



**World Health  
Organization**

**SAGE extraordinary meeting**

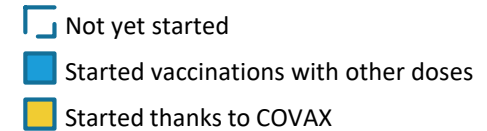
# **Policy recommendations on the use of Janssen Ad26.COVS vaccine**

Dr Kate O'Brien – WHO, Director, Department of Immunization, Vaccines and Biologicals

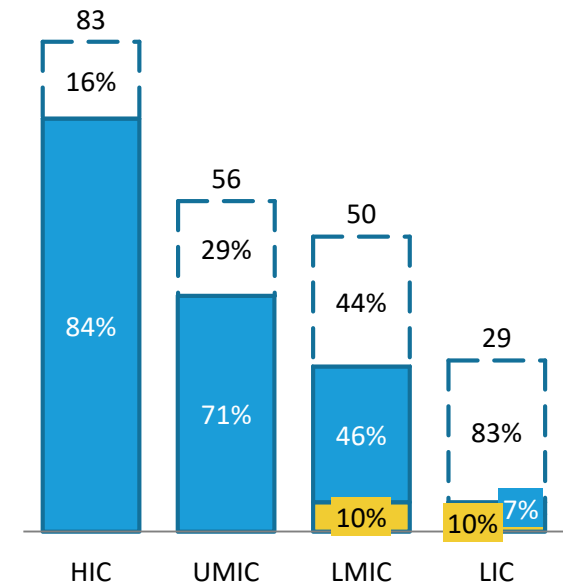
15 March 2021

# State of Vaccines: key numbers (data at 15 March 2021)

- **97 days** since first countries started vaccinating, and **14 days** since first use of COVAX doses<sup>2</sup>
- **359 million vaccine doses** have been administered:
  - 76% in 10 countries (30% in one country)
  - At least 10 different vaccines (4 platforms)<sup>3</sup>
- Campaigns **have started in 143 economies**:
  - **79% of HIC/UMIC** economies have started vaccination campaigns, while only **42% of LMIC/LIC** economies have done so
- **COVAX has shipped ~ 29 M doses to 46 countries** including 36 LMIC/LICs<sup>4</sup>:
  - 5 LMICs & 3 LICs have started their first campaigns thanks to COVAX doses



