

**Re:** Vaccines in Africa Memo Vol.1 no.2

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**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 informed overview on the state of SARS-CoV-2 vaccines in Africa (54 countries and 1 disputed territory) with a view to inform legislators. Data and information sourced for this briefing are drawn from reputable private and public sources.

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<p><b>VacSafe Working Group</b></p> <p><b>Monthly Brief: Congressional Research Services</b></p> <p><b>Africa (54 countries 2 disputed territories)</b></p>
<p><b>1. SARS-CoV-2 Vaccination Status in Africa</b></p> <ul style="list-style-type: none"> <li>• As of May 30, 2021, the <i>Economist</i> reported that 13.5 million doses of COVID-19 vaccines had been distributed in Sub-Saharan Africa, with 2.4% of adults in the region having received at least one vaccine dose, and 0.2% of adults having received a second dose.</li> <li>• As of May 29, 2021, the Our World in Data vaccine tracker reported that a total of 31.04 million vaccine doses had been administered across the entire African continent, accounting for 1.77% of doses administered globally.</li> </ul>

## 2. Emerging Variants

- Multiple variants of the virus that causes COVID-19 are circulating globally. In collaboration with a SARS-CoV-2 Interagency Group (SIG), US CDC 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 WHO Virus Evolution Working Group recently convened and recommended labeling variants using letters of the Greek alphabet.
- The US Centers for Disease and Prevention (CDC) Global Variants Report is tracking the world-wide distribution of six variants; as of May 20, 2021, three variants are reported to be circulating in Africa:
  - B.1.1.7 ( $\alpha$ ): (VOC) initially detected in the UK, December 2020.  
§ Verified in 17 African countries.
  - B.1.351 ( $\beta$ ): (VOC) initially detected in South Africa, December 2020.  
§ Verified in 16 African countries.
  - P.1 ( $\gamma$ ): (VOI) initially identified in travelers from Brazil, January 2021.  
§ Not verified to be circulating in Africa.
  - B.1.617.1 ( $\kappa$ ): (VOI) initially detected in India, December 2020.  
§ Not verified to be circulating in Africa.
  - B.1.617.2 ( $\delta$ ): (VOI) initially detected in India, December 2020.  
§ Verified in two African countries.
  - B.1.617.3 (Unlabeled): (VOI) initially detected in India, October 2020.  
§ Not verified to be circulating in Africa.

## 2. Vaccine Efficacy, Safety, and Approval

- Moderna - WHO Emergency Use Listing and approved in Rwanda.
- Oxford-AstraZeneca (Covishield) - Africa Regulatory Taskforce (ART) approved, WHO Emergency Use Listing and approved in 25 African countries.
- Serum Institute of India (licensed to produce and sell the Oxford-Astra-Zeneca Covishield vaccine) - Africa Regulatory Taskforce (ART) approved, WHO Emergency Use Listing and approved in 10 African countries.
- Pfizer-BioNTech - WHO Emergency Use Listing and approved in Botswana, Rwanda, Tunisia, and South Africa.
- Sinopharm (BBIBP-CorV) - WHO Emergency Use Listing and approved in 15 African countries.

- Sinovac (CoronaVac) - approved in Egypt, Tunisia, and Zimbabwe.
- Bharat Biotech (Covaxin) - approved in Botswana and Zimbabwe.
- Gamaleya Institute (Sputnik V) - approved in 12 African countries.
- Janssen/Johnson & Johnson (Ad26.COV2.S) - WHO Emergency Use Listing and approved in Tunisia, South Africa, and Zambia.

