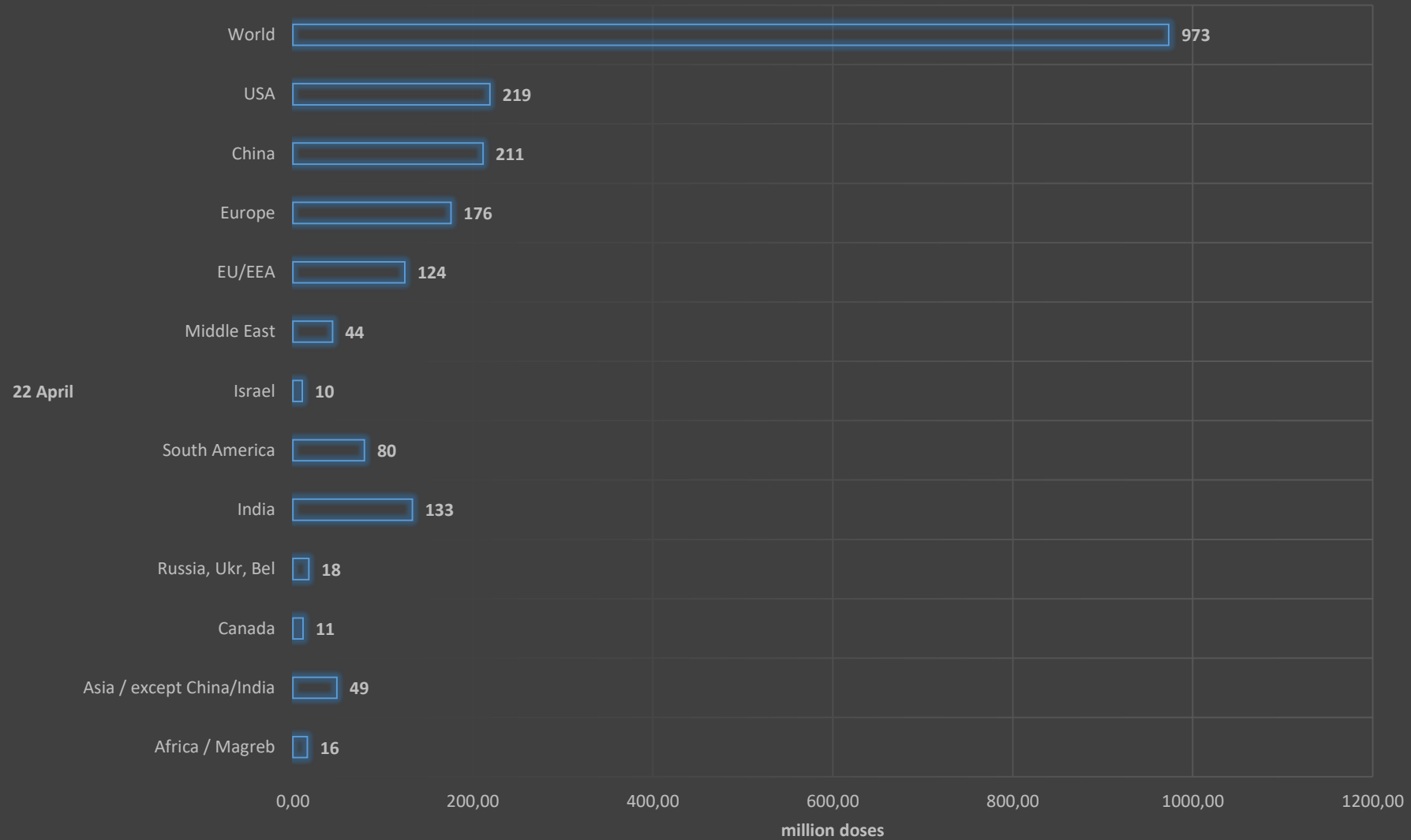


## Cumulative COVID-19 vaccination doses administered





# Dialogue with civil society: ACT-A and COVID-19 vaccines

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23 April 2021

# 944 m doses of COVID-19 vaccine have been administered<sup>1</sup> in 205 countries, areas, territories & economies<sup>2</sup>



## 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

SOURCE for map: WHO COVID-19 Dashboard at <https://covid19.who.int/>

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.