Status of vaccination campaigns by income level, #economies

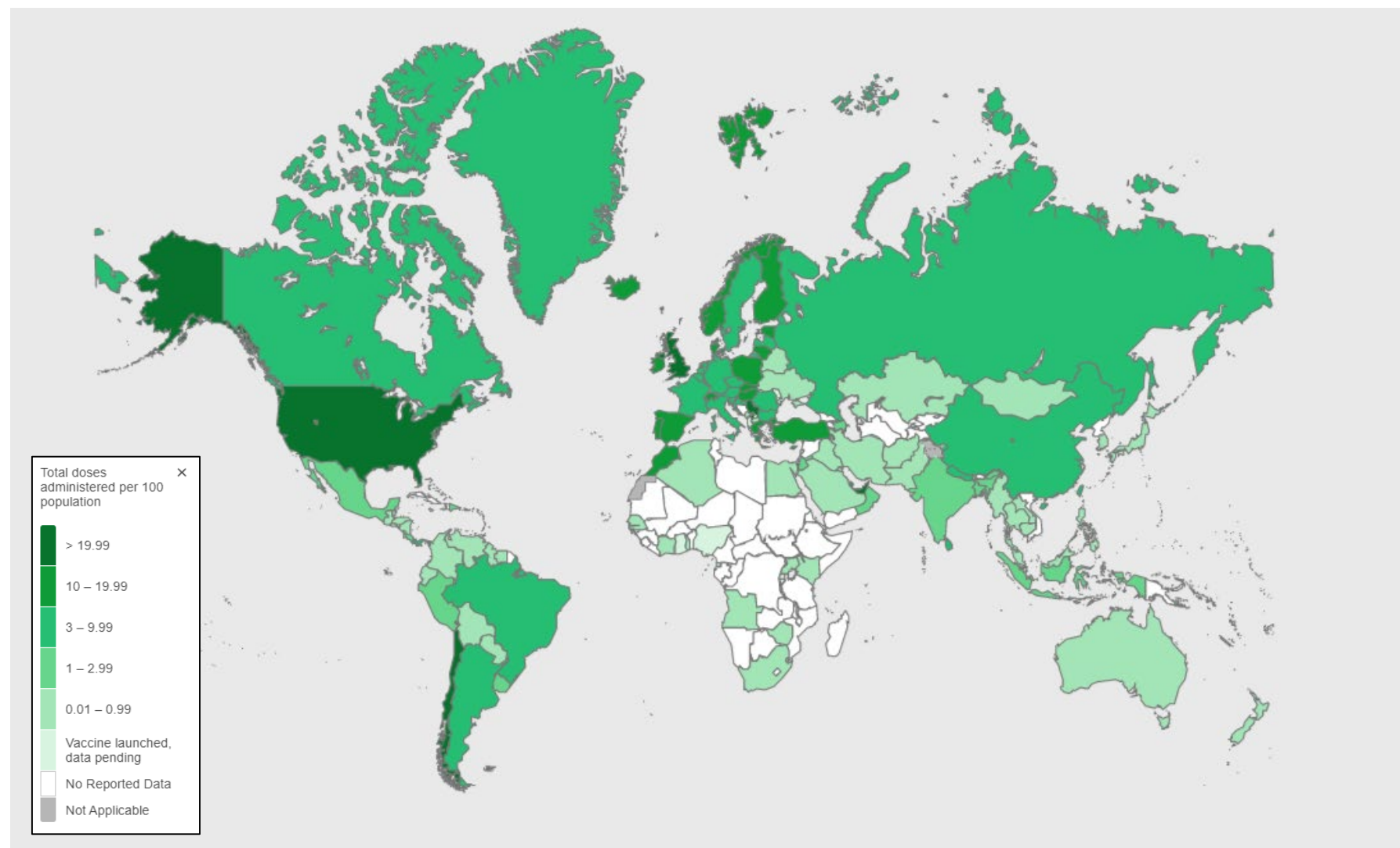


1. March 1 in Ghana and Côte d'Ivoire

2. Pfizer, Moderna, Gamaleya, Sinovac, Sinopharm, SII, Bharat Biotech, AZ, Johnson & Johnson, EpiVacCorona. Platforms: Inactivated virus, mRNA, adenoviral vector, peptide. <sup>2</sup>

Source: Our World in data; WHO COVID-19 dashboard; Bloomberg, Reuters

# Total doses administered per 100 population



SOURCE: 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.

# State of Vaccines: rollout has started in 143 economies

(data at 15 Mar 2021)

				<i>Status of Vx roll out per income group</i> <div> <div>&gt; 50% of countries</div> <div>25% &lt; X ≤ 50%</div> <div>10% &lt; X ≤ 25%</div> <div>≤ 10%</div> </div>	
Economies classified by income level <sup>1</sup>	# of economies per income group	# economies where vaccination has started	% of income group where vaccination has started		<b>Bold:</b> new economy added <b>Green text:</b> First campaign thanks to COVAX doses
High income economies (HICs)	83	70	84%	Andorra, Antigua and Barbuda, Aruba, Austria, Australia, Bahrain, Barbados, Belgium, Bermuda, British Virgin Islands, Canada, Cayman Islands, Channel Islands, Chile, Croatia, Curaçao, Cyprus, Czech Republic, Denmark, Estonia, Faroe Islands, Finland, France, Germany, Greece, Greenland, Gibraltar, Hungary, Hong Kong SAR, Iceland, Ireland, Isle of Man, Israel, Italy, Japan, Kuwait, Latvia, Liechtenstein, Lithuania, Luxembourg, Macao, Malta, Mauritius, Monaco, Netherlands, New Zealand, Norway, Oman, Panama, Poland, Portugal, Qatar, Romania, Saudi Arabia, San Marino, Seychelles, Singapore, Slovakia, Slovenia, South Korea, Spain, St. Kitts and Nevis, Sweden, Switzerland, Trinidad and Tobago, Turks and Caicos, UAE, UK, Uruguay, USA	
Upper-middle income economies (UMICs)	56	40	71%	Albania, Argentina, Azerbaijan, Belarus, Belize, Brazil, Bulgaria, China, Colombia, Costa Rica, Dominica, Dominican Republic, Ecuador, Equatorial Guinea, Grenada, Guatemala, Guyana, Indonesia, Iran, Iraq, Jordan, Kazakhstan, Lebanon, Malaysia, Maldives, Marshall Islands, Mexico, Montenegro, North Macedonia, Paraguay, Peru, Russia, Serbia, South Africa, St. Lucia, St. Vincent and the Grenadines, Suriname, Thailand, Turkey, Venezuela	
Lower-middle income economies (LMICs)	50	28	56%	Algeria, <b>Angola</b> , Bangladesh, Bolivia, Cambodia, <b>Côte d'Ivoire</b> , El Salvador, Egypt, <b>Ghana</b> , Honduras, India, <b>Kenya</b> , Laos, Micronesia, Moldova, <b>Nigeria</b> , Mongolia, Morocco, Myanmar, Nepal, Nicaragua, Pakistan, Philippines, Senegal, Sri Lanka, Ukraine, West Bank and Gaza, Zimbabwe	
Low income economies (LICs)	29	5 <sup>2</sup>	17%	Afghanistan, <b>the Gambia</b> , Rwanda, <b>Togo</b> , <b>Uganda</b>	
Total	218	<b>143</b>	66%	4 LMICs and 4 LICs have started vaccinations using COVAX doses in the last 5 days: Nigeria, Togo, The Gambia, Uganda.	

