



**May 2023**

# **VacTask**

## **South African Vaccine Manufacturing Capabilities Key Findings and Recommendations**

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# South African Vaccine Manufacturing Capabilities: Key Findings and Recommendations

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The Pandemic Center at the Brown University School of Public Health works to ensure that the world better understands these catastrophic threats, their far-reaching casualties, and develops the tools, policies, and practices to mitigate and prevent their impact. The Pandemic Center is an independent and credible voice for positive disruption.

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## Foreword

Minister of State Enterprises Pravin Gordhan approached Dr. Wilmot James and Sir Jeremy Farrar on behalf Ministers of Health Mathume Joseph Phaahla, of Trade, Industry and Competition Ebrahim Patel and of Higher Education, Science and Innovation Bonginkosi Emmanuel “Blade” Nzimande, to conduct an assessment of South Africa’s potential to produce end-to-end vaccines and to make strategic recommendations to turn an aspiration for vaccine independence into a reality. Following on a fact-finding mission to vaccine-related entities in South Africa undertaken by Wilmot James, Martin Veller, Luc Debruyne, Tariro Makadzange, Amadou Sall, Stavros Nicolaou and Robyn Hayes in July 2022, this report was prepared and was presented to the South African Government in December 2022. We are making the report public today, on May 4 2023.

We are grateful to Martin Veller and Shabir Mahdi for their preparatory review of vaccine manufacturing on the continent. Myriam Grubo of the Medicines Patent Pool provided key points of data. We are grateful to Supporting Health Initiatives, a Division of Wits Health Consortium, for funding and coordinating this mission and to Martin Veller for co-leading, the fact-finding mission. With many thanks to Joshua Nott and Malebona ‘Precious’ Matsoso for preparing the final report. Bentley Holt at Brown University’s School of Public Health redesigned the report for public release.

### **Sir Jeremy Farrar and Dr. Wilmot James**

Sir Jeremy is Chief Scientific Officer of the World Health Organisation (WHO) and Dr. James Professor of Practice and Senior Advisor to the Pandemic Center at the Brown University School of Public Health, Rhode Island. At the time this report was prepared and presented to the South African Government, Sir Jeremy served as Chair of VacTask in his private capacity and Dr. James as co-chair whilst being a Senior Research Scholar in the College of Arts and Sciences at Columbia University.

## Executive Brief

There is a brief window of opportunity for the South African government to accelerate the establishment of an integrated, competitive, and cohesive local vaccine manufacturing ecosystem for the African continent. The financial resources and the political will are, for a short period of time, available to support such a far-reaching and impactful intervention.<sup>1</sup>

The consequences of not seizing upon this moment are clear. Africa's population is ballooning. Vaccine demand on the continent is set to more than double in volume over the next decade from approximately 1 billion doses today, to over 2.7 billion doses by 2040.<sup>2</sup> Such a population boom, without appropriately planned public health interventions, will have major societal and economic consequences. Vaccination must be integral to such a plan, as this is the most effective public health intervention available, ranking second only to clean water for disease prevention. Yet Africa produces <1% of global vaccines. Working together, in developing vaccine manufacturing capacity, the South African government and business sector can generate significant economic returns, job creation, positive health outcomes and infrastructure development all while strengthening the country's biosecurity and preparedness capabilities.

Within the year, the South African Government should establish a special **cluster on biotechnology and vaccine manufacturing** co-chaired by the Ministers of Health and Higher Education, Science, and Innovation. The cluster should bring together the key government ministries, including the Ministries of Trade, Industry and Competition, Agriculture, Finance, and State Enterprises with independent members to bring additional expertise and global links. The cluster's overarching goal should be to harmonize policy and regulations to support the critical components of vaccine related R&D and manufacturing, from input resources to advanced technologies and intellectual property (IP) protection.

The **cluster on biotech and vaccine manufacturing** should focus attention on:

**Vaccine Procurement Policy:** the procurement policy must satisfy two key goals: (1) de-risking, and (2) scaling South African vaccine manufacturing for continental consumption. To ensure local vaccine manufactures are both competitive and have an ability to scale, government should - at the Executive and Legislative levels - provide for preferential procurement for local producers across the vaccine manufacturing value chain.

