



**Southern and Eastern African Trade Information and Negotiations Institute (SEATINI), Training and Research Support Centre (TARSC)**



**in the Regional network for Equity in health in east and southern Africa (EQUINET)**

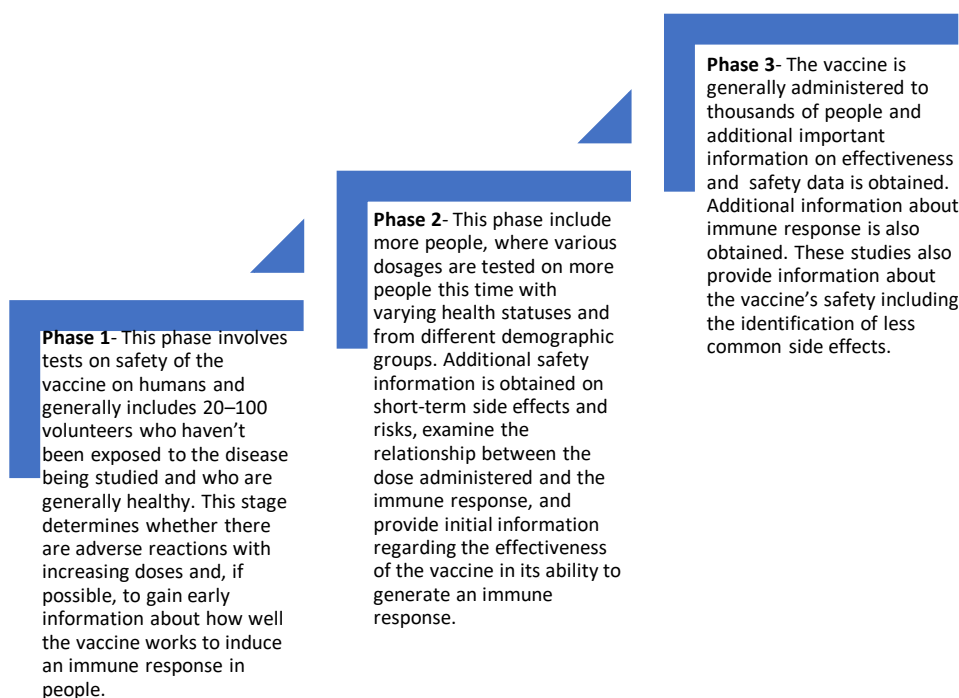
## **Brief: Ensuring access to COVID-19 related vaccines and health technologies in East and Southern Africa February 2021**

The COVID-19 pandemic is not the first global pandemic and certainly will not be the last. As noted in a previous [brief by EQUINET and ECSA HC](#), the ability of African countries to mount effective and equitable responses to COVID-19 reflects in part the access that countries have to reliable, sustained, distributed supplies of diagnostics, medicines, vaccines and other health technologies. That brief noted the constraints already faced in accessing imported reagents for COVID-19 testing and other key health technologies and forewarned of African countries being last in the queue when vaccines are approved. With high income countries having pre-ordered sufficient quantities of many of the vaccine candidates to vaccinate their populations many times over even before they were approved, by 2021 that significant inequality in access to vaccines has become clearly evident. At the World Health Organisation Executive Board meeting on 18 January, the WHO director-general said that the world is on the verge of a “catastrophic moral failure” due to the denial of COVID-19 vaccines to developing and poorest countries, with more than 39 million doses of vaccine administered by that time in 49 higher-income countries and just 25 doses in one lowest-income country. *While noting that vaccine roll out in East and Southern Africa (ESA) is a dynamic situation, this brief discusses the different vaccines and the distribution of vaccines in the region; issues involved in the development and production of vaccines and other health technologies in the region; raises areas where regional co-operation is taking place and suggests where it could be strengthened.*

### **The different vaccines, their use and features**

The phases for development of a vaccine are shown in *Figure 1* below.