# Of WHO's 194 Member States, 179 have started COVID-19 vaccination

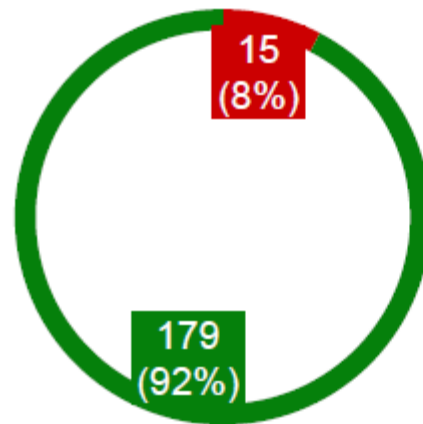
at least 1 additional MS received vaccine & can start in the coming days

Status of COVID-19 vaccine roll out

Started Not started

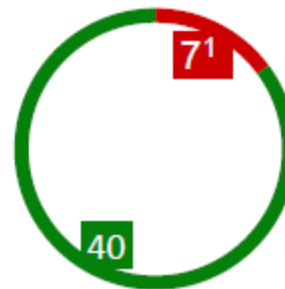
## WHO Member States

N= 194



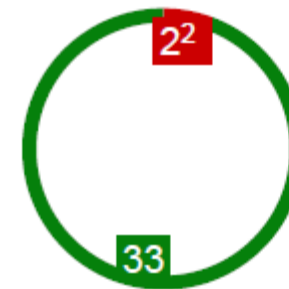
## AFRO

N= 47



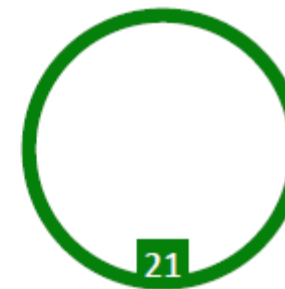
## AMRO

N= 35



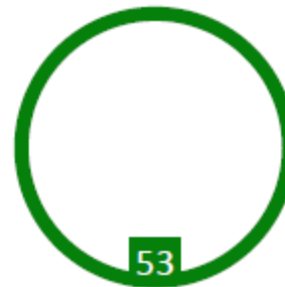
## EMRO

N=21



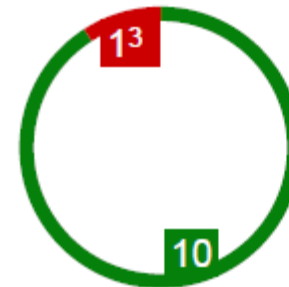
## EURO

N= 53



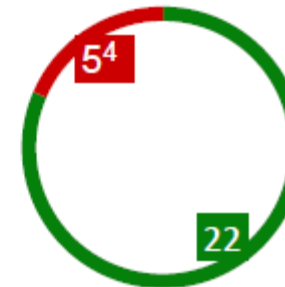
## SEARO

N= 11



## WPRO

N=27



<sup>1</sup> Burkina Faso, Burundi, Central African Republic, Chad, Eritrea, Madagascar, United Republic of Tanzania