Correlated to a preferential procurement policy, are the provision of guaranteed long-term contracts, import and export tax allowances, and related tax incentive schemes for local manufactures.

Finally, procurement policy should empower relevant government Ministries and/or agencies to proactively support local industry in their bids for continental procurement contracts and/or applications for financing from national, multilateral, or private sources.

**Human Capital Investment:** talent is the backbone to any competitive vaccine manufacturing continent-level play. While the scientific community in South Africa is strong in many (but not all) areas of the R&D spectrum, it is dependent on too small several experts. National Treasury should increase expenditure at all levels of the vaccine research, development, and manufacturing value chain, including technical upskilling and advanced training for professionals in QA/QC, R&D, manufacturing, and good manufacturing practice (GMP) build and design processes, regulation, and equipment maintenance.

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<sup>1</sup> J. Daven, W. James, and M. Kahn. (2020). 'Investing in Health Security Preparedness' in Ed. W. James, *Vital Signs: Health Security in South Africa*. (Brenthurst Foundation, Johannesburg <https://www.thebrenthurstfoundation.org/books/vital-signs-health-security-in-south-africa/>) p. 67.

<sup>2</sup> African Union. (3 March 2022). *Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action*. Africa CDC. <https://africacdc.org/download/partnerships-for-african-vaccine-manufacturing-pavm-framework-for-action/>

Where the national budget cannot make allocations, government through the special cluster should unlock financing for human capital investment by employing revenue generating strategies, such as securing capital via results-based financing products offered by multilateral lenders.

Results from such capital expenditure can clearly be tied to educational and R&D outcomes (e.g., number of graduates in Life Sciences and number of patents produced per year). Finally, the Ministries of Health, Higher Education, Science, and Innovation as well as Trade, Industry and Competition should coordinate between each other and the private sector to improve the skills base necessary for vaccine production.

South Africa's academic institutions and research councils<sup>3</sup> should be consulted on the skills gap (demand), and existing training and upskilling (supply) to meet human capital needs of the sector.

**Regulation:** should be designed in a manner that is consistent with, and supportive of, the promotion of South Africa's biotech and vaccine manufacturing ecosystem. Without this underpinning, local producers will not be able to compete regionally and globally. We believe that South Africa should provide expertise and support the leadership of the African Medicines Agency (AMA).<sup>4</sup>

All relevant South African regulations should be harmonized with the AMA rules and standards for local producers to access all AMA ratified markets.<sup>5</sup> Only by opening up vaccine distribution across the continent can South Africa's vaccine R&D and manufacturing be sustained.<sup>6</sup>

AMA regulations should also serve as a minimum standard and therefore be promulgated to advance (1) development of South Africa's knowledge base through the promotion of high-level biotech research; (2) knowledge transmission via the exchange of information to and from academia and the private sector; (3) establishing, retaining, and attracting private sector biotech firms in South Africa's market, and (4) enhancing domestic competitiveness via tax incentives and subsidies for venture capital and institutional investments into the domestic biotech and vaccine manufacturing industry.

Together, these regulations are a *sine quo non* to allow South African vaccine manufacturing entities to compete with government regulations and policy interventions in peer and competing markets.<sup>7</sup>

**R&D infrastructure investment and adjacent industries:** R&D infrastructure investment and adjacent industries: capital must be set aside to support good clinical, laboratory, and manufacturing practices and supply chains. Capital expenditure directed to ensure such international standard practice at animal testing and related laboratory facilities is critical to securing a competitive and compliant end-to-end vaccine manufacturing process from the design to implementation phase.

The South African vaccine manufacturing ecosystem can be a model for continental replication and for other lower middle-income countries generally. It is a difficult task to achieve the desired end goal of a competitive, integrated, and productive vaccine manufacturing system. While difficult, the task is not impossible.

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<sup>3</sup> South African Health Products Regulatory Authority (SAHPRA), South African Medical Research Council (SAMRC), and National Institute for Communicable Diseases of South Africa (NICD).

<sup>4</sup> African Union (2019). 'The treaty for the establishment of the African Medicines Agency' <https://au.int/en/treaties/treaty-establishment-african-medicines-agency/>

<sup>5</sup> The benefits of access an integrated medicines market have been proven in the case of the European Union, T. Reiss and I. Dominguez-Lacasa. (2005). Indicators for benchmarking biotechnology innovation policies. (European Commission. <https://www.oecd.org/sti/inno/37450279.pdf>).

