

The expansion of pharmaceutical manufacturing industries is critical to strengthen African health systems and decrease reliance on foreign imports

Michael Mynhardt,¹ Nicaise Ndembu²

¹Group Executive at Avacare Health Global, Managing Director at Barrs Pharmaceutical Industries (Pty) Ltd, Cape Town, South Africa; ²Chief Science Advisor, Office of the Director General of the Africa Center for Disease Control and Prevention (Africa CDC), Addis Ababa, Ethiopia

Introduction

Our former President Nelson Rolihlahla Mandela is revered worldwide for dedicating his life to the fight against the oppressive and dehumanizing apartheid regime in South Africa. His passion for human rights led to a lifelong commitment to create a better world, in which the dignity, justice and freedom of all would be respected.

He was also a world-renown advocate for our collective public health. He made significant contributions to the well-being of South Africans and is recognized globally for his work on HIV/AIDS.¹ His momentous accomplishments in the realm of health would be enough to earn most people a place in world history.² His legacy in healthcare lives on through the Nelson Mandela Foundation,³ where his work on the HIV/AIDS epidemic helped save millions of lives in our country today.

It has been a decade since his passing,⁴ and just a few years since the global outbreak of Covid-19. It is high time we ask ourselves how we can build on his legacy, by saving millions more lives - not just in our own country, but across the broader African continent. A good starting point would be to take a pan-Africanist⁵ approach towards expanding our pharmaceutical manufacturing

industries, with the aim to strengthen African health systems over the next 10 years to come.

Distribution and accessibility

In Africa, 99% of all vaccines administered to people are imported.⁶ The consequences of this are notably concerning - and became painfully evident after COVID-19. African countries were left last in line to receive their shots, with foreign vaccine manufacturers⁷ controlling their distribution based on their preferred commercial agreements. This meant that affluent countries - where vaccines were being made - received their vaccines first,⁸ simply because they could pay more. Sadly, this is not the first time that Africa and its people have been excluded from the latest developments in healthcare and vaccine technology. And it will be a regretful recurrence if we don't focus on expanding our capacity to manufacture them ourselves, today.

Navigating capital expenditure towards strengthening Africa's healthcare systems

This may sound like wishful thinking to anyone that has played a significant role in healthcare, manufacturing or both. The start-up costs for any manufacturing plant are significant - to simply set-up a respectable tablet or capsule manufacturing facility, you're looking at a minimum spend of R50+ million. For vaccines, that number balloons in excess of R600m+.⁹

This constitutes a material capital outlay to simply lay the groundwork, and it does not include any additional costs or fees associated with the manufacturing of healthcare products in Africa.

Research and development, intellectual property rights, clinical trials and the registration of products will immediately add to these figures. The actual manufacture, distribution and education associated with the product only compounds the final amount. Medical devices, pharmaceutical products and biologics must each have their own production facility as well - with a number of strict controls to prevent the contamination of the products being manufactured. At this point, foreign imports begin to look more favorable - and one could almost forgive national governments for choosing to outsource such costly manufacturing processes.

Correspondence: Michael Mynhardt, Group Executive at Avacare Health Global, Managing Director at Barrs Pharmaceutical Industries (Pty) Ltd, Barrs Pharmaceuticals, 10 Inyoni St, Ndabeni, Cape Town 7405, South Africa.
E-mail: michael.m@avacareglobal.com

Key words: pharmaceutical manufacturing in Africa, vaccines, vaccine technology, healthcare systems, Nelson Mandela, Ubuntu.

Conflict of interest: the authors declare no potential conflict of interest.

Acknowledgements: the authors share their gratitude with the Partnerships for African Vaccine Manufacturing Framework For Action and the South African Health Products Regulatory Authority for their research and work towards improving the conditions associated with vaccine manufacturing in Africa today.

Received for publication: 10 July 2023.

Accepted for publication: 8 August 2023.

This work is licensed under a Creative Commons Attribution NonCommercial 4.0 License (CC BY-NC 4.0).

©Copyright: the Author(s), 2023

Journal of Public Health in Africa 2023; 14:2826
doi:10.4081/jphia.2023.2826

organizations and policymakers on our continent. A global outbreak certainly offers a compelling opportunity to revisit the urgent need to expand our vaccine-manufacturing capabilities, especially when less than 1% of vaccines are being manufactured in Africa.¹⁰

So why invest?

Because the African continent, and the people who live here, deserve access to improved vaccine-supply security. Citizens across Africa should rest assured in the fact that we have strengthened our pandemic preparedness, and have improved our ability to tackle endemic diseases.