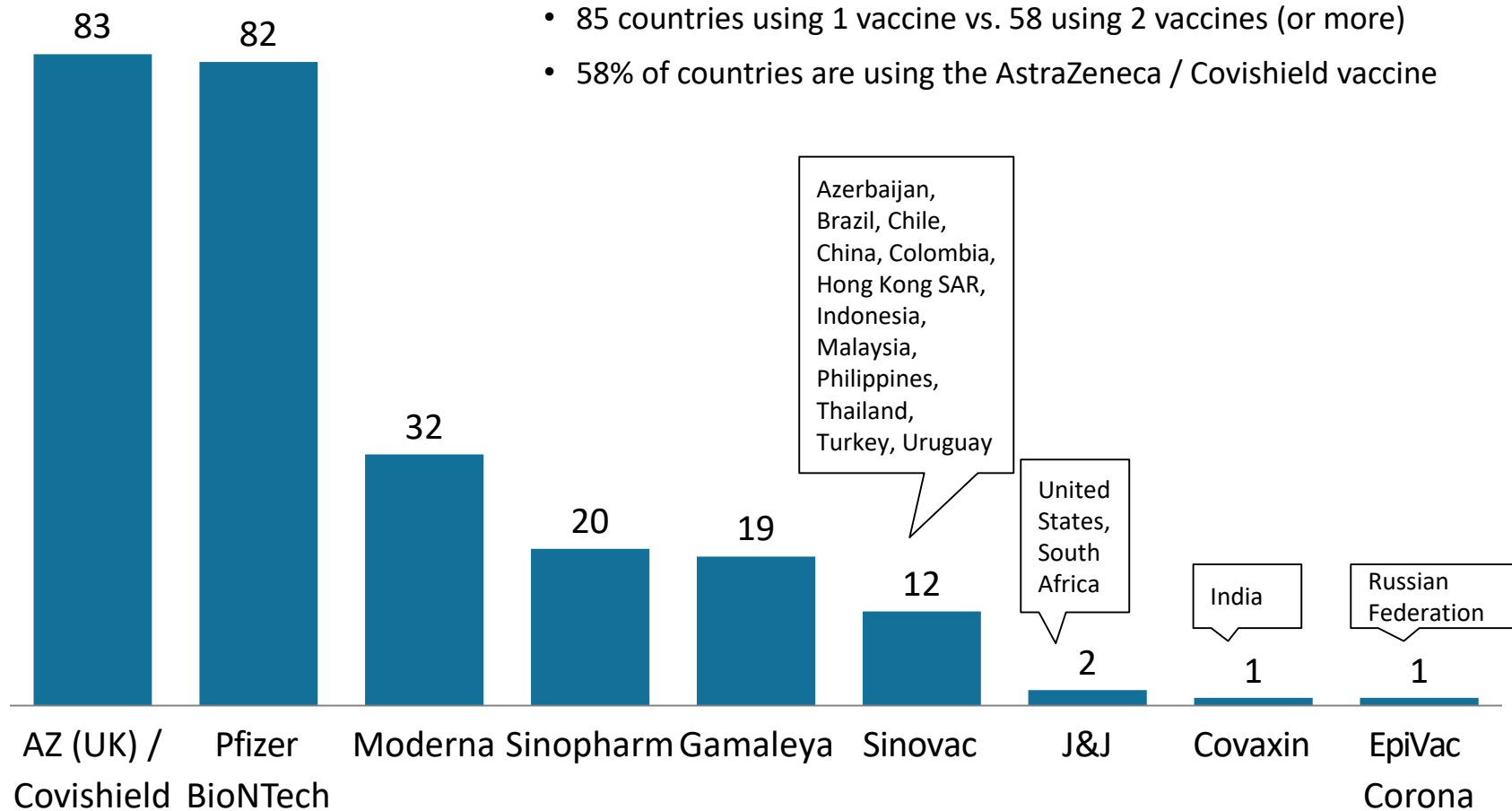
1. World Bank classification (2021). Note: The term country, used interchangeably with economy, does not imply political independence but refers to any territory for which authorities report separate social or economic statistics.