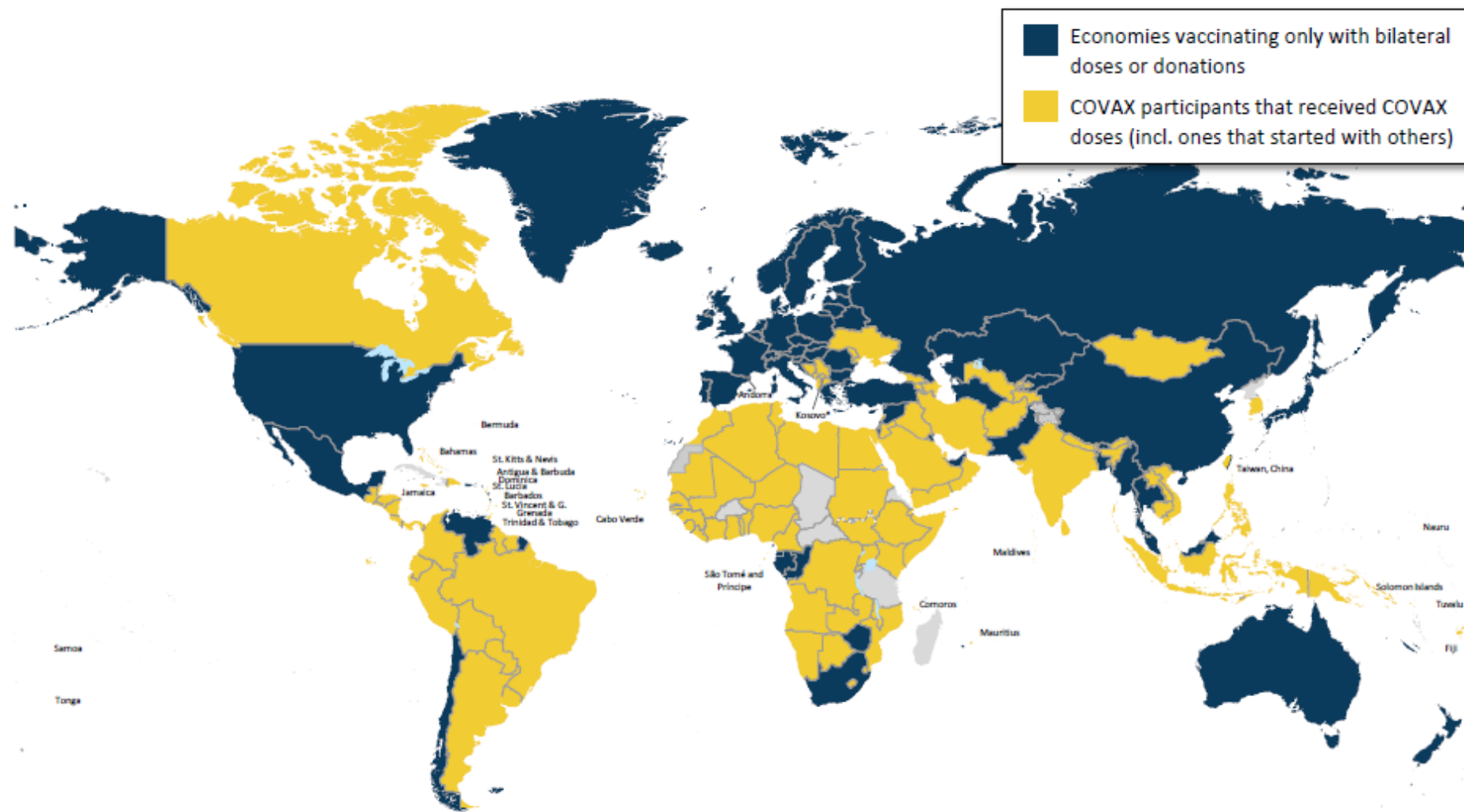
<sup>2</sup> Cuba, Haiti

<sup>3</sup> Democratic People's Republic of Korea

<sup>4</sup> Kiribati, Samoa, Vanuatu, Cook Islands, Niue

# COVAX has now shipped 40.8M doses to 117 participants

incl. 59 LMIC/LICs; 35 participants started their first campaigns thanks to COVAX doses