#### 4. Continental Vaccine Acquisition

With a population of 1.24 billion people, Africa is dependent on three vaccine sources: (1) the WHO's COVAX scheme (co-led with the Global Alliance for Vaccines and Immunization (GAVI) and 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:
  - 600 million doses have been secured for 36 African countries. The timeline for delivery of these vaccines remains uncertain.
  - As of May 21, 2021, leaders of the G20 and other states made a series of declarations at the Global Health Summit — The Rome Declaration. Sixteen key principles were adopted as pillars to upscale current efforts to confront COVID-19 and to build greater resilience in health systems in preparation for the next pandemic. G20 leaders recognized the role of “extensive COVID-19 immunization as a global public good” and affirmed their “support for all collaborative efforts, especially to Access to COVID-19 Tools Accelerator (ACT-A).” Leaders also underscored the importance of addressing the ACT-A funding gap.
  - In 20 countries across Africa, 20 million people are due for their second AstraZeneca shot in June — but their expected doses have not come through. Fifty million people in Africa who were supposed to get their first doses of AstraZeneca in April and May did not either. Compared with 1.5 billion vaccine doses already administered globally, Africa has to date administered 28 million doses.
  - With vaccine doses deliveries delayed, the Africa CDC suggested that COVID-19 could become endemic on the continent. “If we keep vaccinating at this pace, we are not going to achieve our target. And that will delay our ability to eliminate the virus from our population — and my greatest concern is that we may actually begin to move towards the endemicity of this virus,” Africa CDC Director John Nkengasong said at the World Health Assembly (WHA).
  - India’s export ban of the Oxford-AstraZeneca vaccine and delays in production at the Serum Institute in India (SII) has been a setback for vaccination efforts. The SII was due to supply around half of the two billion vaccines for COVAX this year but

there were no shipments for March, April, or May. The shortfall is expected to rise to 190 million doses by the end of June.

- African Union via AVAT:
  - Oxford-AstraZeneca: procurement paused as of April 8<sup>th</sup>, 2021.
  - Johnson & Johnson (J&J): 220 million doses with option of extending to purchase a further 180 million (~\$10 per dose). As of May 10:
    - Afreximbank has provided a non-refundable \$330 million upfront to J&J as 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 countries have signed commitment letters, but not given deposits, and another 17 have expressed interests in pre-orders but not taken further action. 21 countries have not taken any action toward securing these doses.
  - Oxford-AstraZeneca, J&J, Pfizer-BioNTech: in January the 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: 50 million doses of Sputnik V.
  - South Africa: 31 million J&J and 30 million Pfizer-BioNTech.
  - China Vaccine Donations to African States (to date): ~5.8 million doses to eight African countries.
  - Russia Vaccine Donations: >1 million doses of Sputnik V to three African countries (Algeria, Guinea, and Zimbabwe).

## 5. Vaccine Fill & Manufacturing

- 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.

- On May 21, 2021, the European Union (EU) President Ursula von der Leyen announced that the EU would commit \$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 Trade-Related Aspects of Intellectual Property (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 (May 24 to June 1) 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. In South Africa, for example, Aspen Pharmacare was recently able to contribute, locally, to the manufacturing process (notably fill-finish) of 1.1 million doses of the J&J vaccine.
- 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" but unnamed Indian laboratory. It is unclear what will be involved in the Russia-sponsored technology transfer.
- South African-United States billionaire, Patrick Soon-Shiong, committed an initial US\$ 213 million to a collaboration between his company ImmunityBio and Cape Town's Biovac to build capability to produce active pharmaceutical ingredient manufacturing for his hAd5 T-cell SARS-CoV-2 vaccine. Dr. Soon-Shiong remarked that "Biovac's Private Public Partnership model also demonstrates that the private sector can partner with the government in the quest for a common health response."

## 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,
  - 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; and
  - 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 (with the stocks expiring on April 13) and speaks to challenges of both delays in acquisition and country preparedness to distribute and administer vaccines.
- Cold-chain storage requirements remain a significant challenge in distributing the Pfizer-BioNTech vaccine.
- Distribution of 220 million single-dose J&J vaccines secured by the AU through the African Vaccine Acquisition Task Team (AVATT) will take place across 18 months, with delivery expected to begin in Q3 of 2021. Distribution will be facilitated by the African Medical Supplies Platform (AMSP). The contract includes an option to purchase an additional 180 million doses (see section 4).
  - The J&J agreement would bring the continent to around half of its requirements for herd immunity.
  - The J&J vaccine is viewed as an ideal option for the continent due to its single dose, which reduces logistics and administration costs such as reliance on cold-chain storage.

