

**Re**: VacSafe Africa Brief **Last Updated**: July 1, 2021

**Summary**: This report is a product of the VacSafe Working Group, a group of leading scientists, vaccine and public health experts, and policymakers. Its purpose is to provide an up-to-date overview of the state of SARS-CoV-2 vaccines in Africa (54 countries and two disputed territories). This briefing comes as Africa is experiencing its third and potentially deadliest wave of the COVID-19 pandemic, pressing the need for acceleration of vaccine allocation and distribution to the continent. Information included in this briefing is drawn from public sources. For broader context, refer to earlier installments of the Vaccines in Africa Brief.

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# VacSafe Working Group

# Monthly Brief: Congressional Research Services

### Vaccines in Africa (54 countries and two disputed territories)

# 1. SARS-CoV-2 Vaccination Status in Africa

- *The Economist* reported that as of June 30, 2021, 21.5 million doses of COVID-19 vaccines had been distributed in sub-Saharan Africa, with 2.4% of its population above the age of 12 having received at least one dose and 0.6% having received a second.
- The Our World in Data vaccine tracker reported that as of June 29, 2021, a total of 50.48 million vaccine doses had been administered across the entire African continent.

# 2. Emerging Variants

- Multiple variants of the virus which causes COVID-19 are circulating globally. In collaboration with the SARS-CoV-2 Inter-agency Group (SIG), US Centers for Disease Control and Prevention (CDC) have established three classifications for the SARS-CoV-2 variants being monitored: Variant of Interest (VOI), Variant of Concern (VOC), and Variant of High Consequence (VOHC).
- The CDC Global Variants Report, which is tracking the worldwide distribution of four variants, reports that as of June 21, 2021, three of those variants were circulating in Africa:
  - Alpha (B.1.1.7) (VOC): initially detected December 2020 in the United Kingdom; verified in 27 African countries.
  - Beta (B.1.351) (VOC): initially detected December 2020 in South Africa; verified in 23 African countries.
  - Delta (B.1.617.2) (VOC): initially detected December 2020 in India; verified in two African countries
  - Gamma (P.1) (VOC): initially identified January 2021 in travelers from Brazil; not detected in Africa at time of publication.
- The World Health Organization (WHO) has identified seven VOI:
  - Epsilon (B.1.427/B.1.429); initially detected March 2020 in the US.
  - Zeta (P.2); initially detected April 2020 in Brazil.
  - Eta (B.1.525); initially detected December 2020 in multiple countries.
  - Theta (P.3); initially detected January 2021 in the Philippines.
  - Iota (B.1.617.1); initially detected November 2020 in the US.
  - Kappa; Initially detected October 2020 in India.
  - Lambda (C.37); initially detected August 2020 in Peru.

# 3. Vaccine Efficacy, Safety, and Approval

- Moderna Received WHO Emergency Use Listing status and approved for use in Rwanda.
- Oxford–AstraZeneca (Covishield) Approved by Africa Regulatory Taskforce (ART), received WHO Emergency Use Listing status and approved for use in 25 African countries.
- Pfizer-BioNTech Received WHO Emergency Use Listing status and approved for use in Botswana, Rwanda, South Africa, and Tunisia.
- Sinopharm (BBIBP-CorV) Received WHO Emergency Use Listing status and approved for use in 15 African countries.

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- Sinovac (CoronaVac) Approved for use in Egypt, Tunisia, and Zimbabwe.
- Bharat Biotech (COVAXIN) Approved for use in Botswana and Zimbabwe.
- Gamaleya Research Institute of Epidemiology and Microbiology (Sputnik V) Approved for use in 12 African countries.
- Johnson & Johnson (Ad26.COV2.S) Received WHO Emergency Use Listing status and approved in Tunisia, South Africa, and Zambia.

# 4. Continental Vaccine Acquisition

With a population of 1.24 billion, Africa is dependent on three vaccine sources: (1) the WHO's COVAX scheme (co-led by the GAVI Alliance and The Coalition for Epidemic Preparedness Innovations (CEPI)); (2) the African Union (AU) via the African Vaccine Acquisition Trust (AVAT); and (3) bilateral agreements with pharmaceutical companies and/or vaccine-producing countries and donation agreements.