<sup>6</sup> The benefits of access an integrated medicines market have been proven in the case of the European Union, T. Reiss and I. Dominguez-Lacasa. (2005). Indicators for benchmarking biotechnology innovation policies. (European Commission. <https://www.oecd.org/sti/inno/37450279.pdf>).

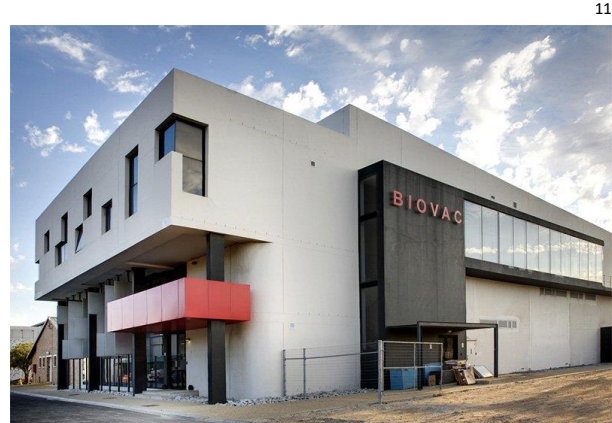
<sup>7</sup> African Union Development Agency. (1 February, 2022). *Manufacturing in Africa needs a strong regulatory framework*. (AUDA-NEPAD. <https://www.nepad.org/news/manufacturing-africa-needs-strong-regulatory-framework/>).

If South Africa’s government can come together, both internally and with the private sector, in a concerted and open manner, then the economic dividends and healthcare benefits of a thriving biotech and vaccine manufacturing ecosystem can be substantial. India is the proven case study. In 1986 India became one of the first countries to have a government unit dedicated to biotech with a budget of \$835,000 USD.<sup>8</sup>

After three decades of concerted effort, favorable regulations, and investment in human capital, India’s biotech industry, created hundreds of thousands of direct and indirect jobs, and reached a valuation of \$70.2 billion (2020) and is expected to be valued at \$150 billion by 2025.<sup>9</sup> South Africa can and must embark on a similar journey.



Aspen Holdings Head Office, Durban, South Africa



The Biovac Institute, Cape Town, South Africa



Serum Institute of India

<sup>8</sup> B. Nogrady (2019), ‘How Indian biotech is driving innovation’, *Nature* <https://www.nature.com/articles/d41586-018-07671-9/>.

<sup>9</sup> India Brand Equity Foundation (July, 2022), *Biotechnology Industry Report*. <https://www.ibef.org/industry/biotechnology-india>.

<sup>10</sup> By SBeukes - Own work, CC BY-SA 4.0, <https://commons.wikimedia.org/w/index.php?curid=76526714>

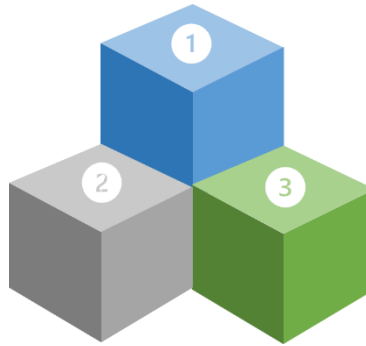
<sup>11</sup> Biovac. <https://www.biovac.co.za/>

<sup>12</sup> SpeedShutter - stock.adobe.com

## VacTask: Who we are

Our group<sup>13</sup> is an independent advisory entity specifically formed to support South Africa as a ‘front runner’ for the Africa CDC’s Partnership for African Vaccine Manufacturing (PAVM).

There is a growing consensus that the world’s public health community should pursue a triple agenda:



1. Establish a global network of highly trained and connected public health professionals, enhancing country-level public health and surveillance capabilities and outbreak response capacity and capability globally.
2. Deliver on the global vision for more effective national and global surveillance networks, especially at the local level in state’s requiring capacity building support.
3. Accelerate and expand Africa’s R&D and manufacturing drive for vaccines, treatments, and diagnostics.

We focused on the 3<sup>rd</sup> pillar of this agenda.