- Despite the promise of this deal, finalizing orders for individual countries has been a challenge.
- The US government could speed global vaccination efforts by requiring J&J to share its vaccine patent rights and formulation guide with third-party manufacturers. Barriers posed by patent laws can be overridden by invoking the Government Patent Use law, and the Defense Production Act can be invoked to facilitate technology transfer between manufacturers.
  - The single-dose and low reliance on cold-chain advantages of the J&J vaccine make it an ideal candidate for patent waivers and international technology transfer in order to increase global production.
  - There is precedent for technology sharing of this nature, as the Defense Production Act helped facilitate cooperation between J&J and rival firm Merck & Co. to increase production of the J&J vaccine in the US.
- UNICEF is partnered with GAVI to aid in vaccine distribution and procurement. As the single largest buyer of vaccines in the world, UNICEF is leveraging its experience and partnerships to help with procurement, shipping, and storage of COVID-19 vaccines. UNICEF has signed an agreement with Human Vaccine, a subsidiary of the Russian Direct Investment Fund, for supply of Sputnik V. The agreement allows UNICEF to access up to 220 million doses of the vaccine for 2021. The procurement depends on a WHO Emergency Use License and an advance purchase agreement with GAVI for COVAX.
- GAVI, partnered with UNICEF, leads the procurement and delivery arm of COVAX.
- China told the WHA on May 26 that it will support developing countries' access to affordable COVID-19 vaccines, but stopped short of any commitment to supply its recently approved Sinopharm vaccine to COVAX. The Chinese delegate said that the country already provided bilateral vaccine assistance to more than 80 countries, along with exports to 43 more nations for a total of 300 million doses.
- CEPI works on the R&D front of COVID-19 vaccines. CEPI has made significant investments in vaccine manufacturing capacity and is investing in the next generation of COVID-19 vaccines, which have the potential to minimize reliance on cold-chain storage. Reducing reliance on cold-chain storage will make delivery and distribution of future vaccine candidates in Africa significantly easier.

## **7. Vaccine Licensing/Intellectual Property/Tech Transfer**

See appendix for key upcoming conventions relevant to vaccine licensing, intellectual property, and tech transfer, as well as a diagram of vaccine patent architecture (Figure 1).