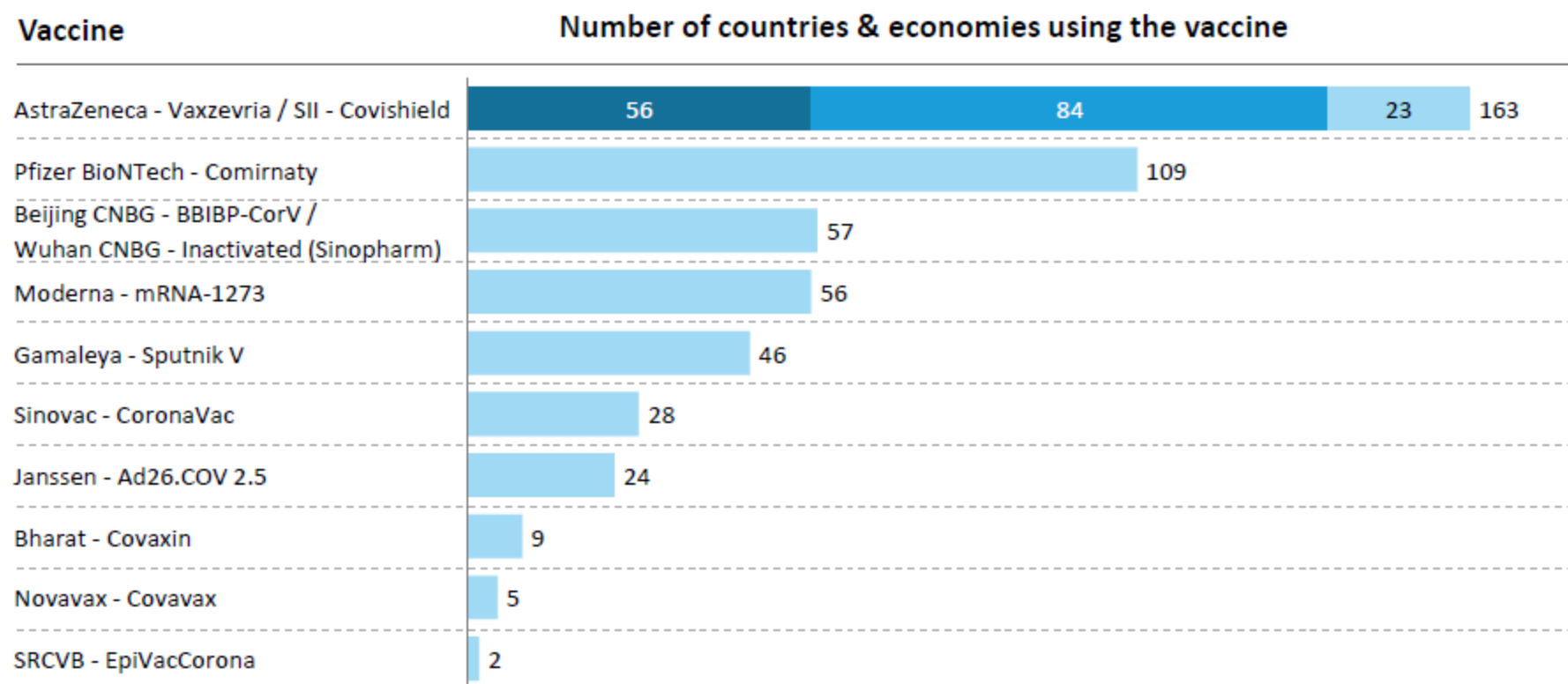
Note: The designations employed and the presentation of these materials do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and 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

■ SII - Covishield only  
■ AstraZeneca - Vaxzevria only



**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



## 6 urgent & ongoing initiatives to increase supply to COVAX

- 1** SII: working with Govt of India COVAX supply for coming months
- 2** AZ/SK Bio: accelerate release, rollout & target territory
- 3** Expedite delivery of newly EUL'd products through COVAX (e.g. J&J)
- 4** Pursue donations of vaccines that have WHO Emergency Use Listing (e.g. New Zealand, France, Spain)
- 5** Expedite EUL review of new products (e.g. Sinopharm, Sinovac, Gamaleya)
- 6** Expand global manufacturing capacity of COVID-19 vaccines

# Regulatory timeline of key Vx candidates

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








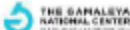



Legend (timing of approval)