Figure 1: Vaccine development phases



Source: Adapted from US Food and Drug Administration, 14 December 2020

There are about 89 vaccines for COVID-19 in a preclinical state being tested on animals, researchers are currently testing 67 vaccines in clinical trials in humans, and of these 20 have reached the final test stages. The 12 that have passed phase 3 trials and are approved and /or in use in different countries are shown in *Figure 2*. Currently none of these vaccines are produced in the ESA region, although there is report of a factory in South Africa for the end stage 'fill and finish' process to put bulk vaccine supplies into vials.

Figure 2: Vaccines in use

Developer	How It Works	Phase	Status
 Pfizer-BioNTech	mRNA	2 3	Approved in Bahrain, Saudi Arabia, Switzerland. Emergency use in U.S., E.U., other countries.
 Moderna	mRNA	3	Approved in Switzerland. Emergency use in U.S., U.K., E.U., others.
 Gamaleya	Ad26, Ad5	3	Early use in Russia. Emergency use in other countries.
 Oxford-AstraZeneca	ChAdOx1	2 3	Emergency use in U.K., E.U., other countries.
 CanSino	Ad5	3	Limited use in China.
 Johnson & Johnson	Ad26	3	
 Vector Institute	Protein	3	Early use in Russia.
 Novavax	Protein	3	
 Sinopharm	Inactivated	3	Approved in China, U.A.E., Bahrain. Emergency use in Egypt, other countries.
 Sinovac	Inactivated	3	Emergency use in China, Brazil, others.
 Sinopharm-Wuhan	Inactivated	3	Limited use in China, U.A.E.
 Bharat Biotech	Inactivated	3	Emergency use in India.

Source: Zimmer et al., 2021

The evidence suggests that the Pfizer, Moderna, Johnson and Johnson, Gamaleya and Astra Zeneca vaccines have 85-100% efficacy in preventing severe disease and deaths from COVID-19. Their impact on preventing transmission of the virus causing COVID-19 – the SARS-CoV-2 virus- is still being tested so as of now it cannot be said that they prevent infection. Also their effectiveness in boosting the immune system to prevent clinical disease is not immediate- it takes about 3 weeks. They differ in other respects however:

- Pfizer requires a -70 degrees centigrade cold chain and limited movement
- Moderna requires a -20 degrees centigrade cold chain
- Astra Zeneca, Gamaleya (Sputnik) and J&J only need regular fridge temperature
- All require 2 doses except J&J which is a single dose vaccine

There is a new 501Y.V2 variant that emerged in South Africa. While there is some evidence emerging on whether the current vaccines are effective for this variant from laboratory assays that suggest some current vaccines may be less effective, raising concern, the evidence from population studies is not yet available on these vaccines. Testing clinical efficacy for severe infection needs large studies with over 40,000 people. The impact of the vaccines on severe disease from this new variant may thus become clearer from early large-scale use.

The decision on which vaccine to use depends on a number of factors:

- Its safety, which is tested in the phase 1 to 3 trials shown in *Figure 1*
- Its efficacy, especially in relation to severe disease and mortality, which for prior variants has been confirmed for the vaccines shown in *Figure 2*, but which is still being assessed for the variant that emerged in South Africa for most vaccines
- Its ease of storage and administration, such as having a cold chain that relies on simpler refrigeration technologies as noted above
- Whether it needs one dose (as for the J&J vaccine) or two (as for all the others)
- Its cost. Media reports ([Guardian 22/1/2021](#) and [Reuters 21/1/21](#)) report for example the AstraZeneca vaccine which is amongst the lower cost vaccines to cost South Africa USd5.25 per unit, and the African Union USd3 per unit, suggesting some gain for the

latter from bulk procurement. The cost to South Africa is reported by these sources to be double the reported average USd2.16 cost of AstraZeneca in Europe. While this has been attributed to countries taking on the risk of pre-purchasing before approvals, it still raises concerns about cost differentials acting as a barrier for lower income countries, beyond the donated COVAX supply covering up to 20% of their populations.