2. Removed Guinea, which had been added due to inaccurate information

Source: World Bank; WHO COVID-19 dashboard; Our World in data; Bloomberg; Reuters





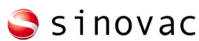



## Which economies are using which vaccine(s)?

(data at 15 Mar 2021)



# Status of vaccines with efficacy results

 COVAX Facility Products

Manufacturer		Release of efficacy results	#Participants	Reported efficacy	Efficacy against...
Pfizer/BioNTech		Published (Nov. 18)	43,000	95%	PCR confirmed COVID-19
Moderna		Published (Nov. 30)	30,000	94.1%	Symptomatic COVID-19
AstraZeneca		Published (Jan. 9)	12,390	62-90%	Symptomatic COVID-19
Gamaleya		Published (Feb. 2)	21,977	91.6%	PCR confirmed COVID-19
Sinovac		Press release Interim results (Jan. 12)	13,000	50.4% / 65% / 91%	COVID-19 with or without symptoms (Brazil / Indonesia / Turkey)
Sinopharm		Press release Interim results (Dec. 31)	21,977	79%	No information given
Novavax		Press release full results (Mar. 11)	15,000	1) 89.3%, 2) 100%	1) Mild, moderate and severe disease, 2) severe
Johnson & Johnson		Press release Interim results (Jan. 28)	43,783	1) 66-72%, 2) 85%	1) Moderate and severe, 2) severe only

1. [NEJM on Pfizer / BioNTech](#), [NEJM on Moderna](#), [The Lancet on AZ/Oxford](#), [The Lancet on Sputnik V](#), [Bloomberg on Sinovac](#), [BBC on Sinovac](#), [Bloomberg on Sinopharm](#), [Novavax website](#), 1) [J&J website](#) 2) [J&J website](#)