Approval / Emergency use

Decision expected date

No info

COVAX Facility product

		Estimated dates of approval / Emergency use				Regulatory authority of record
Vx candidates		FDA	MHRA	EMA	WHO EUL/PQ	
   AZ with EMA as authority of reference AZ with EMA as authority of reference AZ South Korea w/ MFDS Korea as authority of record SII / AZ vaccine (Covishield) with DCGI India as authority of record	Pfizer BioNTech - Comirnaty	Dec. 12, 2020 Emergency Use	Dec. 2, 2020 Emergency Use	Dec. 21, 2020 Cond. Authorization <sup>1</sup>	Dec. 31, 2020 Emergency use	EMA
	AstraZeneca - Vaxzevria	No FDA approval	Dec. 30, 2020 Emergency Use <sup>2</sup>	Jan. 29, 2021 Cond. Auth. <sup>1</sup> (non-Covax)	Apr. 15, 2021 (donations only)	EMA
	AstraZeneca - AZD1222	No FDA approval	Not applicable	1 COVAX node	Apr. 15, 2021, 1 COVAX node	EMA
	AstraZeneca - AZD1222	Not applicable	Not applicable	Not applicable	Feb. 15, 2021 Emergency use	MFDS (Rep. Korea)
       	SII - Covishield	-	-	-	Feb. 15, 2021 Emergency use	DCGI (India)
	Beijing CNBG - BBIBP-CorV				April 2021 (Earliest)	NMPA
	Sinovac - CoronaVac	No FDA approval		No EMA approval	May 2021 (Earliest)	NMPA
	Moderna - mRNA-1273	Dec. 18, 2020 Emergency Use	Jan. 8, 2021 Emergency Use	Jan. 6, 2021 Cond. Authorization <sup>1</sup>	April 2021 (Earliest)	EMA
	Janssen - Ad26.COV 2.5	Feb. 27, 2021 Emergency Use		Mar. 11, 2021 Cond. Authorization <sup>1</sup>	Mar. 12, 2021 Emergency use	EMA
	Gamaleya - Sputnik V				Rolling submission started - Add. data awaited	Russian NRA
	CanSino - Ad5-nCoV				Rolling submission of data from April 2021	NMPA
	Wuhan CNBG - Inactivated					NMPA
	Novavax - Covavax <sup>3</sup>				Novavax submitted EOI on 23 Feb	EMA

## Key messages

- WHO EUL:** Pfizer BioNTech – Comirnaty, SII – Covishield, Janssen - Ad26.COV 2.5, AstraZeneca – Vaxzevria/AZD1222
- AstraZeneca:** WHO EUL for European nodes (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 on May 7
- Bharat and CureVac / Bayer** submitted EOI
- BioCubaPharma** is in discussions to submit EOI

\*. 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 Institute of Biological Products Co-Ltd

SOURCE: [https://extranet.who.int/pqweb/sites/default/files/documents/Status\\_COVID\\_VAX\\_08Feb2021.pdf](https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_08Feb2021.pdf); <https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/>