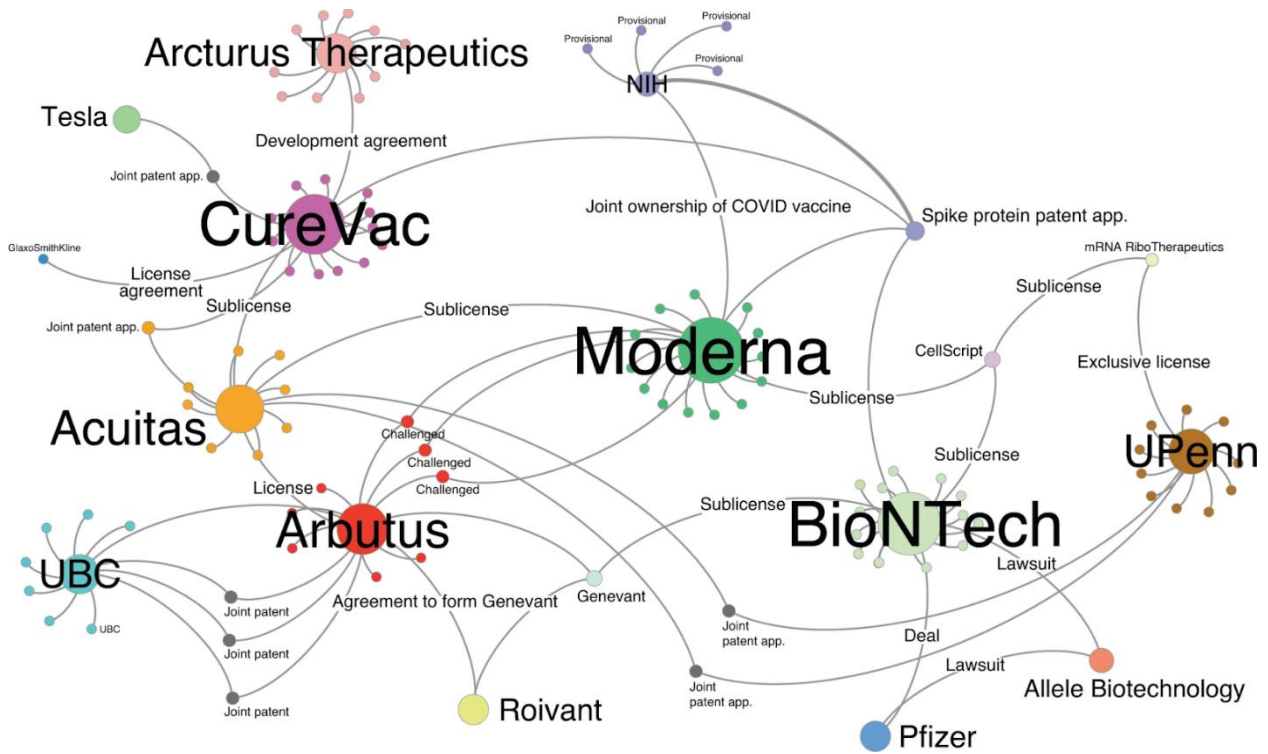
- Vaccine Licensing and Intellectual Property:
  - The Biden Administration announced that the US support for a waiver on COVID-19 vaccines is the first step in what could be a lengthy process. In its announcement the US broke from, amongst others, Switzerland's opposition to India's and South Africa's petition to the World Trade Organization to remove patent and trade-secret protections for all COVID-related products, including therapeutics and diagnostics. US Trade Representative Katherine Tai mentioned waiving intellectual-property protections, but only for vaccines.
  - Director-General Okonjo-Iweala on May 10 said she hopes that by December 2021 World Trade Organization (WTO) members will have reached a “pragmatic” solution over whether to go with a COVID-19 vaccine waiver. She understood that waiver advocates were preparing a revised proposal which she hoped would be presented to the WTO “as soon as possible.” China's Commerce Minister Gao said on May 13 that Beijing supported a proposal to enter into text-based negotiations.
  - New research highlights the complex nature of the IP surrounding mRNA Vaccines. Authors identified patents that were relevant to various vaccine tech platforms and used US Securities and Exchange Commission (SEC) filings to highlight pertinent licensing deals.
  - In a *Foreign Affairs* article Peter Hotez, Maria Bottazzi and Prashant Yadav point out that producing technology as complex as messenger RNA (mRNA) inoculations against COVID-19 requires not only patents but an entire infrastructure that cannot be transferred overnight. They made the sobering observation that sharing of patents is an important and welcome development for the long term, but it may not even be the most pressing first step.
  
- Technological Transfer:
  - The World Health Organization (WHO) has received 42 expressions of interest from countries, institutions, and biotechnology companies interested in the creation of a technology transfer hub. The hub and training center are expected to launch by 2022, according to WHO, Gavi, and CEPI, who are urging “realism” against the calls from LMICs to expand manufacturing capacity more rapidly. At the WHA (May 24 to June 1), Costa Rica and the WHO called again on countries to support WHO's COVID-19 Technology Access Pool (C-TAP).