# COVAX Facility candidate-specific supply

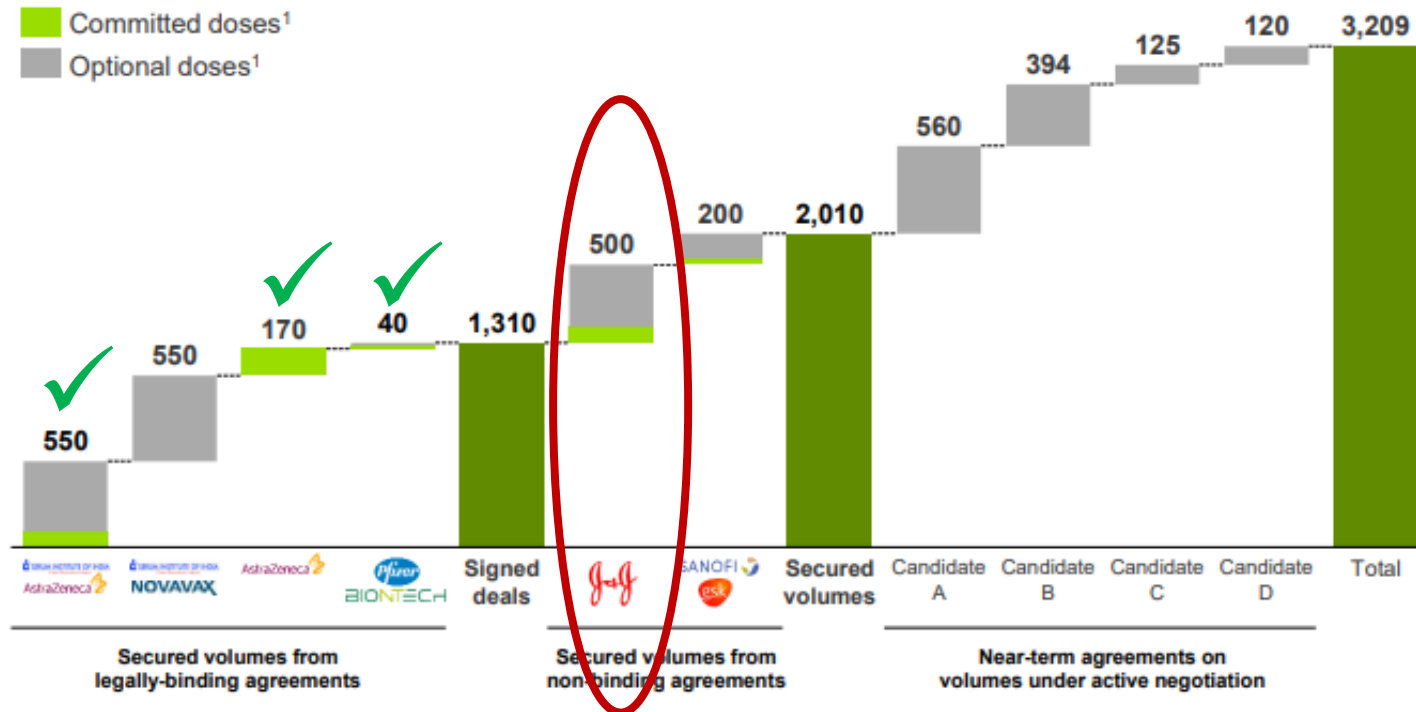
2021 and 2022

AS PER 2021-03-02

**PRELIMINARY**

✓ SAGE recommendations published  
○ For review today

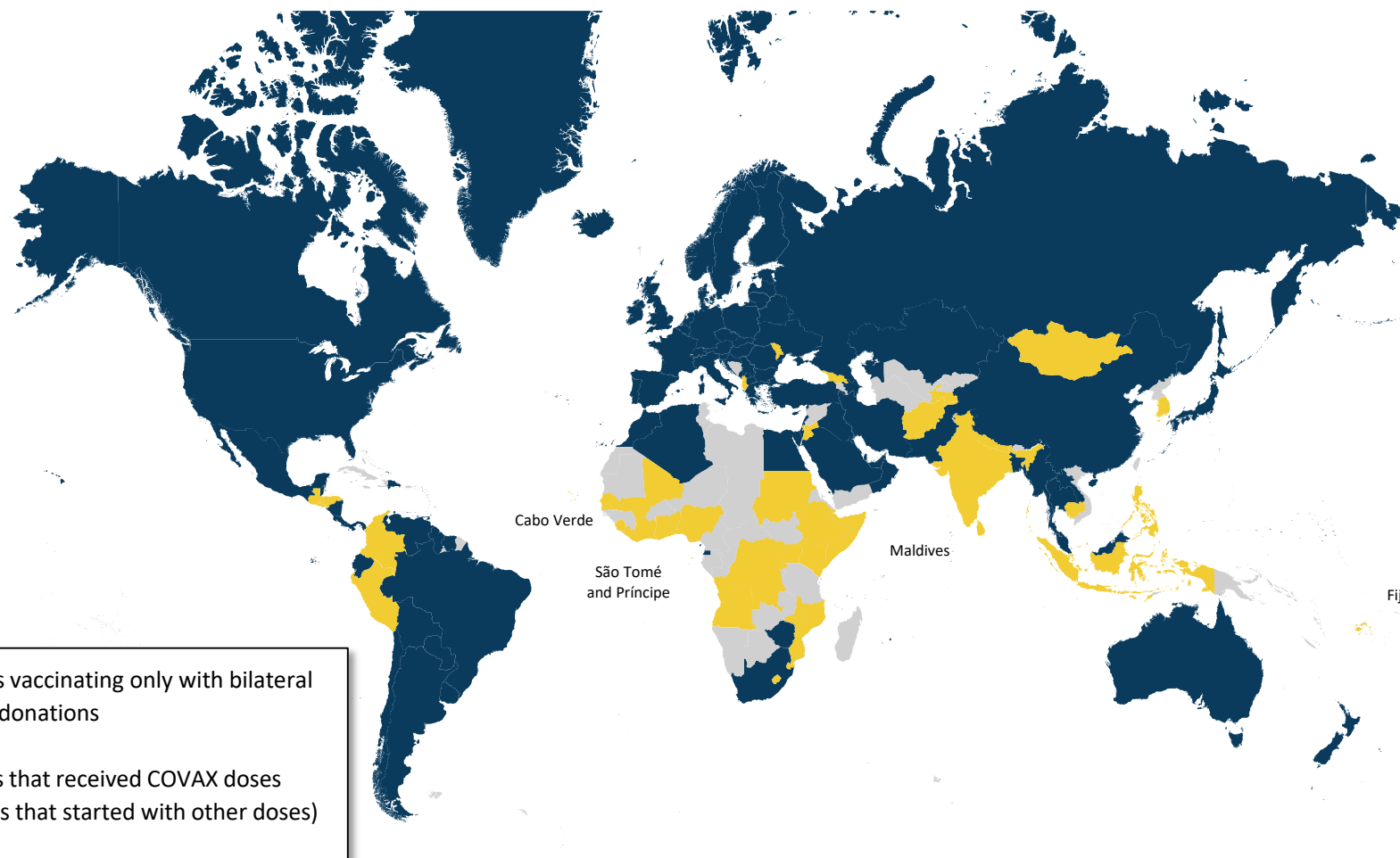
## COVAX Available Supply, Mn doses, 2021 and 2022