## VacTask: Our Work

To meet challenges facing public health in Africa, we assembled a team of scientists (medical and social), business representatives, non-government organizations, philanthropies, and policymakers. This team:

- Conducted a fact-finding mission in South Africa — Johannesburg, Pretoria and Cape Town.
- Had site visits to Biovac, Afrigen, Aspen Pharmacare, and Onderstepoort Biological Products (OBP) facilities where we conducted formal, semi-formal, and informal interviews across the whole value chain of research, clinical implementation, and manufacture (including R&D).
- Produced a first policy recommendation for the South African Government.
- Hosted virtual meetings on the latest developments in the pandemic response and planning arenas.



<sup>13</sup> VacTask consisted of a core group, and an on-call group of persons whose advice and expertise were sought on a need basis. **Core:** Sir Jeremy Farrar, Chair (Wellcome Trust), Wilmot James Co-Chair (Brown University & University of the Witwatersrand), Dame Kate Bingham (SV Health Investors), Barbara Bush (Schmidt Futures), Luc Debruyne (KU Leuven), Gordon Dougan (Wellcome Trust), Glenda Gray (SA Medical Research Council), Marc Grodman (Columbia University), Margaret Hamburg (Foreign Secretary, National Academy of Medicine), Gagandeep (Cherry) Kang (Christian Medical College, Vellore, India), Barney Graham (formerly US NIH), Tariro Makadzange (Charles River Medical Group, Zimbabwe & Stanford University), Phil Mjwara (SA Department of Science and Innovation), Kate O’Brien (WHO), Amadou Sall (Pasteur Institute, Senegal), Paul Schreier (Wellcome Trust), Martin Veller (University of the Witwatersrand) and Solomon Zewdu (Bill and Melinda Gates Foundation). **On-call:** Trevor Mundel (Bill and Melinda Gates Foundation), Stavros Nicolaou (Aspen Pharmacare), Joseph E. Stiglitz, (Columbia University), Martin Friede (WHO) and Morena Makhoana (BioVac).

## Scoping Africa's Public Health Challenge

A VacTask sub-group<sup>14</sup> recently completed a visit to South Africa's vaccine related entities. It is our view, based on research and engagement with our core team (composed of world-renowned scientists and leaders), that competitive vaccine production in South Africa is feasible, viable, and politically prudent. Research, development, and manufacturing should focus on Africa-specific vaccines against known and emerging pathogens, including those of yet unknown origin.

Our work is modelled on the Partnership for African Vaccine Manufacturing (PAVM) Framework for Action<sup>15</sup> which proposes a methodology of building a robust and coherent vaccine manufacturing ecosystem on a vast and resourced-stressed continent. The core tenant of PAVM's Framework for Action is strengthening public health. As stated by a member of the task group, Dr. Tariro Makadzange, from the African context this means that "Africa's public health must be led by its political leadership with an all of government approach that works towards a bold vision to improve the lives of Africans."<sup>16</sup>

### The need for vaccines is irrefutable, and the benefits, real:

It is common cause that vaccination is the most effective public health intervention available, ranking second only to clean water for disease prevention. But, despite the availability and affordability of vaccines, immunization rates are falling in some countries.<sup>17</sup>

Global immunization coverage dropped from 86% in 2019 to 81% in 2021. An estimated 25 million children under the age of 1 year did not receive basic vaccines for routine immunization, which is the highest number since 2009.<sup>18</sup> One in five children in Africa still do not receive all the basic vaccines, resulting in approximately 30 million African children acquiring vaccine-preventable diseases and half a million of these children dying annually.<sup>19</sup>

It is estimated that every \$1 spent on childhood immunizations in Africa, returns \$44 in economic benefits. Investing in immunization keeps children healthy, safe from preventable diseases, and has an obvious economic dividend.<sup>20</sup>

Four major vaccine-preventable diseases – rotavirus, pneumococcal diseases, measles, and rubella – collectively cost the Africa \$13 billion each year, due to loss of productivity because of premature death (\$10 billion), prolonged sickness (\$2 billion), hospitalizations (\$260 million), and outpatient visits (\$73 million).<sup>21</sup>

It is probable that within this decade there will be vaccines for malaria and tuberculosis, it is critical that these vaccines are manufactured on the continent as part of a sustainable approach to African vaccines.

