

Vaccine production in Africa: Will initiatives survive?

For decades, there have been huge concerns at the lack of vaccine production in Africa. Africa is the only major world region that does not have significant vaccine manufacturing capacity.^[1] Early on during the COVID-19 pandemic, it became evident that once again there was an acute need to develop local manufacturing capacity, and to increase that capacity where already present. For a significant period, Africa received only relatively small doses of vaccines. Frequently, the supplies were unpredictable, and there was little warning on when the vaccines would arrive and what type of vaccines they would be.^[2]

Challenges to vaccine manufacturing in Africa include weak investments for vaccine manufacturing by African governments, weak regulatory capacity for vaccine research, development and production, low interest in vaccine production in Africa by global vaccine stakeholders, uncertainties in the demands for vaccines made in Africa by African countries,^[3] manufacturers ceasing production as a result of inability to compete with imported vaccines, dependence on global supply chains, which at times are hampered by intellectual property issues, trade barriers, monopolised supply and export bans, dependability on external suppliers posing severe problems to Africa's health resilience, and a preference by African countries and their governments for ready-made vaccines that they can import.^[2] Therefore, the focus has been on securing deliveries rather than manufacturing. It is easier to secure funding or pool resources from foreign donors to facilitate payment and procurement, compared with the cost of vaccine development, preclinical testing and clinical trials. While significant investments and grants backed by the state are made available to produce vaccines in wealthier countries, African manufacturers face the high costs of vaccine production with little or no funding support from the states, and a lack of political commitment in this context. This will have a bearing on problems of sustainability of any vaccine manufacturing initiative undertaken. In addition to insufficient funds to medical scientists, research and development, African technological innovations have been undermined to create markets for the foreign-led products, including vaccines.^[2] Africa's reliance on foreign suppliers for vaccines impacts public health security, as evidenced during the COVID-19 pandemic. This means that Africa could remain last in line and face significant procurement challenges in the future. These many longstanding barriers faced by African research centres and biotechnology facilities in accessing several important steps of the value chain, such as pre-clinical research and good manufacturing practice (GMP) batch manufacturing for clinical trials, means that it is currently not possible to move a vaccine concept from research through to clinical trials entirely on the African continent.^[4] This market failure needs to be addressed urgently.

Seven out of 10 vaccines used in Africa are donated to the continent by the Global Vaccine Alliance (Gavi). Most are for childhood immunisation programmes, and are manufactured in India or by multinational vaccine manufacturers in North America or Japan.^[5] It can be stated that these donations perpetuate dependence and add to the impediments in the development of vaccines and other

interventions against diseases in Africa. The COVID-19 pandemic underscored how fatal this dependency on imported vaccines could be. In addition, Africa cannot rely on fellow states in the Global South. This is well illustrated by India halting vaccine supplies to the continent early in 2021, at the height of the Delta variant outbreak, when only 1.5% of the African population had received a vaccine dose at that time.^[5]

As a response to these bottlenecks, a foundation to provide financial and strategic support for the development of the pharmaceutical industry and the consolidation of regional vaccination programmes in Africa has been established by the African Export-Import Bank and the African Development Bank. Development and/or expansion of national vaccine industries commenced in several countries from 2020. Egypt, South Africa (SA) and Senegal have each partnered with private-sector manufacturers to expand volume capacity. Ghana has reconfigured part of its pharmaceutical industry to make vaccines. Rwanda has commenced on work to manufacture messenger RNA (mRNA) vaccines from scratch. These countries have moved forward, signed major agreements, and continue raising finance.^[4,6]

Even though only 1% of vaccines used in Africa are manufactured on the continent, there are more than 30 new vaccine manufacturing initiatives underway, with momentum gathering to make the expansion possible. The first technology transfer hub for mRNA COVID-19 vaccines was established in SA in the second half of 2021 to scale up production and access to doses across the continent. The hub also provides training on mRNA technologies for manufacturers from low- and middle-income countries, and issues licences to them so that they can move forward with manufacturing. The World Health Organization (WHO) took the lead in establishing the hub in partnership with the international COVAX initiative, Biovac, a SA company that serves as a vaccine developer, Afrigen Biologics and Vaccines, a SA company that serves as a manufacturer, universities and the Africa Centres for Disease Control and Prevention (Africa CDC). The WHO received assistance from the Medicines Patents Pool to negotiate with technical partners and support governance of the hub.^[7] In February 2022, SA scientists at this hub reproduced Moderna's COVID-19 vaccine, achieving a major milestone for the hub and the continent.^[8]

To address the many bottlenecks described above, the African Union (AU) and the Africa CDC have called for a New Public Health Order, the aim of which is to safeguard the health and economic security of the continent, with a key pillar being that of expanding the local manufacture of vaccines, diagnostics and therapeutics. In April 2021, at a gathering of African leaders, the Partnerships for African Vaccine Manufacturing (PAVM) was established by the AU to deliver on the goal of enabling the African vaccine manufacturing industry to develop, produce and supply over 60% of the total vaccine doses for Africa by 2040.^[4]

For the vision of the New Public Health Order to be realised, an integrated ecosystem approach will be necessary. Investment will be required in all steps of the vaccine manufacturing supply chain. This includes research and development (R&D), drug substance, and

fill and finish. R&D will need to increase to include preclinical and clinical trials. Supporting industries will need to grow as well for the provision of raw materials, active ingredients, inactive ingredients and consumables such as vials, sterile bottles, syringes and rubber stoppers. Key benefits of developing an enabling environment include reducing production costs and increasing sustainability of vaccine production on the continent, thereby promoting self-reliance and health security.^[4]

This plan by the AU and Africa CDC is laudable, albeit ambitious. It will require shared responsibilities from within individual countries on the continent, and positive political will, to see it executed successfully. Already, the lack of commitment to the New Public Health Order is evident from the SA government's recent decision to procure pneumococcal vaccines from India-based manufacturer CIPLA instead of supporting its local manufacturer, Biovac.^[1] Rather than backing more local production, SA chose the easier and cheaper route of importing the vaccines, despite Biovac's ability to deliver the vaccines. It is left to be seen whether the AU and Africa CDC will hold SA to account for undermining PAVM and the New Public Health Order so early in the process.

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