<sup>1</sup> "Committed doses" are doses that the COVAX Facility is required to purchase once a legally-binding agreement has been signed. "Optional doses" are doses that the COVAX Facility has the option to make a firm order commitment for in the future, but is not required to purchase. Note: Building on the recently announced memorandum of understanding with Novavax, negotiations on the final terms of the agreement and the distribution of volumes between Novavax and the Serum Institute of India are ongoing; updates will be published in due course.

Additional investments through CEPI and by the COVAX Facility are currently in negotiation

# Countries that have received doses through COVAX



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SOURCE: COVAX, WHO COVID-19 dashboard, Our World in Data; Press research







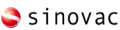






# Regulatory timeline of key Vx candidates

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

*Legend (timing of approval)*

- Approval / Emergency use
- Expected March 2021
- From April 2021
- No info
- COVAX Facility product

Estimated dates of approval / Emergency use

Vx candidates	FDA	MHRA	EMA	WHO EUL/PQ	Country reliance on PQ
 <b>Pfizer</b> <small>BIONTECH</small>	Dec. 12, 2020 Emergency Use	Dec. 2, 2020 Emergency Use	Dec. 21, 2020 Cond. Authorization <sup>1</sup>	<span style="border: 2px solid red;">Dec. 31, 2020 Emergency use</span>	Since Jan
 <b>AZ with EMA</b> as authority of reference	April 2021 <sup>2</sup>	Dec. 30, 2020 Emergency Use <sup>3</sup>	Jan. 29, 2021 Cond. Auth. <sup>1</sup> (non-Covax)	Between March and April 21 (Covax sites)	Between April and July 21 onwards
 <b>AZ South Korea w/ MFDS Korea</b> as authority of record	Not applicable	Not applicable	Not applicable	<span style="border: 2px solid red;">Feb. 15, 2021 Emergency use</span>	Since Feb
<b>SII / AZ vaccine (Covishield)</b> with DCGI India as authority of record	-	-	-	<span style="border: 2px solid red;">Feb. 15, 2021 Emergency use</span>	Since Feb
 <b>Sinopharm / BIBP<sup>5</sup></b>				March 2021 (Earliest)	April 2021 onwards
 <b>sinovac</b>	No FDA approval		No EMA approval	March 2021 (Earliest) – add. Data expected	April 2021 onwards
 <b>moderna</b>	Dec. 18, 2020 Emergency Use	Jan. 8, 2021 Emergency Use	Jan. 6, 2021 Cond. Authorization <sup>1</sup>	March 2021	April 2021 onwards
 <b>janssen</b> <small>Infectious Diseases &amp; Vaccines</small>	Feb. 27, 2021 Emergency Use		Mar. 11, 2021 Cond. Authorization <sup>1</sup>	<span style="border: 2px solid red;">Mar. 12, 2021 Emergency use</span>	Expect March onwards
 <b>THE GAMALEYA NATIONAL CENTER</b> <small>for Research and Development of Vaccines</small>				Rolling submission started from Gamaleya. Add. data awaited	
 <b>康希诺生物</b> <small>CanSinoBio</small>				Rolling submission of data from April 2021	April 2021 onwards
 <b>Sinopharm / WIBP<sup>4</sup></b>					
 <b>NOVAVAX</b>				<span style="border: 2px solid red;">Novavax submitted EOI on 23 Feb</span>	