- COVAX:
  - COVAX has met only 4% of its goal to deliver two billion doses by the end of 2021, though a significant increase in supplies is expected by early 2022. Thus far, 80 million doses have been distributed to 129 participating countries. Managing Director of the COVAX office, Aurelia Nguyen, recently stated that deliveries will continue to be "very lean through July and August."
  - On June 3, the US pledged 80 million vaccine doses to poorer countries, of which Africa is to receive five million via COVAX. At the Carbis Bay G7 Summit, the US pledged a further 500 million Pfizer-BioNTech doses (200 million in 2021 and 300 million in 2022) to 92 poorer nations and the African Union the exact details of the apportionments are undisclosed. The United Kingdom pledged the donation of 100 million doses of COVID-19 vaccine, 5 million of which will be made available to poorer nations. Similar to the US declaration, little detail on process and timing is available.
- A COVAX shake up now underway was discussed at the GAVI board held on Friday, June 25.
  - In the run up to the meeting, some board documents indicated that the overhaul was meant to reduce COVAX's financial risks, increase its focus on the countries most in need, and reduce the participation of richer countries as recipients.
  - About 190 countries are currently part of COVAX; one third do not use its vaccines and about 40 have launched their vaccine drives with doses from COVAX. In a separate internal document, Gavi estimates that membership may

shrink to 120-130 countries next year. Many rich nations are expected to step aside voluntarily.

• The planned policy change may also make it costlier for middle income countries (MICs) to take part. From next year, MICs that still need COVAX vaccines may have to pay/co-pay for them in advance. This means that countries like South Africa, Nigeria and Egypt may face higher costs and need to borrow money to secure doses.

According to a statement published by GAVI after the Board meeting, the Board approved "an evolution in the model of participation for self-financing participants (SFPs) of the COVAX Facility. Starting in 2022, the model will enable SFPs that rely on the Facility to access doses to continue procuring vaccines through COVAX under revised terms and conditions. The move, based on lessons learned over the past year, will enable simplified operations and reduce financial risks to Gavi and COVAX."

- African Union via AVAT:
  - Oxford–AstraZeneca: procurement paused as of April 8<sup>th</sup>, 2021.
  - Johnson & Johnson: 220mn doses with option of extending to purchase a further 180mn (~\$10 per dose). As of May 10:
    - Afreximbank has provided \$330 million to J&J as a non-refundable down payment for the doses. Countries can secure doses through the Africa Medical Supplies Platform and can participate in a payment plan of up to five years with the bank, with a subsidized interest rate between 3% and 5%.
    - Only Botswana, Cameroon, Tunisia, Togo, and Mauritius have completed orders and submitted a 15% deposit as a down payment for the doses.
    - Another 13 have signed commitment letters, but not given deposits, and another 17 have expressed interests in pre-orders but not taken further action. Twenty-one countries have not taken any action toward securing these doses.
  - Oxford–AstraZeneca, Johnson & Johnson, Pfizer-BioNTech: in January AU agreed to purchase a combined total of 270 million doses of these three vaccines. Gamaleya Institute (Sputnik V): 300 million doses at \$9.75 price per dose.
- Significant Bilateral Vaccine Purchases & Vaccine Diplomacy:
  - Egypt: 50mn doses of Sputnik V.
  - South Africa: 31mn J&J and 30mn Pfizer BioNTech.
  - China (to date): Approximately 6.59 million doses donated to Africa and 44.7mn doses purchased by African countries. 33 African countries have been receiving sales and donations of vaccines from China

• Russia Vaccine Donations: >1mn doses of Sputnik V to 3 African countries (Algeria, Guinea, and Zimbabwe).

# 5. Vaccine Fill & Manufacturing

- Only 30% of medicines used in Sub-Saharan Africa are locally produced. EU Commissioner Jutta Urpilainen said Team Europe aims to work with partners in Africa to develop and strengthen pharmaceutical production in the continent. The issue is high on the agenda of the first World Local Production Forum this week.
- Mastercard Foundation pledges \$1.3 billion to Africa vaccine efforts. On June 8 the Mastercard Foundation announced that it will donate \$1.3 billion to boost vaccine manufacturing and distribution in Africa in partnership with the continent's Africa Centers for Disease Control and Prevention.
- The WHO and COVAX partners are working with a South African consortium comprising Biovac, Afrigen Biologics and Vaccines, a network of universities and the A-CDC to establish Africa's first COVID mRNA vaccine technology transfer hub.
- WTO's ED Ngozi Okonjo-Iweala said Africa was also working with the EU and other partners to help create regional vaccine manufacturing hubs in South Africa, Senegal and Rwanda, with Nigeria under consideration.
- AMA Momentum is building for the African Medicines Agency, which could boost local manufacturing of health products and protect consumers against counterfeits. Algeria this week ratified the treaty that will create the agency once at least six more countries sign on.
- Africa uses roughly 25% of the annual global vaccine supply (representing approximately 1.3 billion doses). 99% of those doses are imported.
- Current vaccine manufacturing capacity in the continent is limited and focused on internal markets; there is an absence of large-scale production at present and limited export of vaccine products.
- UK AID listed 10 players in vaccine manufacturing on the continent. These manufacturers collectively produce about 12 million doses per annum. The majority of Africa's vaccine manufacturing capacity is concentrated on fill-finish, and packaging and labeling.
- Recognizing that there are no facilities in Africa that have capacity to produce RNA or vector-based vaccines, and following the launch of the African Union/Africa CDC *Partnership for African Manufacturing Framework*, CEPI is concluding an MOU with the Africa CDC to help push Africa's manufacturing capacity.