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<sup>14</sup> VacTask Sub-group: Wilmot James, Martin Veller, Luc Debruyne, Tariro Makadzange, Amadou Sall, Stavros Nicolaou and Robyn Hayes.

<sup>15</sup> African Union (2022). 'Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action', p. 21.

<sup>16</sup> Tariro Makadzange (27 July 2022), 'Public Health in Africa: What Is It?' (Charles River Medical Group. <https://www.charlesrivermedicalgroup.com/post/public-health-in-africa-what-is-it>).

<sup>17</sup> Oxford Vaccine Group, (27 June, 2019). 'The global value of vaccination'. (University of Oxford <https://www.ovg.ox.ac.uk/news/the-global-value-of-vaccination#:~:text=Vaccination%20is%20the%20most%20effective,are%20falling%20in%20some%20countries>).

<sup>18</sup> World Health Organization. 'Business case for WHO immunization activities on the African continent, 2018-2030.' (2018, WHO Regional Office for Africa. [https://www.afro.who.int/sites/default/files/2018-05/WHO\\_Bcase\\_Brochure\\_2018\\_05\\_11\\_FINAL%20VERSION\\_ISBN\\_WEB\\_0.pdf](https://www.afro.who.int/sites/default/files/2018-05/WHO_Bcase_Brochure_2018_05_11_FINAL%20VERSION_ISBN_WEB_0.pdf)).

<sup>19</sup> WHO, 'Business case for WHO immunization activities on the African continent, 2018-2030.'

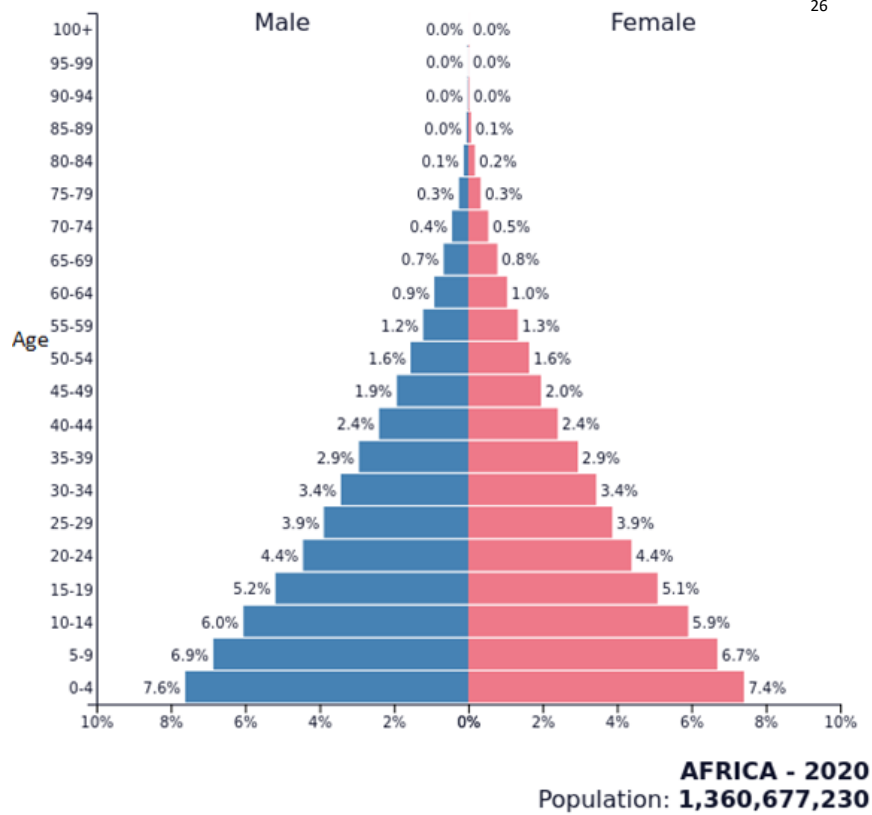
<sup>20</sup> S. Ozawa, S. Clark, A. Portnoy, S. Grewal, L. Brenzel, and D.G. Walker. (2016) 'Return on investment from childhood immunization in low- and middle-income countries, 2011–20', *Health Affairs* v. 35 no.2 ( <https://pubmed.ncbi.nlm.nih.gov/26858370/>).