### Vaccine roll out in the region

The total population of the 17 countries in the ESA region is about 450 million, of which about 60 % is estimated to require immunisation to achieve herd immunity. This translates to 540 000 000 doses of double dose vaccines. At present there are three routes of supply to meet this need:

1. The **WHO/GAVI/CEPI COVAX facility** aims to provide vaccine doses for 20% of the population in 92 low-income countries focusing on priority groups such as health workers and other key workers and elderly or other highly vulnerable people. The COVAX facility: interim distribution forecast on 3 February 2021 indicated the doses for distribution in the region in an indicative distribution based on estimated availability from manufacturers.as shown in *Table 1* below.

Table 1 Reported indicative distribution of vaccines in the ESA region from COVAX

Country	Self-financing purchase (SFP) or Advance market commitment (AMC)	# Doses Astra Zeneca /Serum Institute India (AZ/SII)	# Doses Astra Zeneca /SK Bio (AZ/SKbio)	# doses – Pfizer-BioNTech (exceptional allocation)
Angola	AMC	2 544 000	-	-
Botswana	SFP	-	117 600	-
DRC	AMC	6 948 000	-	-
Eswatini	AMC	108 000	-	-
Kenya	AMC	4 176 000	-	-
Lesotho	AMC	156 000	-	-
Madagascar	-	-	-	-
Malawi	AMC	1 476 000	-	-
Mauritius	SFP	-	100 800	-
Mozambique	AMC	2 424 000	-	-
Namibia	SFP	-	127 200	-
Seychelles	-	-	-	-
South Africa	SFP	-	2 976 000	117 000
Uganda	AMC	3 552 000	-	-
UR Tanzania	-	-	-	-
Zambia	AMC	1 428 000	-	-
Zimbabwe	AMC	1 152 000	-	-

DRC = Democratic Republic of Congo UR= United Republic

AMC refers to vaccines that will be supplied through resources raised globally and not as a cost to countries. Source: The Covax Facility: Interim Distribution Forecast, 3/2/21

Note: Countries not shown as having doses have either opted out or not prepared their plans yet

2. **Regional or continental procurement.** The African Union, which includes countries in the ESA region, launched the African Vaccine Acquisition Task Team (AVATT) initiative and the Africa Report indicated on 18 January 2021 that it had by that date acquired 270 million doses of vaccine supplied by a combination of Pfizer, Johnson and Johnson and also as AstraZeneca (Serum Institute of India), with 50 million doses made available in each of April and June 2021 (Jerving, 2021).
3. **Self-purchasing by or bilateral donations from countries.** No ESA countries did any advance purchasing of vaccines. Advance purchasing before vaccines were approved was implemented mainly by high income countries who had the resources to do this, giving them also lower prices in some cases in part due to the risk taken. However some

ESA countries are now directly purchasing supplies, often in smaller volumes and at higher cost in a competitive global market. For example there is report that:

- South Africa purchased one million doses of the AstraZeneca (AZ) from the Serum Institute of India to arrive in February 2021 to use in vaccinating health workers, although this use is now reported to be on hold awaiting further efficacy data.
- Seychelles received [a donation of 50,000 doses of the Sinopharm from Abu Dhabi](#) and further reports a donation of 100 000 doses of the AZ vaccine from the Indian government.
- Mauritius [reported](#) a donation of 100 000 doses of the AZ vaccine from the Indian government.

Vaccinating the target of at least 60% of the population is estimated to require [1.5 billion](#) vaccine doses for the entire African continent. At current prices securing this is estimated to cost between US\$8 billion and US\$16 billion, with an additional 20-30% required for delivery and administration of vaccinations (Gitahi et al., 2020). In total this would be about 2% of the total GDP for Africa [estimated by the IMF \(2020\)](#) to be USd2.3 trillion at current prices.