- On May 21 2021, the European Union (EU) President Ursula von der Leyen announced that the EU would commit US\$1.2 billion towards the establishment of vaccine manufacturing hubs in Africa. China has also signaled its intention to support vaccine manufacturing on the continent.
- The Biden-Harris Administration's support of the proposed TRIPS waiver in relation to COVID-19 vaccines has also been recognized as a significant step towards greater global vaccine equity, which could ultimately include enhancing vaccine manufacturing capacity in developing countries. At the World Health Assembly (24 May to 1 June) the US reaffirmed its support for COVID19 vaccine IP waiver when delegates discussed local production in lower to middle income countries.
- At the WHA Ethiopia led a resolution to strengthen 'local production of medicines and other health technologies to improve access.' The resolution has support from the WHO Africa Region, the EU, the US, China, Brazil and other nations. The resolution seeks to 'strengthen local production and know-how' and 'promotes technology transfer and innovation.' Costa Rica and the WHO called on countries to support WHO's COVID-19 Technology Access Pool (C-TAP).
- There is an increased role of the private sector in bolstering the continent's vaccine manufacturing capacity.
  - Following the contamination of a key J&J ingredient at U.S.-based Emergent BioSolutions, 2 million doses produced in South Africa had to be discarded. South African based Aspen Pharmacare expects the first locally produced J&J doses to be ready for use by the last week of June. Aspen Pharmacare has committed to supplying 300 million doses of J&J vaccines.
  - Egypt's Minapharm has entered into an agreement with the Russian Direct Investment Fund to locally produce over 40 million doses of Sputnik V per year for global distribution
- Sputnik V is said to be ready for manufacturing in Algeria come September 2021. The vaccine will be produced in partnership with state pharmaceutical product's firm Saidai in the eastern city of Constantine, in a tie-up with what is described as 'a leading Indian laboratory.' It is unclear what will be involved in the Russia-sponsored technology transfer.
- In late May, Egypt received raw materials for the production of 2 million Sinovac doses. These materials are expected to be manufactured into vaccines by the end of June. Egypt expects to locally produce 5 million doses by August and 40 million doses of Sinovac by the end of 2021. These doses will go to Egypt as well as other African countries.

## 6. Vaccine Distribution

- COVAX has initiated three rounds of vaccine allocation to participant countries (See Appendix Table 1 for country-level allocation in the AFRO region).
  - The first round of allocation was announced in early February and outlined an exceptional distribution of 1.2 million doses of the Pfizer/BioNTech vaccine; distribution of these doses took place during Q1 of 2021.
  - The second round of allocation covered 237 million doses of the Oxford AstraZeneca (Covishield) vaccine. Many of these doses are being manufactured by the Serum Institute in India. Distribution was intended to be completed in May, but rising COVID-19 cases in India and bans on the export of the Oxford– AstraZeneca vaccine have caused significant delays.
  - The third round of allocation covered 14.1 million doses of the Pfizer-BioNTech vaccine. Distribution will take place between April and June 2021.
- Seven countries in Africa have used almost 100% of the allotted COVAX doses including Botswana, Ghana, Rwanda and Senegal. In addition to these states, there is some partial use and discarding:
  - Kenya and Malawi have used nearly 90% of their COVAX doses.
  - Cabo Verde and the Gambia have used 60% of their COVAX doses.
  - 1.3 million doses have been redistributed from Democratic Republic of Congo to other parts of Africa because the country will not be able to use them all before their expiry date in June.
  - South Sudan plans to discard 59,000 doses and Malawi has already destroyed 20,000 doses of the vaccines. This is largely due to the very late stage at which the vaccine doses were received by the countries and speaks to challenges of both delays in acquisition and country preparedness to distribute and administer vaccines.