<sup>21</sup> Ozawa, Clark, Portnoy, Grewal, Brenzel, and Walker. 'Return on investment from childhood immunization in low- and middle-income countries, 2011–20.'



**Scope of the immunization challenge in Africa is threefold:**

- Supply Constraints:** Africa produces <1% of its vaccine needs.<sup>22</sup> Local and regional factors such as last mile delivery, cold chain storage, limited infrastructure, and the lack of integrated supply chains further hinder public health outcomes.<sup>23</sup>
- Demographic Boom:** by 2035 the number of 15–24-year-old Africans will reach 295 million and by 2050, 362 million. In 2030, Africa will have a working population of 1 billion people. More people mean greater burdens on healthcare systems and increased demand for vaccines. Vaccine demand is set to more than double in volume over the next decade from approximately 1 billion doses today, to over 2.7 billion doses in 2040.<sup>24</sup>
- State & expenditure limitations:** total spending on health in sub-Saharan Africa in 2020 was US\$91 billion, 38% was government spending (US\$35 billion). Governments in sub-Saharan Africa spend on average US\$73 per capita; this is less than 2% of the per capita spending by high income governments and well below national needs. Most countries in Africa spend <1% of GDP on research and development (R&D) with very little funding for R&D from the local private sector.<sup>25</sup> Moreover, there is acute dependence on donor funding in the procurement and roll-out of vaccines — alleviating dependence on private philanthropy increases the long-term viability of local manufacturing.



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<sup>22</sup> Z. Usman and J. Ovidia. (13 September, 2021). *Is There Any COVID-19 Vaccine Production in Africa?* (Carnegie Endowment for International Peace. (<https://carnegieendowment.org/2021/09/13/is-there-any-covid-19-vaccine-production-in-africa-pub-85320/>).

<sup>23</sup> Nature Editorial (2022). 'Africa is bringing vaccine manufacturing home', *Nature* 602 no.184.

<sup>24</sup> Kristalina Georgieva, 'Support for Africa's vaccine production is good for the world' (12 January 2022, IMF, <https://blogs.imf.org/2022/01/12/support-for-africas-vaccine-production-is-good-for-the-world/>).

<sup>25</sup> Georgieva, 'Support for Africa's vaccine production is good for the world'.

<sup>26</sup> © 2023 by PopulationPyramid.net, made available under a Creative Commons license CC BY 3.0 IGO. <https://www.populationpyramid.net/africa/2020/>

## Response Mapping

To meet the public health challenge, African countries have organized at the country, regional and continental level with the Partnerships for African Vaccine Manufacturing (PAVM). PAVM exists as an initiative of the African Union (AU). Its goal is for the continent to produce 60% of its vaccines locally by 2040.<sup>27</sup>

PAVM's Framework for Action exists to establish a fully integrated ecosystem to generate investment in all the steps of the vaccine manufacturing supply chain, namely R&D, drug substance manufacture, and fill and finish.

At the multilateral and global level, the WHO's vaccine technology transfer hubs involve the WHO and its partners (states, corporations, nonprofits) bringing production know-how, quality control and necessary licenses to facilitate broad and rapid technology transfer to multiple recipients around the world.

An example of the WHO's vaccine tech hub sees the South African and French governments coordinating in establishing African vaccine production centres. The South African effort is led by the South African Medical Research Council (SAMRC), Afrigen, Biovac, Africa CDC and five South African universities (the University of the Witwatersrand or WITS, University of Cape Town, University of Kwazulu-Natal, University of Stellenbosch and Northwest University).<sup>28</sup>



<sup>27</sup> African Union. (2022) 'Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action.'

<sup>28</sup>South African Medical Research Council. <https://www.samrc.ac.za/>; Afrigen Biologics and Vaccines. <https://www.afrigen.co.za/>; Biovac. <https://www.biovac.co.za/>; Africa CDC. <https://africacdc.org/>; University of the Witwatersrand, Johannesburg. <https://www.wits.ac.za/>; University of Cape Town. <https://www.uct.ac.za/>; University of Kwazulu-Natal. <https://ukzn.ac.za/>; Stellenbosch University. <http://www.sun.ac.za/english>; North-West University. <https://www.nwu.ac.za/>.