Beyond vaccine doses, ESA countries need to prepare the local quality testing and controls, secure cold chain measures and technologies, logistics support for transporting and storing vaccines, databases for management of vaccinated populations and for tracking and ensuring repeat doses, legal and administrative requirements, training of health workers and other prior capacities for the programme. The World Health Organization (WHO), UNICEF and the Global Vaccine Alliance (GAVI), are working with countries on readiness for vaccine outreach using a 10-point assessment tool that includes planning and coordination; resources and funding; vaccine regulation; prioritization; service delivery strategies; training and supervision of the health workforce; monitoring and evaluation; vaccine cold chain and logistics; safety and surveillance as well as demand generation and communication. (WHO AFRO, 2021).

### **The need for regional co-operation on vaccines and other health technologies**

There has been wide report of 'vaccine nationalism', whereby high-income countries have secured supplies, as noted earlier, and have begun vaccinating the priority groups in the populations, including frontline health and care workers, elderly and other vulnerable groups. While populations in some African countries were included in vaccine trials, notably South Africa and Egypt due to their high COVID-19 case rates, this did not lead to any earlier access benefit from the producers of the vaccines tested. There are estimates that at current levels of market access it may take until 2023 for ESA countries to vaccinate the 60% target population needed to reduce the risk of transmission. If this is not achieved and cases remain high, even if asymptomatic, then in highly dense urban areas with large populations there is a further risk of new variants of concern emerging, and as found with the current variant that emerged in South Africa, some of the current vaccines may not be effective for these new variants.

ESA countries have thus intensified global demand for constraints to access of key health technologies to be addressed while the pandemic still puts their populations at risk, including at the World Trade Organisation (WTO). In October 2020, India and South Africa with Eswatini, Kenya, Mozambique and Zimbabwe as ESA co-proposers with countries from other regions made a request to the General Council of the WTO to waive the implementation, application and enforcement of four forms of IPRs covered by the TRIPS Agreement for some years to enable the prevention, containment and treatment of COVID-19. The scope of the proposed waiver covers copyright and related rights, industrial designs, patents and trade secrets. While it has received support from many countries, it has been opposed by the United States, the European Union, Switzerland, Japan, Canada, Brazil, Australia, among others (WTO, 2020). While some countries are amending their national patent laws to expedite the issuing of compulsory /government use licenses for this, many lower income countries face institutional and legal difficulties when using these available flexibilities. Discussions continue to seek common ground in preparation for the next meeting of the TRIPS Council scheduled for 10-11 March 2021.

For the region the current situation raises some critical technology needs beyond vaccines:

1. **To continue secure and improve the supply of the technologies and outreach of the services needed for prevention of cases.** This includes the various reagents and kits for antigen and antibody testing to be able to test, trace and prevent onward infection from cases and to identify cases needing treatment or other forms of protection.
2. **To ensure the availability of infection control measures and personal protective equipment for health workers and other frontline workers** to reduce their risk of exposure.
3. **To ensure the supply of oxygen, ventilation equipment and medicines** and other care resources and health workers for treatment of cases and prevention of mortality

Hence, in addition to ESA countries and the regional economic communities (RECs) implementing measures to support preparedness for vaccine programmes and to explore options for pooled procurement beyond the COVAX and AU measures, there is also need to ensure the supplies for the prevention, protection and care measures noted above. This will be a sustained need even as vaccine programmes roll out.

One of the measures to ensure this sustainability of supplies is to establish or strengthen local production facilities in the region for the full range of health technologies required. As noted in the [EQUINET –ECSA brief](#), COVID-19 has shown that in relation to vital health commodities, decisions based on lowest cost, prices, cost/benefit or return on investment analyses that lead to importation rather than local or regional production in Africa can leave the continent without adequate and affordable access to health technologies. In a pandemic the key issue is rapid availability of products, and in the face of broken supply chains, cost escalation and self-protective behaviours from high income countries this can only be secured by distributed production systems located closer to where need is. UN Economic Commission for Africa report medicine, PPE and other technology capacities in Kenya, Uganda, Tanzania, South Africa, Malawi, Mozambique, Zambia and Zimbabwe, suggesting that capacities exist to build on. While factories are being set up or retooled to produce vaccines in many countries globally, the only public domain reporting of this in the ESA region is of Aspen which will be producing the J&J vaccine in South Africa, as noted earlier, and the Biovac Institute in South Africa which is at early stages of building the capability for vaccine manufacturing (Dorfman and Kirstein, 2021).