# COVAX Facility in 5 Metrics



**\$6.6 Billion**

Total resources mobilized for  
COVAX AMC in 2020 and 2021



**7 Vaccine Candidates**

Have signed COVAX agreements

**2.2 Billion Doses**

Secured through signed agreements  
or in negotiation for delivery in 2021



**40.8 Million Doses**

Have been delivered from 251mn  
doses initially allocated

**117 Initial Participants**

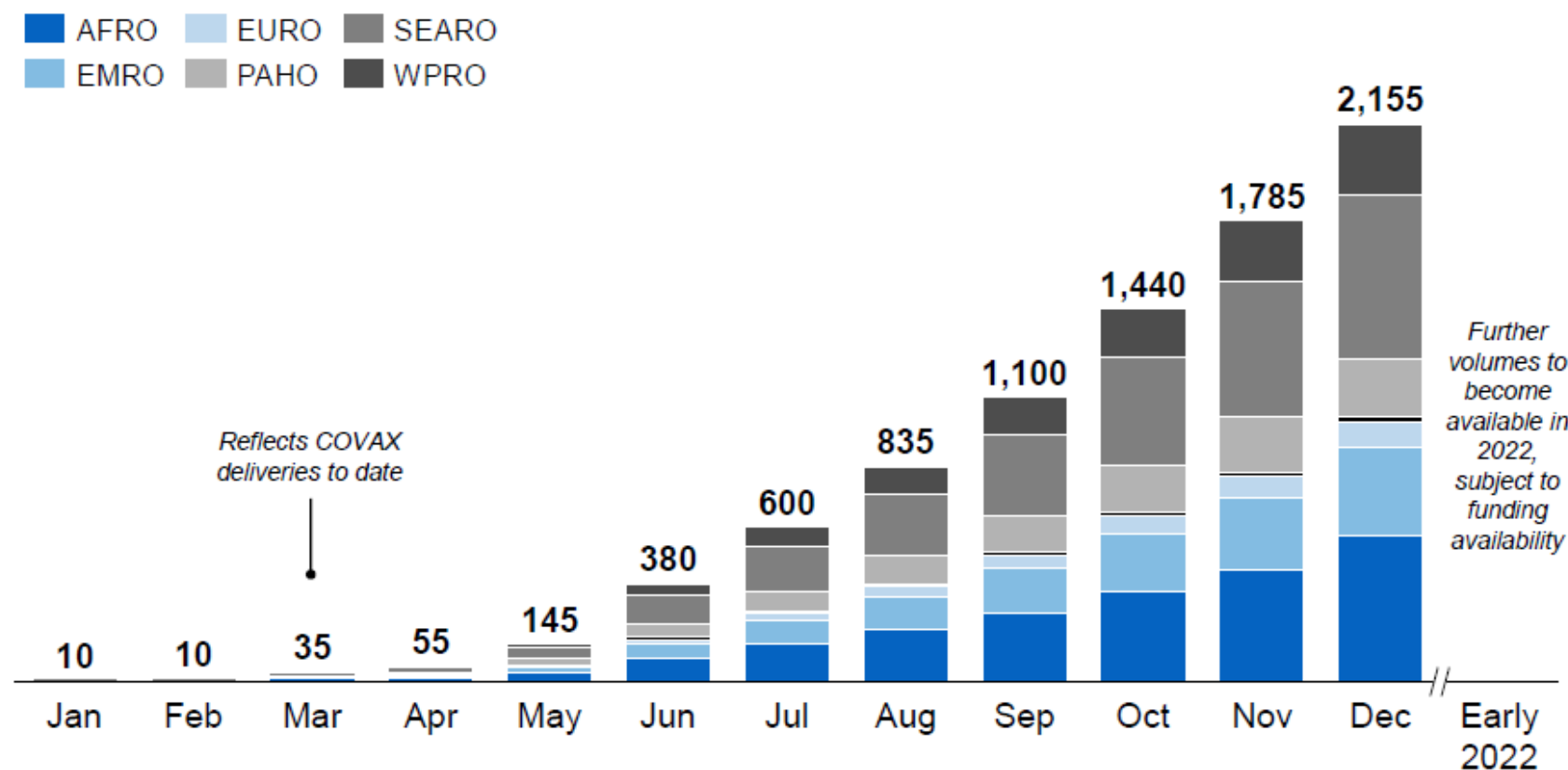
Have received doses of 190 confirmed  
and eligible participants

# COVAX Facility global supply forecast

By WHO region

**PRELIMINARY AND SUBJECT TO ASSUMPTIONS**

**COVAX Available Supply, Cumulative, Mn doses, 2021<sup>1</sup>**



<sup>1</sup> 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 those less than 10M, and so totals may not equal sum of segments.

