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## COVAX PLAN BOOSTS COVID-19 VACCINE HOPES FOR DEVELOPING COUNTRIES

On the heels of extraordinarily successful results announced by four coronavirus disease 2019 (COVID-19) vaccine developers within three weeks of one another, the question of whether developing countries will be “left behind” continues. COVAX (one of the three pillars of the Access to COVID-19 Tools (ACT) Accelerator), a massively funded global collaboration involving 187 countries, aims to ensure that they are not. It plans to help 92 of the least advanced countries to buy and roll out a vaccine for the most vulnerable 20 percent of their populations – although only about 3 percent of all countries’ populations will receive vaccines through COVAX, early in 2021.

The past few weeks have seen astonishingly uplifting news about COVID-19 vaccines: Global pharmaceutical giants Pfizer/BioNTech, Moderna, and AstraZeneca all announced better-than-expected effectiveness of three vaccines from large-scale clinical trials (two above 90 percent, one at 70 percent), making the longstanding promise of vanquishing coronavirus a reality. (A fourth, Sputnik V, from Russia’s Gamaleya Research Institute of Epidemiology and Microbiology, also announced 95 percent efficacy, but the lack of available data on its clinical trials has cast a skeptical pall over this one.)

But these are still early days: the best estimates of large-scale vaccine availability—for any country—point to the end of the first quarter of 2021. Newly announced limitations of the AstraZeneca vaccine—that the clinical trial did not include anyone over 55, a surprising omission given the well-known higher risk borne by older people—have dimmed some of the excitement, and none of the vaccines have yet achieved regulatory approval (Pfizer and Moderna have applied for “emergency use authorization” from the United States Food and Drug Administration).

Though news headlines have touted the prospect of Pfizer’s vaccine becoming available in the United

States as early as 11 December 2020, that is simply a date on which approval might be granted in an office in Washington, DC, not the date on which millions will receive their vaccinations. In the absence of a very large magic wand, no country will immediately be able to vaccinate very large numbers of people.

For developing countries, including South Africa, the hurdles between a vaccine approval in the northern hemisphere and a needle going into someone's arm in the "global south" are infinitely more complex and challenging.

All countries are working hard on three main elements: cost, logistical feasibility and regulatory approval. For low- and middle-income countries, "vaccine readiness", especially regarding logistics, is critical.

To help African countries, the World Health Organization (WHO), United Nations International Children's Emergency Fund (UNICEF), and other partners have provided all 47 countries in the WHO's Africa region with a "vaccine readiness assessment tool", intended as a "road map" for use by countries' health ministries to plan their vaccine distribution, and build on their already existing routine-immunization infrastructure.

At a WHO media briefing late last week, Dr Matshidiso Moeti, the organization's regional director for Africa, reported that 40 of those countries so far had shared data with the WHO based on their self-assessments of 10 "key areas", including planning and coordination, resources and funding, regulatory processes, delivery, training and supervision, monitoring and evaluation, vaccine logistics, risk communication, community engagement and safety monitoring.

"What we see is that so far the average readiness score is 33 percent," Moeti said, "well below the desired benchmark of 80 percent." The WHO's experience had revealed that an average weighted score of about 80 percent had shown that a country could "safely conduct a vaccine campaign to reach the maximum impact ... so we are doubling down on planning and preparation, because this will make or break the vaccine endeavor."

The WHO's further analysis shows that only 49 percent of the 40 reporting countries have identified their priority populations and have plans to reach them, 44 percent have coordination structures in place, only 25 percent have satisfactory plans for funding, 17 percent have data-collection and monitoring tools in place, and only 12 percent have plans to communicate with communities "to build trust and drive demand for immunization", said the organization.

It is unclear where South Africa, for instance, is on the vaccine readiness spectrum (a national Department of Health spokesperson did not respond to Maverick Citizen's request for comment). It is expected that "priority populations" will be frontline health workers, possibly in areas where infection rates are still escalating such as the Eastern Cape province, and where personal protective equipment is in short supply – but this is yet to be confirmed.