## South African Vaccine Manufacturing Capabilities: Key Findings

In conducting our research, we have consolidated our findings regarding the state of the South African vaccine manufacturing market into five parts:

**R&D and Product Development:** South Africa has the underlying infrastructure in place, and most of the infrastructure is reasonably resourced. However, funding constraints do limit many laboratories, particularly when urgent investigations and product development is required. Specifically, the translation from discovery to phase 1 human trials is unnecessarily delayed (in part also by constraints in the manufacture of study/prototype vaccines meeting GMP standards).

We found there to be limited funding for pathogen immunobiology to support the development of vaccine immunogens and limited R&D funding for developing and optimizing vaccine technologies and manufacturing processes.

**Public health and clinical sciences:** South African universities and research institutes conduct high quality research and are staffed by individuals with high-end biomedical and public health expertise in many key areas, if not all sub-disciplines, of the overall research enterprise.

These institutions attract competitive grants raised from outside of South Africa (e.g., NIH, US CDC, other US government agencies, the Bill and Melinda Gates Foundation, UK MRC, and the Wellcome Trust).

While outside funding is welcomed, it does raise questions about the sustainability of South Africa's clinical sciences ecosystem without additional domestic investment.



**South African Medical Research Council (SAMRC) & National Institute for Communicable Diseases of South Africa (NICD):** Our assessment is that a critical skills shortage is reported at all levels and by the entities visited. There is a real need to attract GMP compliant manufacturing capacity and skills to South Africa and translate this talent into effective training programmes to support skills transfer.

The skills shortage is, in fact, an issue at all levels of vaccine infrastructure in South Africa. Both the SAMRC and NICD however, were found to be effectively addressing their mandates despite funding constraints. For example, the leadership at SAMRC has been central to bringing the mRNA core and one of the hubs to South Africa.

The NICD has been outstanding in addressing multiple epidemics and pandemics in SA and across the continent. A further development, and important one at that, is the signing of the National Public Health Institute of South Africa (NAPHISA) Act, 2020.



Once established NAPHISA, should leverage existing skills and knowledge from the SAMRC and NICD to deliver on its mandate to conduct disease (communicable and non-communicable) and injury surveillance. NAPHISA’s budget for training and research directed towards major health challenges should, in part, be used to support existing training programmes within the SAMRC and NICD.

**Vaccine and Vaccine Adjuvant Manufacture (formulation and fill and finish):** South Africa has for some time sorely lacked an emergency response regime to pathogens of endemic and pandemic potential.

COVID-19 displayed the country’s inability to deploy vaccines quickly due to lack of supply, a key component of any emergency response counter-measure plan. South Africa must address its lack of an *end-to-end manufacture of vaccines for human use* in South Africa.

Without guaranteed procurement, pharmaceutical firms, like that of Aspen, cannot establish themselves in this space. To evaluate this, the VacTask core team visited the Biovac, Afrigen and Onderstepoort Biological Products (OBP) manufacturing facilities.

Our findings are:

- Basic infrastructure is in place, primarily a robust fill and finish capacity. However, translation into an end-to-end production process will require significant capital expenditure.
- OBP does have the end-to-end capacity to make veterinary vaccines but is only now developing the processes to do so to meet GMP. This has caused significant disruption to their capacity to continue to manufacture essential vaccines such as that required for African Horse Sickness.

**South African Health Products Regulatory Authority (SAHPRA):** SAHPRA’s officials believe that it is important to have a local vaccine manufacturing capacity — this staff level buy-in is critical. SAHPRA’s responsiveness and alignment across African markets is a competitive edge for South Africa. Important and related to our Regulation recommendation, the Authority is well versed at working with the African Medicines Agency.

The special cluster should support SAHPRA in its aspirations to become a WHO reference authority with Maturity Level 4 accreditation (ML4). Government should support SAHPRA in this bid and encourage the Authority to pursue ML4 accreditation thereafter.

Finally, SAHPRA needs to draft a blueprint to ensure seamless licensing and technology transfer arrangements and, where necessary, accommodating closed paths of IP. The special cluster should similarly support SAHPRA in this regard.