## 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.

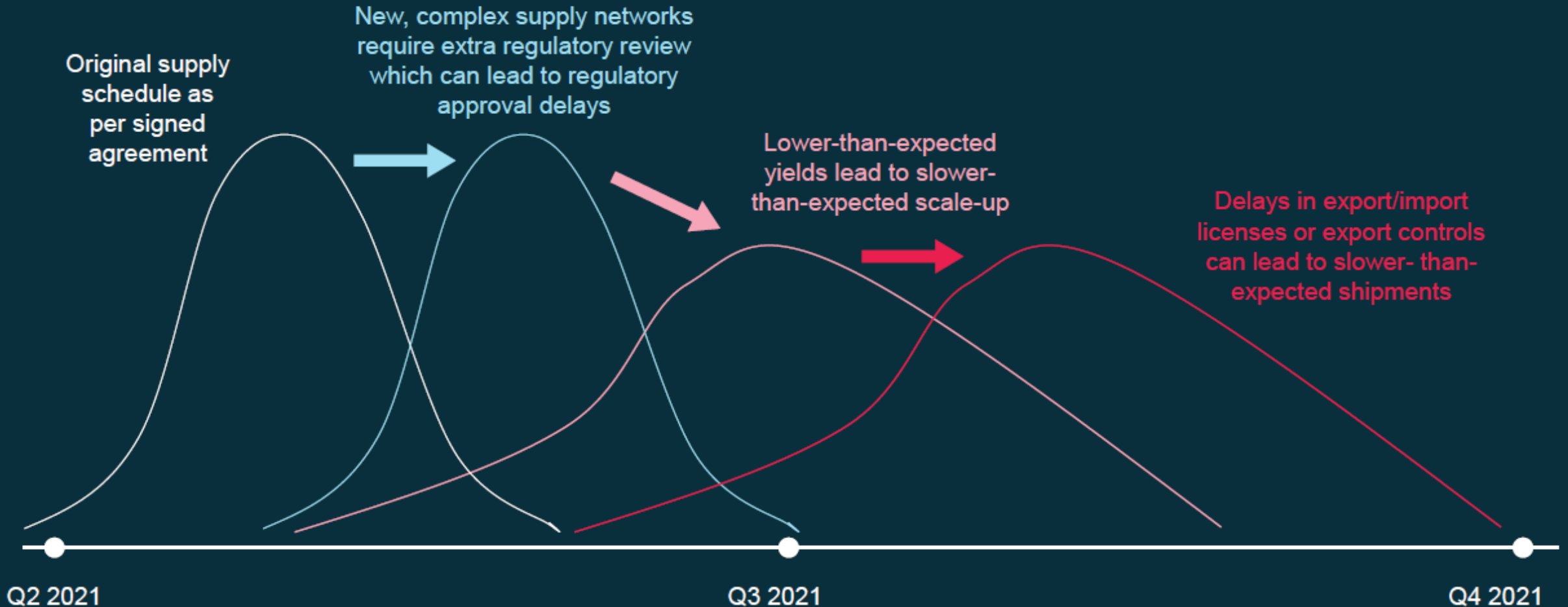
**Delivery:** Timing of delivery will depend on various factors, including local regulatory approval, country readiness, export licenses, logistics, indemnification and liability in place, in-country distribution etc.

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

# All buyers are facing delays to supply schedules; COVAX is actively monitoring these and putting mitigation measures in place, although some are beyond our control

## Illustrative manufacturer supply schedule



## **Current COVID-19 Vaccine Manufacturing Bottlenecks & Challenges**

- Shortages of raw materials – single use filters, bags, etc
- Shipment - import/export of vaccines, raw materials and vaccine components
- Multiple tech transfers – requiring complex comparability studies
- Quality Control assay robustness and validation
- Sufficient resourcing – e.g. product release
- Appropriate stability program to support shelf-life through release, distribution and administration



# Outputs: Expand capacity, promote equitable access, leave no one behind

- Free flow of goods and workforce
- Continue technology transfer and manufacturing partnerships between innovators and manufacturers to scale up & out C19 vaccine capacity
- Better demand forecasting and inventory management of raw materials and critical consumables
- Support from the highest political level is needed
- Value of regulatory harmonization and streamlining to accelerate manufacturing capacity and supply
- Better production, demand and supply, forecast and visibility
- Give consideration to the potential impacts of C19 production on non-C19 products



International Federation  
of Pharmaceutical  
Manufacturers & Associations

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09 March, 2021

18:15 to 18:45 UTC+01:00



Virtual Press Briefing following the  
Global COVID-19 Vaccine Supply  
Chain & Manufacturing Summit

## PROGRAM

6:15 PM – 6:45  
PM CET - Geneva /  
10:15 – 10:45 AM  
EDT - New York