As part of COVAX's assistance to countries, following the vaccine readiness assessments, Gavi, the Vaccine Alliance, UNICEF and the WHO are providing technical support—including for cold-chain infrastructure—to receive and deliver COVID-19 vaccines.

"We have a very short window of opportunity to make sure that countries are improving their preparedness for rollout," said Dr Richard Mihigo, the WHO program area manager for immunization and vaccine development.

Easier, cheaper, faster

As for the vaccines themselves, the AstraZeneca vaccine seems much better suited to African and other developing countries with less money, fewer clinical resources, and weaker supply and cold chains. It is

much cheaper than the others, at between \$3 (about R45) to \$4 per dose (Pfizer's is \$20, Moderna's is \$33), and it is much easier to store, in a regular refrigerator at 2-3 degrees Celsius (Pfizer's vaccine needs to be stored at -70 degrees Celsius and can be kept in a refrigerator for up to five days once on the road; Moderna's needs to be stored at -20 degrees Celsius and can be kept refrigerated for up to 30 days). This is partly because AstraZeneca's vaccine vehicle is a "viral vector", which is less complicated and more stable than the mRNA vehicle being used for the first time in the other two vaccines. Pfizer is allegedly looking at ways to modify its vaccine so that it doesn't need ultra-cold storage.

"This means we have a vaccine for the world," said Dr Andrew Pollard, the chief investigator of the Oxford-led development of the vaccine for AstraZeneca.

Still, there are some unknowns. After last Friday's sharp intake of breath at the news that AstraZeneca's clinical trials did not involve elderly volunteers, the company has announced that it will undertake a smaller follow-up trial to test the vaccine's effectiveness in older people. Also, its results did not include data from the South African arm of the clinical trial though it is known that very few people among the 2 000 trial volunteers in South Africa developed COVID-19 across both the "real" and placebo arms of the study.

Dr Pontiano Kaleebu, director of the Uganda Virus Research Institute, says "it would be desirable to have studies in Africa to know how these vaccines fare in the African population, but it's not a condition for us" because safety and effectiveness had already been proven, and because monitoring and surveillance of the vaccine would continue over time.

Data from the South Africa trial cohort will ultimately form part of AstraZeneca's final safety and immune-response results, says Professor Helen Rees, executive director of the Wits Reproductive Health and HIV Institute, chairperson of the South African Health Products Regulatory Authority (SAHPRA) and chairperson of the African Regional Immunization Technical Advisory Group.

Is this a turning point for equity in global health?

"Equitable distribution" is the term on the lips of most sensibly minded politicians, and the global mechanism for this is the vaccines "arm" of the WHO-led ACT Accelerator, which was established to ensure equitable access and fair allocation of vaccines, treatments and tests for COVID-19.

COVAX is co-convened by the WHO, the Coalition for Epidemic Preparedness Innovations (CEPI) and Gavi, the Vaccine Alliance, and 187 countries have signed up for it. It aims to provide the first 20 percent of all countries' vaccine needs by sharing investments from 90 wealthier economies ("advance market commitments" or AMCs) with 97 "AMC-eligible" poorer countries.

This upends the "vaccine nationalism" that has compelled many wealthy countries to pre-buy vaccines just for their own populations, in some cases in parallel with their participation in COVAX. And vaccine nationalism has not gone away: rich countries including Canada, Australia, the United States, the United Kingdom and Japan, as well as a European "bloc" of countries, have each, in advance, bought between two and 10 vaccine doses per person, hedging their bets by placing orders with a few different manufacturers. But the COVAX facility means poorer countries will at least get their "starter" vaccines for priority high-risk populations.

Initial COVAX funding and supply will support equitable access covering only 3 percent of the targeted 20 percent population coverage by the end of 2021, but "the end game is to incrementally go up," Rees says.

