

Vaccine rollout: Here is where South Africa stands

By James Stent 22 Dec 2020

Only a massive global rollout of an effective vaccine can end the Covid-19 pandemic in the short term. The vaccine is being rolled out in the United Kingdom and United States. It's expected to become available in Europe imminently.



Johnson & Johnson is trying to get approval for a vaccine against Covid-19 that only requires one shot. Details of the vaccine's trial are expected to be released in January.

This is where things stand in South Africa.

The Department of Health is playing its cards very close to its chest. The department has been extremely reluctant to provide any details of how a vaccination plan would work. In response to our questions, spokesperson Popo Maja said that the department is not commenting on any vaccine related to Covid-19, and that "the minister will pronounce on this at an appropriate time".

Covax is key

Critical to getting vaccines rolled out across the globe is Covax, an initiative started in April with a noble aim: "people in all corners of the world will get access to Covid-19 vaccines once they are available, regardless of their wealth". It is coordinated by the Global Vaccine Alliance (GAVI), the Coalition for Epidemic Preparedness Innovations (CEPI) and the World Health Organisation. It is supporting the research, development and manufacturing of Covid-19 vaccines. But to do this effectively, it needs money.

In that regard, South Africa got off to a bad start. On 17 November, it was reported that the government failed to give the Solidarity Fund approval to pay a R327m deposit to Covax, the 15% deposit that would guarantee access to vaccines secured through this facility. The Department of Health said this was an administrative lapse, and that payment would be made by 22 December.

Department officials <u>said</u> on SABC 3's Morning Live on 17 December that South Africa will only receive vaccines via Covax in the second quarter of 2021.

On 20 December, *City Press* reported that the allocation to South Africa of this programme would cover only 3% of the population (approximately 1.7 million people) in the first half of 2021, a considerable downward adjustment from the 10% figure touted by President Cyril Ramaphosa. Even this diminished figure was not definite.

Covax has positioned itself as the only means by which poor countries could access Covid-19 vaccines that have been <u>snapped</u> <u>up by rich countries</u>. In a <u>3 September press release</u>, Dr Seth Berkley, CEO of GAVI, said: "Covax is quite literally a lifeline and the only viable way in which [people living in poorer countries] will get access to Covid-19 vaccines."

The health department appears to agree. Speaking on Morning Live on SABC 3, deputy director general of health in charge of health regulation and compliance Dr Anban Pillay said that, "We will hear from Covax as to which vaccine exactly has been allocated to South Africa."

So far, Covax has agreements with nine manufacturers of candidate vaccines, including the Oxford University/AstraZeneca vaccine which appears to be safe and effective. But Covax's vaccine candidates do not include the high-profile Pfizer/BioNTech or Moderna vaccines, which are, to-date the only candidate vaccines to have secured regulatory approval in the US and UK.

On 18 December, Covax [https://www.reuters.com/article/us-health-coronavirus-covax-idUSKBN28S1PW? taid=5fdce72654859c0001437f73&utm_campaign=trueAnthem:+Trending+Content&utm_medium=trueAnthem&utm_source=twitter announced]] that it had reached agreements with other pharmaceutical manufacturers including Johnson & Johnson, which is developing a vaccine the South African government may be keen on.



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J&J's vaccine

In his SABC interview, Pillay suggested that a shortage of refrigeration infrastructure would mean that the Pfizer/BioNTech and Moderna vaccines would not be vaccines that "many developing countries would be able to implement". Moreover, for ideal effectiveness, both vaccines need two shots administered weeks apart. The same goes for the Oxford one.

"So clearly, we would be looking more for a vaccine we could roll out that could be stored at room temperatures and kept in a fridge," Pillay said. He also said that a vaccine with a single dose is ideal. He suggested that such a vaccine would be going through regulatory approval in January. The only current single-dose candidate vaccine is the one being developed by <u>Johnson & Johnson (J&J)</u>. And it is the first candidate vaccine to seek regulatory approval in South Africa.

But the company has not released any results about the vaccine's safety or efficacy, although this is expected to be announced in January.

J&J <u>launched</u> the second of its phase three trials of its candidate vaccine in mid-November. The first phase three trial was <u>launched</u> in September. (Phase three trials are the last stage of testing for a new drug or vaccine, in which typically thousands of people are assigned randomly to either get the vaccine or a placebo.)