This incredible undertaking is already being led by the Partnerships for African Vaccine Manufacturing Framework for Action (PAVM FFA), which, with our continued support, will certainly result in success. The PAVM has already set itself an ambitious goal, towards ensuring that 60% of Africa's vaccine demand is supplied by Africa's own vaccine-manufacturing industry by 2040.¹¹

Vertical over horizontal integration is key

If we are to meaningfully tackle the expansion of our manufacturing capabilities, we cannot ignore the need to ensure vertical integration in the healthcare manufacturing sector. If we are not able to control the entire manufacturing process, then all we will achieve is a number of fill and finish facilities. This means that we need to empower players in the sector with the regulatory and financial support they require to become innovators, with their own research and development, to ensure they have sole control of the intellectual property of their products ahead of any clinical trials. This support must remain in effect across all four stages of clinical trials, until there is a proven claim regarding the efficacy of the product being manufactured. Once manufacturers reach the regulatory space, we need to ensure that the local authorities (*i.e.* SAHPRA) create an enabling environment with quick turnaround times for the registration of pharmaceuticals and biologics.¹² If entities like SAHPRA can expedite the licensing of plants and product registrations in a manner that is both efficient and timeous, local manufacturers will decrease their time to market and citizens will have improved access to healthcare, faster than ever before.

This view to enable vertical integration in the healthcare manufacturing sector should also include skills transfers in its approach, as well as the education of healthcare professionals (to ensure that local healthcare practitioners know how to use locally manufactured medicines too).

Case studies for success

The world-renowned Afrigen Biologics mRNA hub in Cape Town already aims to contribute significantly to our continental independence, by working on the development of new vaccines for diseases that are rampant in lower and middle-income countries.^{13,14}

The first vials should be making their way to the market by 2024.¹⁵ What makes Afrigen a particularly valuable case study, is that they're willing to transfer their knowledge with a number of selected manufacturers in Africa as well.¹⁶ Afrigen's Pan-Africanist approach to decreasing Africa's reliance on foreign imports will help put South Africa at the forefront of this remarkable undertaking over the next 5-10 years.

Support from Government: critical

Support from local government structures will remain critical if we are to improve our healthcare systems with an expanded capacity to manufacture our own vaccines. The public sector should offer preferential treatment to local manufacturers in their public contracts and tenders, and should consider duties on imports - perhaps restricting them altogether.

Government should also consider offering exclusive rights to local manufacturers, based on the economic multiplier effect. This is a long-term plan, which cannot be implemented if we get stuck on the costs in the short-term. Price preference must be weighed equally against the opportunity for job creation, skills development, improved health outcomes, investment and overall economic growth. Our national government would also have to support local manufacturers with subsidies and sound offtake agreements, in an environment that is defined by a stable political economy to create the right climate for continued investment.

Providing private sector players with equity in exchange for their years of expertise and business acumen would contribute significantly to improving the operating environment of any healthcare manufacturer in Africa as well.

Let Ubuntu define the trajectory

Pan-Africanism,¹⁷ underpinned by the principles of Ubuntu,¹⁸ will have to play a central role in every step we take if we are to reach the PAVM's targets, with just 17 years on the clock.

Thankfully, the momentum is already beginning to build. Just last month, the Africa Health Business Symposium, together with the Africa Centres for Disease Control and Prevention launched a Memorandum of Understanding with the United States Pharmacopeia Convention to expand our access to quality-assured medical products on our continent,¹⁹ by increasing regional manufacturing, strengthening enabling regulatory and market environments, while bolstering clinical and public health laboratory networks.²⁰

This proves that it will take a concerted effort, between all public and private industry players, to decrease Africa's reliance on foreign imports towards strengthening our healthcare systems, while becoming more self-sufficient instead. But it's possible - and we should endeavor to meet the PAVM's target even faster than their preferred timeline would suggest.

References

- Magarro P. Nelson Mandela's Public Health Legacy. Columbia University Irving Medical Center. December 30, 2013. Available from: <https://www.cuimc.columbia.edu/news/nelson-mandelas-public-health-legacy>
- Magarro P. Nelson Mandela's Public Health Legacy. Columbia University Irving Medical Center. December 30, 2013. Available from: <https://www.cuimc.columbia.edu/news/nelson-mandelas-public-health-legacy>
- Nelson Mandela Foundation. Turning off the Tap: Understanding and Overcoming the HIV Epidemic in Southern Africa. Nelson Mandela Foundation. [Date unknown]. Available from: <https://www.nelsonmandela.org/publications/entry/turning-off-the-tap-understanding-and-overcoming-the-hiv-epidemic-in-southern-africa>
- Karimi F. Nelson Mandela, anti-apartheid icon and father of modern South Africa, dies. CNN. December 5, 2013. Available