According to the 25/1/21 Africa Report, other bilateral negotiations reported between some ESA countries and China and India include:

- Kenya-India's AstraZeneca (Serum Institute) for 24 million doses
- Seychelles-AstraZeneca for 100 000 doses
- South Africa AstraZeneca for 1.5 million doses
- Zimbabwe -Sinopharm 200 000 doses donated and received and 600 000 purchased.

### **Strengthening availability of vaccines and other health technologies**

Steps for regional co-operation to support vaccine roll out thus include:

- **Leveraging African country participation in the governance of the COVAX Facility** to strengthen collective bargaining power in securing a fair share of the global vaccine supply.
- **Allocating the necessary resources for public sector** capacities for vaccine supply, cold chains, storage and delivery to populations and for population enrolment and monitoring
- **Accelerating harmonised regulatory processes and fast-track country** authorisation of safe and effective COVID-19 vaccines and other diagnostics and medicines.
- **Building laboratory capacities for genomic surveillance** to detect and respond rapidly to variants. The AU Africa CDC has, together with the African Society for Laboratory Medicine and partners have developed training and are supporting capacities for genomic testing for detection and surveillance of new variants of SARS-CoV-2 (AU CDC, 2021).
- **Engaging communities and frontline health workers** to ensure informed public uptake and minimise vaccine hesitancy
- **Maintain and strengthen** other routine immunisation, health and social protection services.

In addition to the above and the TRIPs waiver discussed earlier, ESA countries need to assert their legal rights to ensure that their laws provide them with ability to use the flexibilities provided



in the TRIPs agreement, such as for compulsory licensing / government use to enable procurement and production of diagnostics, health technologies, medicines and where feasible vaccines. The wider difficulties ESA countries face in unilaterally applying these flexibilities in the past is one of the motivations for the waiver proposal noted earlier (EQUINET, ECSA, 2020). At the same time, the region needs to more rapidly localise portions of the value chain to produce essential health technologies to limit dependence on global value chains.

This implies regional co-operation to:

- identify capacities for preparing or switching production to key technologies and products, sharing expertise where needed;
- ensure quality production, prequalification of plants, and to organise forward and backward linkages and address upstream and downstream bottlenecks;
- identification of current vaccine production capabilities to negotiate investment (such as by Gates Foundation or the US\$12 billion World Bank Facility) in factory retooling for this; and
- dialogue between governments, pharmaceutical companies and training institutions on human resource requirements for supporting manufacturing and distribution of COVID-19 health related technologies and products.

ESA countries with greater capacities may lead in these processes, but with regional co-operation to ensure technology and capacity transfer to others in the region.

Key issues to address to build the capacities, secure the necessary assets and address obstacles and bottlenecks to locally producing the range of health technologies needed include:

1. **Contain price:** Reducing the cost of imported or locally produced supplies, considering the relative cost benefit of guaranteed supplies and employment in local production; with measures, including regional measures, to standardise prices and prevent cost escalation.
2. **Increase local production** of key technologies, including through in regional co-operation.
3. **Build capacities** in chemical, pharma engineering, R&D, infrastructures, in contracting and partnerships for technology transfer and techniques
4. **Ensure adequate personnel:** including scientists, laboratory technicians, clinical and industrial pharmacists, business and market skills and leadership, among others
5. **Improve legal provisions to use intellectual property flexibilities** in local legislation
6. **Strengthen system preparedness and distribution**, such as availability of cold chain, distributed laboratory capacities, information, monitoring and communication systems.

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