## Key messages

- Pfizer:** WHO EUL on Dec. 31<sup>st</sup> with EMA as authority of record; ongoing country reliance on PQ
- AZ:** WHO EUL confirmed 15 Feb with MFDS (South Korea) as authority of record
- SII/AZ:** WHO EUL confirmed on 15 Feb with DCGI (India) as authority of record
- J&J:** WHO EUL confirmed on 12 Mar with EMA as authority of record
- Focus on assessment of SinoPharm, Sinovac, and Moderna.
- Others: awaiting completion of data.

\*. SII/Novavax needs to be specified

1. Conditional marketing authorization 2. According to the chief adviser for the U.S. COVID-19 vaccine program (Dec. 30, 2020; [Source](#)) 3. Temporary authorisation of supply of the vaccine in the emergency use setting (which is distinct from a marketing authorisation) 4. Wuhan Institute of Biological Products Co Ltd 5. Beijing Bio-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/>

# SAGE working to issue policy recommendations, coordinated with Regulatory process

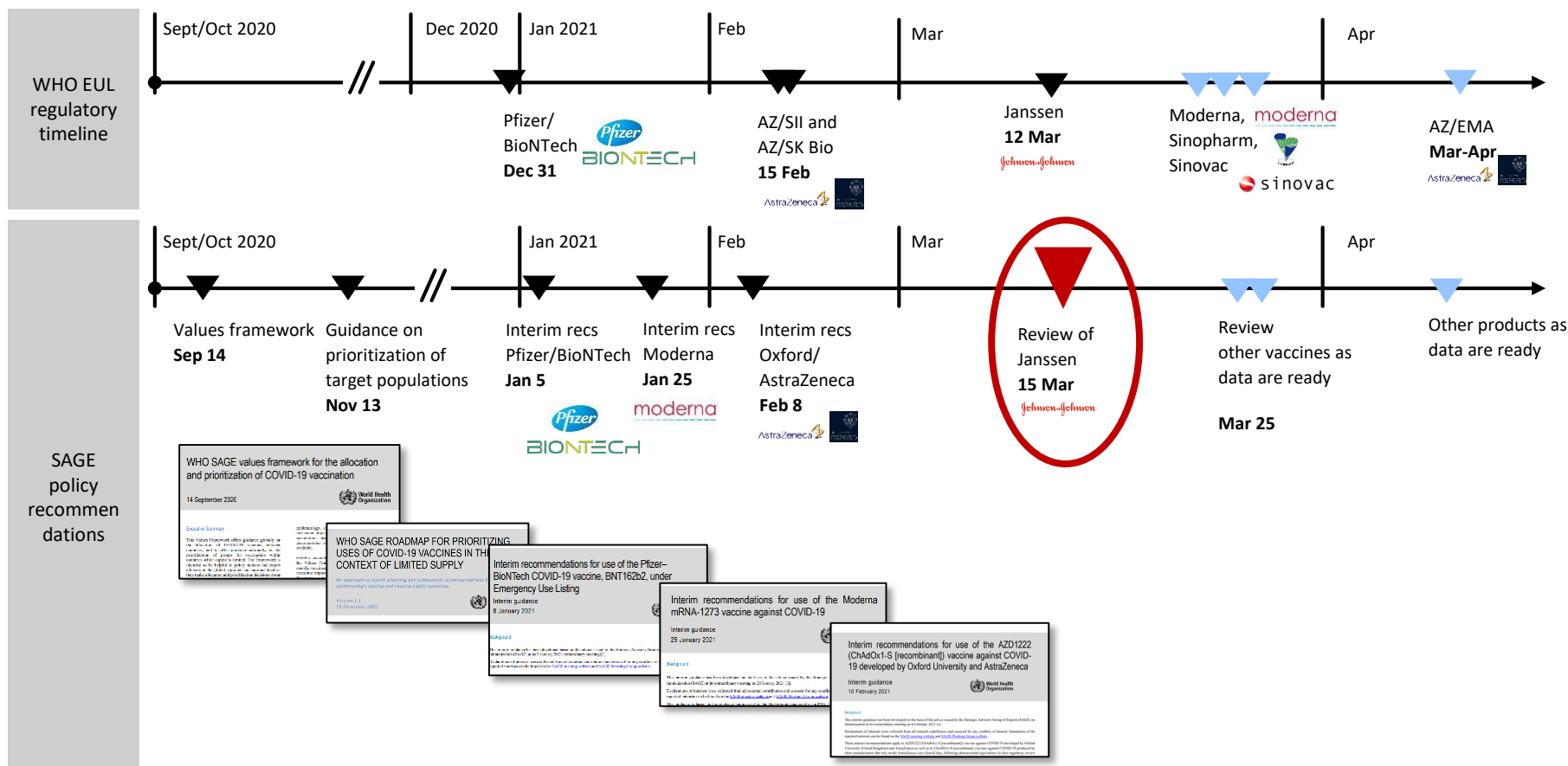
STATUS 15 MAR

ACTaccelerator  
ACCESS TO COVID-19 TOOLS

Hosted by  World Health Organization

 For discussion today

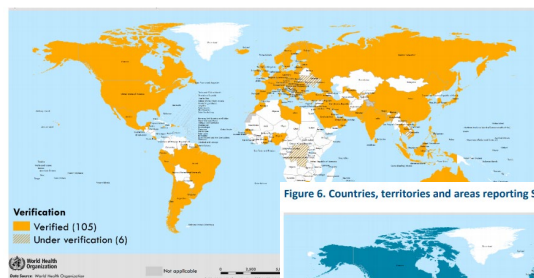
 Complete  Earliest expected date



<https://www.who.int/publications/i/item/who-sage-values-framework-for-the-allocation-and-prioritization-of-covid-19-vaccination> ; <https://www.who.int/publications/m/item/who-sage-roadmap-for-prioritizing-uses-of-covid-19-vaccines-in-the-context-of-limited-supply> ; [https