<sup>29</sup> By South African Health Products Regulatory Authority - South African Health Products Regulatory Authority, Public Domain, <https://commons.wikimedia.org/w/index.php?curid=102144389> ; Onderstepoort Biological Products. <https://www.obpvaccines.co.za/>

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## Recommendations

Within the year, the South African Government should establish a special **cluster on biotechnology and vaccine manufacturing** co-chaired by the Ministers of Health and Higher Education, Science and Innovation with independent members to bring additional expertise and global links.

The cluster should bring together the key government ministries to harmonize policy and regulations to support the critical components of vaccine related R&D and manufacturing, from input resources to advanced technologies and intellectual property protection.

The **cluster on biotech and vaccine manufacturing** should focus attention on:

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Moreover, such policies must be able to accommodate changes in capital flow, human resource requirements, inventory management and sustainable contract management.

Finally, procurement policy should empower relevant government Ministries and/or agencies to proactively support local industry in their bids for continental procurement contracts and/or applications for financing from national, multilateral, or private sources.

**Human Capital Investment:** talent is the backbone to any competitive vaccine manufacturing country-level play. While the scientific community in South Africa is strong in many (but not all) areas of the R&D spectrum, it is dependent on a small number of experts.

National Treasury should increase expenditure at all levels of the vaccine development and manufacturing value chain, including technical upskilling and advanced training in for professionals in QA/QC, R&D, manufacturing, good manufacturing practice (GMP) build and design processes, and equipment maintenance. Where the national budget cannot make allocations, government through the special cluster should unlock financing for human capital investment by employing revenue generating strategies, such as securing capital via results-based financing products offered by multilateral lenders.

Results from such capital expenditure can clearly be tied to educational and R&D outcomes (e.g., number of graduates in Life Sciences and number of patents produced per year).

Finally, the Ministries of Health, Higher Education Science and Innovation as well as Trade, Industry and Competition should coordinate between each other and the private sector to improve the skills base necessary for vaccine production.

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Together these regulations are a *sine quo non* in order to compete with government regulations and policy interventions being used in peer and competing markets.<sup>35</sup>

**R&D infrastructure investment and adjacent industries:** R&D infrastructure investment and adjacent industries: capital must be set aside to support good clinical, laboratory, and manufacturing practices. Capital expenditure directed to ensuring such good practice at animal testing and related laboratory facilities is critical to securing a competitive and compliant end-to-end vaccine manufacturing process from the *design to implementation phase*.



<sup>30</sup> South African Health Products Regulatory Authority (SAHPRA), South African Medical Research Council (SAMRC), and National Institute for Communicable Diseases of South Africa (NICD).

<sup>31</sup> African Union [@\_AfricanUnion]. (2022, July 17). *Rwanda’s been selected to host the HQ of the African Medicines Agency by the Executive Council meeting in Lusaka. AMA...* [Tweet]. Twitter. [https://twitter.com/\\_AfricanUnion/status/1548560073076932608](https://twitter.com/_AfricanUnion/status/1548560073076932608)

<sup>32</sup> African Union (2019). ‘Treaty for the establishment of the African Medicines Agency’.

<sup>33</sup> The benefits of access an integrated medicines market have been proven in the case of the European Union, T. Reiss and I. Dominguez-Lacasa. (2005). Indicators for benchmarking biotechnology innovation policies. (European Commission. <https://www.oecd.org/sti/inno/37450279.pdf>).

<sup>34</sup> The benefits of access an integrated medicines market have been proven in the case of the European Union, T. Reiss and I. Dominguez-Lacasa. (2005). Indicators for benchmarking biotechnology innovation policies. (European Commission. <https://www.oecd.org/sti/inno/37450279.pdf>).

<sup>35</sup> African Union Development Agency. (1 February, 2022). *Manufacturing in Africa needs a strong regulatory framework*. (AUDA-NEPAD. <https://www.nepad.org/news/manufacturing-africa-needs-strong-regulatory-framework>).



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The Pandemic Center at the Brown University School of Public Health works to ensure that the world better understands these catastrophic threats, their far-reaching casualties, and develops the tools, policies, and practices to mitigate and prevent their impact. The Pandemic Center is an independent and credible voice for positive disruption.



*Sustainable Vaccine Manufacturing on the African Continent*