- from: <https://edition.cnn.com/2013/12/05/world/africa/nelson-mandela/index.html>
5. Pan-Africanism. In: Cambridge Dictionary. [Accessed July 6, 2023]. Available from: <https://dictionary.cambridge.org/dictionary/english/pan-africanism>
 6. Wellcome, Biovac. Scaling up African vaccine manufacturing capacity: An overview of opportunities and challenges. 2023. Available from: https://www.biovac.co.za/wp-content/uploads/2023/02/Wellcome-Biovac-BCG-Scaling-up-African-vaccine-manufacturing-capacity-report-2023_0.pdf [Accessed July 6, 2023].
 7. Amnesty International. Sub-Saharan Africa: Millions denied vaccines, deepening inequality and human suffering from conflicts sum up 2021. Amnesty International. March 29, 2022. Available from: <https://www.amnesty.org/en/latest/news/2022/03/sub-saharan-africa-millions-denied-vaccines/>
 8. Soy A. Africa's long wait for the Covid-19 vaccine. BBC News. January 22, 2021. Available from: <https://www.bbc.com/news/world-africa-55751714>
 9. Daniel L. It's going to cost around R1.6 billion to get SA producing mRNA vaccines – half is already raised. News24. December 9, 2021. Available from: <https://www.news24.com/news24/bi-archive/south-africa-makes-its-own-covid-19-vaccines-2021-12>
 10. Lamptey E, Senkyire EK, Benita DA, Boakye EO. COVID-19 vaccines development in Africa: a review of current situation and existing challenges of vaccine production. National Library of Medicine. January 11, 2022. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8844666/>
 11. Wellcome, Biovac. Scaling up African vaccine manufacturing capacity: An overview of opportunities and challenges. 2023. Available from: https://www.biovac.co.za/wp-content/uploads/2023/02/Wellcome-Biovac-BCG-Scaling-up-African-vaccine-manufacturing-capacity-report-2023_0.pdf
 12. South African Health Products Regulatory Authority (SAPHRA). Removing Barriers And Promoting Access To Health Products. South African Health Products Regulatory Authority. March 1, 2023. Available from: <https://www.sahpra.org.za/news-and-updates/removing-barriers-and-promoting-access-to-health-products/>
 13. Mancini DP. South Africa's Afrigen to collaborate with US researchers on mRNA vaccines. Financial Times. July 8, 2022. Available from: <https://www.ft.com/content/fb2de235-059f-4ab5-937b-bf9033628c7f>
 14. Pretorius L, Malan M. Inside SA's mRNA hub: What it looks like and how it works. Bhekisisa Centre for Health Journalism. October 14, 2022. Available from: <https://bhekisisa.org/health-news-south-africa/2022-10-14-inside-sas-mrna-hub-what-it-looks-like-and-how-it-works/>
 15. Pretorius L, Malan M. Inside SA's mRNA hub: What it looks like and how it works. Financial Mail. October 14, 2022. Available from: <https://www.businesslive.co.za/fm/features/2022-10-14-inside-sas-mrna-hub-what-it-looks-like-and-how-it-works/>
 16. World Health Organization. mRNA technology transfer programme moves to the next phase of its development. April 20, 2023. Available from: <https://www.who.int/news/item/20-04-2023-mrna-technology-transfer-programme-moves-to-the-next-phase-of-its-development> [Accessed July 6, 2023].
 17. Pan-Africanism. In: Cambridge Dictionary. [Accessed July 6, 2023]. Available from: <https://dictionary.cambridge.org/dictionary/english/pan-africanism>
 18. Metz T. What Archbishop Tutu's Ubuntu credo teaches the world about justice and harmony. News24. December 16, 2021. Available from: <https://www.news24.com/citypress/voices/what-archbishop-tutus-ubuntu-credo-teaches-the-world-about-justice-and-harmony-20211216>
 19. Africa CDC. USP and Africa CDC launch MoU to advance regional manufacturing and strengthen regulatory and laboratory systems in Africa. Africa CDC. July 3, 2023. Available from: <https://africacdc.org/news-item/usp-and-africa-cdc-launch-mou-to-advance-regional-manufacturing-and-strengthen-regulatory-and-laboratory-systems-in-africa/>
 20. Africa CDC. USP and Africa CDC launch MoU to advance regional manufacturing and strengthen regulatory and laboratory systems in Africa. Africa CDC. July 3, 2023. Available from: <https://africacdc.org/news-item/usp-and-africa-cdc-launch-mou-to-advance-regional-manufacturing-and-strengthen-regulatory-and-laboratory-systems-in-africa/>