# 7. Vaccine Licensing/Intellectual Property

See appendix for a diagram of vaccine patent architecture (Figure 1)

Vaccine Licensing and Intellectual Property:

• An informal WTO TRIPS meeting that kicked-off text-based negotiations over the waiver took place the week of 14 June. Members remained divided on fundamental issues, but agreed to schedule meetings over the next 6 weeks to discuss waiver proposals. This suggests that there lies a long road ahead. The WTO's TRIPS Council agreed on Wed to move ahead with a "text-based process," effectively green-lighting negotiations over the proposal to waive IP associated with COVID Dx, Tx and vaccines.

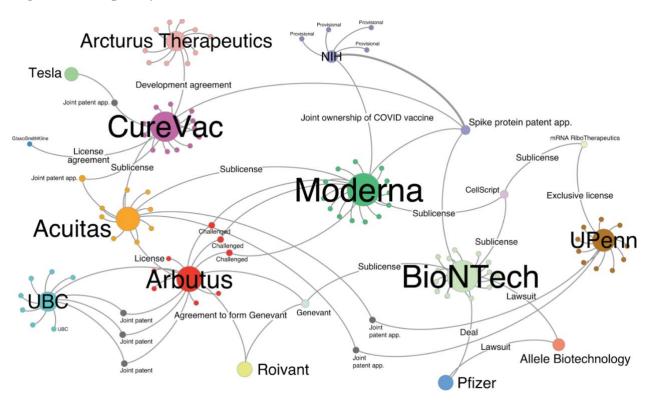
The chair said that he foresees an intensive schedule of meetings and consultations, beginning immediately after the TRIPS Council meeting. The chair intends to consult members urgently on how the process can be arranged in practical terms, aiming at agreement on a report to the next General Council meeting scheduled for 21-22 July.

- The move was the latest in a series of incremental advances on the initiative by India and South Africa. The UK parliament came out in support of the waiver, but the UK is still opposed. Same for the EU as a bloc. France, Japan, China came out in support. The EU proposal which has proposed alternative measures to expand medicines and vaccines production will remain on the table side by side with the waiver proposal as part of the overall negotiations. The EU alternative, under heavy fire from medicines access groups since it was published in early June, calls for the better use of existing WTO measures permitting countries to issue compulsory licenses. It also calls upon IP holders to step up their issuance of voluntary licenses for COVID-related health products in short supply.
- WTO General Council Chair Dacio Castillo of Honduras has selected Ambassador David Walker of New Zealand to be the facilitator responsible for leading WTO members in finding a multilateral response to the COVID-19 pandemic. According to some of those pushing for the waiver, the WTO's future now rests on what happens next: "The credibility of the WTO will depend on its ability to find a meaningful outcome on this issue that truly ramps-up and diversifies production," says Mlumbi-Peter, South Africa's ambassador to the WTO. Meanwhile, the EU continues to push for a declaration at WTO, in parallel with waiver efforts.
- The Medicines Patent Pool (MPP) launched a new patents database devoted to COVID-19 vaccines. VaxPaL builds on MPP's 10-year experience in mapping patents on key health technologies. As of now, VaxPaL provides patent information on COVID-19 vaccines compiled into an Excel workbook. In the coming months, VaxPaL will be turned into a fully searchable online database.

#### -Appendix-

#### **Figures and Supplemental Information**

The VacSafe Working Group recently launched a website that houses publicly facing versions of these briefings, an interactive map that tracks COVID-19 vaccination rates and their correlates in Africa, and up-to-date information on the working group's convenings and projects. The website can be found at <u>www.vacsafe.columbia.edu</u>.



# Figure 1: Complexity of Vaccine Patent Architecture

Source: "A Network Analysis of COVID-19 MRNA Vaccine Patents" - Nature Biotechnology Vol. 39 no. 5 (May 1, 2021)

# Figure 2: Africa's Vaccine Value Chain Entities and Status Source: Expanding vaccine manufacturing in Africa (February 2021, Great for Growth: UKAID