-Appendix-

Figures and Supplemental Information











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**

**Africa’s vaccine value chain players by value chain step<sup>5</sup>** 2020, total = ~10 ✔ Current    ⚪ Planned

Manufacturer	Products	Value Chain Step				
		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	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		✔			✔

Source: *Expanding vaccine manufacturing in Africa* (February 2021, Great for Growth: UKAID)

**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	AFRO	AMC	-	1,881,600	AZ	-	
Angola	AFRO	AMC	-	2,172,000	SII/AZ	100,620	
Benin	AFRO	AMC	-	792,000	SII/AZ	-	
Botswana	AFRO	SFP	-	100,800	AZ	19,890	
Burkina Faso	AFRO	AMC	-	1,380,000	SII/AZ	-	
Cabo Verde	AFRO	AMC	5,850	108,000	SII/AZ	-	
Cameroon	AFRO	AMC	-	1,752,000	SII/AZ	-	
Central African Republic	AFRO	AMC	-	312,000	SII/AZ	-	
Chad	AFRO	AMC	-	1,080,000	SII/AZ	100,620	
Comoros	AFRO	AMC	-	108,000	SII/AZ	-	
Congo, Dem. Rep.	AFRO	AMC	-	5,928,000	SII/AZ	-	
Congo, Rep.	AFRO	AMC	-	360,000	SII/AZ	-	
Cote d'Ivoire	AFRO	AMC	-	1,740,000	SII/AZ	100,620	
Eswatini	AFRO	AMC	-	108,000	SII/AZ	-	
Ethiopia	AFRO	AMC	-	7,620,000	SII/AZ	-	
Gambia, The	AFRO	AMC	-	166,000	SII/AZ	-	
Ghana	AFRO	AMC	-	2,052,000	SII/AZ	-	
Guinea	AFRO	AMC	-	864,000	SII/AZ	-	
Guinea-Bissau	AFRO	AMC	-	120,000	SII/AZ	-	
Kenya	AFRO	AMC	-	3,564,000	SII/AZ	-	
Lesotho	AFRO	AMC	-	132,000	SII/AZ	-	
Liberia	AFRO	AMC	-	324,000	SII/AZ	-	
Malawi	AFRO	AMC	-	1,260,000	SII/AZ	-	
Mali	AFRO	AMC	-	1,332,000	SII/AZ	-	
Mauritania	AFRO	AMC	-	300,000	SII/AZ	-	
Mauritius	AFRO	SFP	-	100,800	AZ	-	
Mozambique	AFRO	AMC	-	2,064,000	SII/AZ	-	
Namibia	AFRO	SFP	-	108,000	AZ	-	
Niger	AFRO	AMC	-	1,596,000	SII/AZ	-	
Nigeria	AFRO	AMC	-	13,656,000	SII/AZ	-	
Rwanda	AFRO	AMC	102,960	744,000	SII/AZ	100,620	
Sao Tome and Principe	AFRO	AMC	-	96,000	SII/AZ	-	
Senegal	AFRO	AMC	-	1,104,000	SII/AZ	-	
Sierra Leone	AFRO	AMC	-	528,000	SII/AZ	-	
South Africa	AFRO	SFP	117,000	2,426,400	AZ	1,275,300	
South Sudan	AFRO	AMC	-	732,000	SII/AZ	-	
Togo	AFRO	AMC	-	540,000	SII/AZ	100,620	
Uganda	AFRO	AMC	-	3,024,000	SII/AZ	-	
Zambia	AFRO	AMC	-	1,212,000	SII/AZ	-	
Zimbabwe	AFRO	AMC	-	984,000	SII/AZ	-	
non-UN Member States	-	-	-	1,125,600	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

## Key Upcoming Convenings

- June 9: WTO TRIPS Council meeting
- June 11-13: G7 Leaders' Summit
- June 24: Columbia-WITS VacSafe Working Group Meeting
- July 21-22: WTO General Council meeting

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