AstraZeneca has made a “no-profit pledge” on its vaccine price, so that “it will be affordable and globally available, supplying hundreds of millions of doses on approval,” AstraZeneca CEO Pascal Soriot said that this is aimed at low- and middle-income countries.

And, because more vaccines than anticipated have already proved to be effective, countries that have already bought multiple doses per person from several different manufacturers may ultimately have a surplus. There is a suggestion in global health circles that rich countries may be willing to put their excess doses back into the global system, making even more vaccines available for countries that have not had the funding to secure supplies in advance.

Eventually, with more vaccines still in clinical trials, many of which are expected to work too, there may be enough to go around. We could see South Africa and all of Africa starting to deploy vaccines at the same time as the advanced economies, even if in smaller numbers.

#### Vaccine readiness from a ‘people’ perspective

For “the largest immunization drive in Africa’s history”, as Moeti called it, the vast majority of any country’s population needs to be vaccinated to achieve “herd immunity” (the exact percentage required for COVID-19 is still unknown). Moeti appealed to national authorities and communities to fight “anti-vaccination” misinformation.

“Developing a safe and effective vaccine is just the first step in a successful rollout,” she said. “If communities are not on board and convinced that a vaccine will protect their health, we will make little headway. It’s critical that countries reach out to communities and hear their concerns and give them a voice in the process.”

At the same WHO briefing, Rees said: “I think we should regard vaccines, in this current environment and more generally, as one of the biggest global health ‘goods’ that we have in the world, and they really need to be made available to everyone as fairly as we can. This is the beginning of setting new standards in global health and in how we regard each other as global citizens.” As long as there were large amounts of a circulating virus in any country “that virus is going to transport. We understand that countries want to look after their own citizens, but it’s as global citizens that we’re going to get on top of this.”

Rees said that in involving communities to inspire vaccine confidence, it was essential to be “very transparent about what we know about vaccine safety and efficacy, why we want people to be vaccinated, why we want to build up population protection, and why we are targeting some groups and not others”.

#### What’s next for COVID-19 vaccines for South Africa?

In South Africa, SAHPRA would normally need to license any vaccine (as with any other medical product) for use in this country. SAHPRA already has a vaccine working group ready to leap into action once pharmaceutical companies lodge their applications for approval, and they may need additional clinical evidence to register vaccines that have not held clinical trials in South Africa (such as Moderna’s). In such a case a “bridging” study—a small-scale assessment of safety and efficacy within the population that will be vaccinated—can be done first.

There is also a quicker path to domestic registration of a new medicine: In 2019, SAHPRA agreed to use a “reliance” mechanism provided by the WHO, for countries that may not have regulatory authorities or when their decisions may take too long. The authorities on which countries can formally “rely” include the United States’ Food and Drug Administration and the European Medicines Agency, the ones most likely to soon be licensing successful COVID-19 vaccines.

In addition, SAHPRA has the power to bypass all of that and authorize emergency use of an unregistered medical product through Section 21. In any case, we can anticipate a rapid local approval process once it becomes clear which vaccines South Africa can feasibly procure.

The three vaccine frontrunners so far could together produce more than four billion doses by the end of 2021 – still far short of what is needed to immunize the global population of 7.8 billion, especially as some of the effective regimens so far already require two doses per person. But if recent history is anything to go by, several more vaccines will prove successful in the near future.

Though donor countries have so far invested more than \$2 billion in COVAX's AMC financing, surpassing its 2020 target, another \$5 billion is needed for COVAX to deliver its targeted two billion doses for developing countries by the end of 2021. To supplement this, the World Bank has announced a \$12 billion financing facility that poorer countries will be able to access to increase their 20 percent vaccine "coverage" to about 60 percent.

"COVAX is highly subsidized as a solidarity mechanism and platform to enable African countries to have the vaccine like every other country," Moeti said, "but they are also expected to make some effort."

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