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Manufacturer	Products	R&D	Drug substance mfg	Fill & finish	Pack & label	Import for distribution
🚹 Institut Pasteur Dakar	Yellow Fever					
Egy Vac (Vacsera)	BCG-T, Tuberculin, Tetanus, DTP, Typhoid, Cholera					
Institut Pasteur Tunis <sup>2</sup>	BCG					
Biovac Biovac	BCG <sup>6</sup> , Measles <sup>6</sup> , Pneumococcal conj. <sup>3</sup> , Hepatitis B <sup>3</sup> , Hexavalent Vaccine <sup>7</sup>					
🔀 Aspen Pharmacare	Covid-19 candidate					
Institut Pasteur Morocco	BCG, DT, Yellow Fever, Typhoid Fever, Influenza, Rabies					
EPHI: Eth Public Health Institute	Plan to produce vaccines <sup>4</sup>					
Biovaccines	Plan to produce Hep-B Plan to produce Tetanus Plan to produce DTP+Hep-B Plan to produce Yellow Fever Plan to produce Measles					
Innovative Biotech	HIV					
Institut Pasteur Algeria	Rabies					

# Table 1: To-date COVAX Allocation of Vaccine Doses in WHO AFRO Region by Country and Manufacturer

Participant	Region	SFP/AMC	Round 1: Pfizer/BioNTech (Exceptional Distribution, Q1 2021)	Round 2: AZ & SII/AZ (Feb - May 2021)		Round 3: Pfizer/BioNTech (April - June 2021)	
Algeria				1,881,600	AZ		
Angola	AFRO	AMC		2,172,000	SI/AZ	100,620	
Benin	AFRO	AMC		792,000	SI/AZ		
Botswana	AFRO	SFP		100,800	AZ	19,890	
Burkina Faso	AFRO	AMC		1,380,000	SI/AZ		
Cabo Verde	AFRO	AMC	5,850	108,000	SI/AZ		
Cameroon	AFRO	AMC		1,752,000	SI/AZ		
Central African Republic	AFRO	AMC		312,000	SI/AZ		
Chad	AFRO	AMC		1,080,000	SI/AZ	100,620	
Comoros	AFRO	AMC		108,000	SI/AZ		
Congo, Dem. Rep.	AFRO	AMC		5,928,000	SI/AZ		
Congo, Rep.	AFRO	AMC		360,000	SI/AZ		
Cote d'Ivoire	AFRO	AMC		1,740,000	SI/AZ	100,620	
Eswatini	AFRO	AMC	-	108,000	SI/AZ		
Ethiopia	AFRO	AMC	-	7,620,000	SI/AZ		
Gambia, The	AFRO	AMC	-	156,000	SI/AZ		
Ghana	AFRO	AMC	-	2,052,000	SI/AZ		
Guinea	AFRO	AMC	-	864,000	SI/AZ		
Guinea-Bissau	AFRO	AMC		120,000	SI/AZ		
Kenya	AFRO	AMC	-	3,564,000	SI/AZ		
Lesotho	AFRO	AMC		132,000	SI/AZ		
Liberia	AFRO	AMC		324,000	SI/AZ		
Malawi	AFRO	AMC		1,260,000	SI/AZ		
Mali	AFRO	AMC	-	1,332,000	SI/AZ	-	
Mauritania	AFRO	AMC		300,000	SI/AZ		
Mauritius	AFRO	SFP		100,800	AZ		
Mozambique	AFRO	AMC	-	2,064,000	SI/AZ	-	
Namibia	AFRO	SFP		108,000	AZ		
Niger	AFRO	AMC		1,596,000	SI/AZ	-	
Nigeria	AFRO	AMC	-	13,656,000	SI/AZ	-	
Rwanda	AFRO	AMC	102,960	744,000	SI/AZ	100,620	
Sao Tome and Principe	AFRO	AMC	-	96,000	SI/AZ	-	
Senegal	AFRO	AMC		1,104,000	SI/AZ		
Sierra Leone	AFRO	AMC		528,000	SI/AZ		
South Africa	AFRO	SFP	117,000	2,426,400	AZ	1,275,300	
South Sudan	AFRO	AMC		732,000	SI/AZ		
Togo	AFRO	AMC		540,000	SI/AZ	100,620	
Uganda	AFRO	AMC		3,024,000	SI/AZ		
Zambia	AFRO	AMC		1,212,000	SI/AZ		
Zimbabwe	AFRO	AMC		984,000	SI/AZ		
non-UN Member Sates	-	•	-	1,125,800	AZ		

Source: COVAX -- 'Allocation Round 3: Pfizer-BioNTech Vaccine, April - June 2021' (12 Apr 2021)

#### KEY:

SFP - Self-Financing Participant | AMC - Advance Market Commitment | AZ - AstraZeneca | SII - Serum Institute of India

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#### **Key Upcoming Convenings**

- July 9-10: G20 Finance Ministers
- July 21-22: WTO General Council meeting

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