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Vaccine production in South Africa: how an industry in its infancy can be developed

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The issue of vaccine production has become a topic of hot debate following the approval of treatments for Covid-19. In South Africa angry exchanges have been spurred by the country's <u>lagging access</u> to Covid-19 vaccines.



South Africa does not have large-scale vaccine manufacturing capability. Shutterstock

Generally, vaccines are produced by private companies who sell the vaccine under contracts. In some cases, producers will make provisions for access in particular markets. This is sometimes as a condition for receiving early development funding or for allowing parts of production to occur in a particular country. Some middle-income countries, particularly India, <u>Argentina and Mexico</u>, have sufficient production capacity to be partly indispensable. These countries have strategic leverage to get vaccines because of their own vaccine <u>manufacturing capacity</u>.

India illustrates this well. The <u>Serum Institute of India</u>, a privately owned pharmaceutical company, is manufacturing large quantities of the University of Oxford/AstraZeneca and Novavax Covid-19 vaccines. The company scheduled to reach 100 million doses produced a month <u>by March 2021</u>. In return, <u>India will keep a portion</u> of the vaccines it manufactures – reportedly 100-million doses in the first instance.

What about South Africa's own capacity to produce vaccines? What can the country do?

South Africa does not have large-scale vaccine manufacturing capability. The <u>Biovac Institute</u> – a <u>public-private partnership</u> between the South African government and a consortium of South African healthcare companies – is beginning to get into vaccine manufacture with an eye on more secure and accessible childhood vaccine supplies for southern Africa. But this capability is still in its infancy. It's small compared to the Covid-19 vaccine market.

In addition, a publicly traded South African-owned global pharmaceutical company, <u>Aspen Pharmaceuticals</u> operates four pharmaceutical manufacturing and packaging plants in the country. The company is also moving into the vaccine packaging market.

We see a clear disconnect between what would be needed to make the Biovac Institute a strategic vaccine asset going forward and what is planned for Biovac.

If South Africa is serious about supplying anti-pandemic vaccines in the future, it needs to rethink the scale of financial, technical and strategic investment into vaccine production. This investment must be made not only into the private sector, but also, critically, into publicly accountable institutions such as the Biovac Institute. Only if investment is increased, sustained, and backed by political commitment, will the country have sufficient vaccine production capacity to use as a lever to get national and regional access to future anti-pandemic vaccines.

Vaccine production capacity

The Biovac Institute's primary remit is to make childhood vaccines available for the southern African market, mostly for the public sector.

For its part, Aspen's existing pharmaceutical manufacturing capacity is about <u>10 billion tablets a year</u>. It produces generic drugs (including analgesics, a proton pump inhibitor and sleeping aids), nutritional supplements (notably iron supplements) and hormones for local African markets and other middle income markets, such as Turkey.

Aspen is scheduled to <u>start producing</u> the Johnson & Johnson Covid-19 vaccine in March or April of 2021 at these facilities. It will be <u>filling and packaging vials</u> with vaccine product manufactured in bulk outside of South Africa.

Most of the vials will be shipped back to Johnson & Johnson for international distribution. A recent <u>announcement</u> indicates that 9 million doses will remain in South Africa for local use. The original packaging deal between Aspen and Johnson & Johnson <u>was announced</u> more than two months prior. There had been no mention of a procurement deal for South Africa until pressure began to mount recently on all parties.

Unlike Aspen, Biovac's remit is to provide vaccines in the public interest. Part of its mission is

to provide in the long term, capacity for the development and introduction of novel vaccines, focusing on the development of vaccines relevant to South Africa and Africa's particular needs.

Biovac's main activity is to import, <u>label and distribute vaccines</u> to the South African market. For example, it has supplied <u>six vaccines</u> made by international vaccine manufacturers for South Africa's childhood immunisation programme. It also supplies other countries in the region.

Biovac's crowning achievement has been the local production (filling and packaging) of <u>Hexaxim</u>, a combination of six childhood vaccines from Sanofi, the French multinational pharmaceutical company. Production started very recently, in November 2020.

Biovac is the first external company with which Sanofi has partnered to fill and package Hexaxim.

Biovac is also planning to <u>manufacture</u> Prevnar-13, a vaccine made by Pfizer, the US multinational pharmaceutical company. The vaccine prevents pneumococcal disease and death. Biovac will formulate the product using components provided by Pfizer before filling and packaging the bulk vaccine. Production is due to start in the <u>next six months</u>.

The development of local capacity for formulation of a <u>complex vaccine</u> marks another important step towards the establishment of vaccine manufacturing capacity in South Africa.

How to be more prepared next time

To be in a better position to procure anti-pandemic vaccines South Africa will need to have greater vaccine manufacturing capacity. And the country would need to be more willing to use that capacity as leverage.

Scale is a key consideration. Biovac is planning to fill <u>4 million doses of hexaxim</u> in 2021. This is tiny compared to Serum Institute of India's <u>huge capacity</u> and to Aspen's reported capacity of <u>300 million vaccine doses a year</u>.

Beyond scale, two other conditions need to be met.

The first is simply more experience. The technology transfer for each vaccine that Biovac produces would give the company experience and technical capacity in re-tooling for formulation, filling and testing of each particular vaccine. The second is that a more savvy entrepreneurial risk-taking environment needs to be developed. This needs to be backed by political commitment in government.

The Aspen example shows that the development of local manufacturing capacity is possible if enough capital is available, and if the right strategic partnerships are established. Private facilities like Aspen clearly can become leverage for local access; but, that does not seem to well assured.

If Biovac's current trajectory is maintained and supported, it should be able to supply other vaccines (childhood vaccines, mostly) in the future. The strategic value of this assured supply should not be underestimated.

In addition, Biovac could be one of the answers to this problem because it is a publicly accountable institution and because it can point to its remit to make vaccines accessible locally when making any production deals. But in its current incarnation and scale, Biovac won't be able to provide anti-pandemic vaccines for southern Africa. Nor can it act as a strategic asset in the way that Serum Institute of India has been for India. South Africa has about one twentieth the population of India. This means it will need its public vaccine production capacity to grow to a more modest size to be a strategic asset.

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