Can Aspen manufacture a vaccine?

South Africa's interest in the success of the J&J vaccine is significant, particularly as local pharmaceutical manufacturer <u>Aspen</u> has entered an agreement with J&J to manufacture its vaccine.

between J&J and Aspen. Ramaphosa also said that Biovac, a part-state-owned company, was in negotiations with a vaccine manufacturer to secure rights to manufacture a candidate vaccine.

The details of the agreement between Aspen and J&J are vague. It appears that domestic production will not include the manufacture of the vaccine itself; rather Aspen will be responsible for late-stage processing, including packaging the vaccine. Further, it is not clear that this deal will grant South Africa any of the doses of the vaccine. There was no response to questions sent by GroundUp to J&J.

The Health Justice Initiative (HJI) has been calling on the government to release its vaccination plans, but has not received any response. Speaking to GroundUp, HJI founder Fatima Hassan said that the government must explain how it will allocate limited vaccine supplies in an equitable and rational manner. She is worried that government is not sufficiently prepared.



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18 Dec 20



Will patents block access?

Despite the huge amount of public money from several countries that has been invested in vaccines, the pharmaceutical companies either own or have exclusive rights to the vaccines that have so far been shown to be successful. For practical purposes, they have exclusive say as to where, who, how and how much of the vaccines are manufactured or sold for. (Moderna's CEO has <u>suggested</u> his company will not enforce its patent rights on its vaccine.)

South Africa and India, with the support of over 100 countries and of organisations like the Nobel peace prize winner <u>Médecins</u> <u>Sans Frontières</u>, have called for the World Trade Organisation to suspend intellectual property rights related to Covid-19. But this proposal has been blocked by the US, the United Kingdom, Canada and other high-income countries.

On 8 December, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) released a <u>press</u> <u>statement</u> condemning the proposal, and any move to weaken intellectual property regimes that might allow people in poorer countries to access Covid vaccines. IFPMA argued that any such move would "undermine confidence in what has proven to be a well-functioning intellectual property system", and that the progress that has been made in vaccine development has only been possible due to "a thriving innovation ecosystem, underpinned by intellectual property rights".

The press release goes on to say that the end of the pandemic is a possibility due to the "contribution of millions of people who joined clinical trials". Ironically, for people living in South Africa, thousands of whom have participated in a number of clinical trials for Covid-19 vaccines, this participation alone does not mean anything when it comes to access to these vaccines.

In 2001, member countries in the World Trade Organisation released the <u>Doha declaration</u> on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and public health, which affirmed that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health". While South Africa was one of the countries that led the way to the now 19-year-old declaration, our domestic patent legislation has not yet fully incorporated the advances won in this declaration.

Nevertheless, existing patent law has provisions that would empower the government to circumvent patents in the interest of public health. Section 56 of the <u>Patents Act</u> allows the government to issue compulsory licences if "the demand for the patented article in

the Republic is not being met to an adequate extent and on reasonable terms". This means that if a manufacturer cannot produce enough supply, it cannot stand in the way of those who have capacity.

Clearly demand for vaccines far exceeds supply and will do so for some time. Does South Africa have the capacity to produce a vaccine if it grants a compulsory licence, or in the unlikely event that the TRIPS waiver succeeds?

In a <u>30 June op-ed</u>, researchers from the NICD, Biovac, and animal vaccine manufacturing companies said that South Africa has the domestic capacity to produce certain types of vaccines. A <u>19 November report</u> in *Business Day* quotes Biovac CEO Morena

iviaknoana saying that his company has the capacity to manufacture mixina vaccines, such as those developed by Pfizer/BioNTech and Moderna.

In September, Adar Poonawalla, CEO of the Serum Institute of India, the largest vaccine producer in the world, told the [https://www.ft.com/content/a832d5d7-4a7f-42cc-850d-8757f19c3b6b *Financial Times*]] that global vaccination coverage could only be achieved by 2024 with poor countries waiting the longest for vaccines.

It's hard to think of a more pressing need for humanity in the short-term than ending the Covid-19 pandemic. Perhaps with a concerted global effort that puts lives and equality before profits and patents, Poonawalla's pessimistic outlook will turn out to be wrong.

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