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE\\_recommendation-BNT162b2-2021.1](https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1) ; <https://www.who.int/publications/i/item/interim-recommendations-for-use-of-the-moderna-mrna-1273-vaccine-against-covid-19> ; [https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE\\_recommendation-AZD1222-2021.1](https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-AZD1222-2021.1)

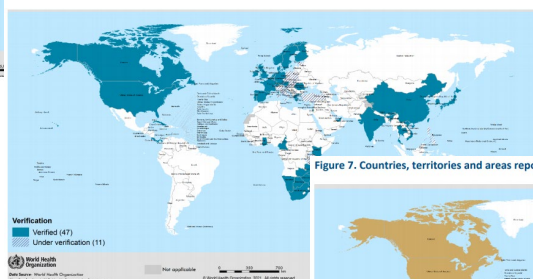
# There are currently three variants of concern

Figure 5. Countries, territories and areas reporting SARS-CoV-2 VOC 202012/01 as of 9 March 2021



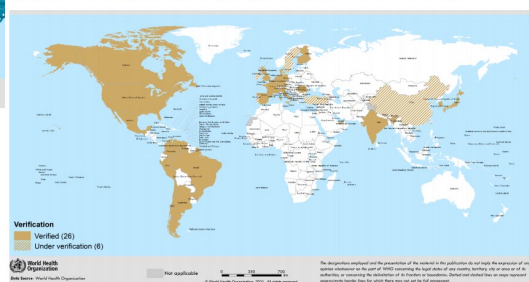
VOC  
202012/01  
(first identified  
in the UK)

Figure 6. Countries, territories and areas reporting SARS-CoV-2 501Y.V2 as of 9 March 2021



501Y.V2 or  
B.1.351  
(first identified  
in South Africa)

Figure 7. Countries, territories and areas reporting SARS-CoV-2 P.1 variant as of 9 March 2021



P.1 (first identified  
in Brazil)

**Variants of concerns are defined by WHO** by their transmission, disease severity, or impact on COVID-19 counter measures

**Evidence supports ongoing use of existing vaccines** – with some concerns about B.1.351 vs. some vaccines (*available data still limited, and incomplete*)

The preliminary findings highlight the **urgent need for a coordinated approach for surveillance and evaluation of variants** and their potential impact on vaccine effectiveness