



INNOVATION COUNCIL SUMMARY

Spotlight on Biovac: Building Local Biomanufacturing Capacity in South Africa

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Currently, African producers make only one per cent of the vaccines used in Africa. That is one-tenth of one per cent of the global supply of vaccines. The COVID-19 pandemic underscored Africa's need for quality vaccine manufacturing capacity across the continent so that every nation can respond effectively to health crises. This case study on the Biologicals and Vaccines Institute of Southern Africa (Biovac) — a South African biopharmaceutical company — traces its evolution from a vaccine supplier to manufacturer and biopharmaceutical innovator. It highlights the process, partnerships, and technology transfers that have underpinned the company's progress.

At a time when policymakers and funders are heavily invested in extending biomanufacturing capacity in Africa, Biovac's experience provides insights into the public policies and other factors that support capacity building and that leaders of such initiatives ought to put in place. The insights show how governments, industry, and other stakeholders can build on the existing capabilities of over a dozen companies across the continent—companies with experience in filling and finishing products, producing drug substances, and conducting research and development (R&D). Session and Preparatory Committee meetings held in Geneva. Those agreed changes slightly update the official negotiating text.

African vaccine supply: A sense of urgency

The COVID-19 pandemic starkly illuminated Africa's vulnerability to health crises, as affluent nations prioritized their needs, leaving the continent critically underserved in the acquisition of essential medical supplies. African leaders recognized the urgent need to establish a robust, independent vaccine supply, including through manufacturing capability building. They committed to building a sustainable ecosystem capable of producing high-quality vaccines and other vital biologics. The goal is not merely to react to future pandemics but to establish long-term health security and self-sufficiency.

Central to this endeavor is the Partnership for African Vaccine Manufacturing (PAVM), established in April 2021 by the African Union (AU) and Africa Centers for Disease Control and Prevention (AfricaCDC). PAVM's mandate is to achieve 60 per cent African vaccine self-sufficiency by 2040 and to expand production to encompass the full range of biologics over time.

The AU's 2022 public health order further reinforced this commitment, calling for increased local manufacturing and the removal of trade barriers to facilitate local production. The order also called on GAVI (Gavi, the Vaccine Alliance, formerly the Global Alliance for Vaccination and Immunization) and other so-called "vaccine purchasing mechanisms" such as the Revolving Fund for Access to Vaccines of the Pan American Health Organization (PAHO), to buy 30 per cent of their vaccines from African manufacturers.

International agencies like UNICEF and GAVI use bulk purchasing mechanisms to provide low-cost vaccines to countries in need, sometimes facilitating advance market commitments (AMCs) that aid new manufacturers to secure financing for expansion and that offer purchasing agencies predictable supply at lower costs. PAVM's objective is to evolve from relying on these agencies to become a supplier to bodies like GAVI, WHO, and UNICEF through growing local production. Achieving this will require the generation of adequate (and predictable) demand and long-term financial commitments for African producers to enable them to invest and scale. Demand certainty is vital for sustainable manufacturing capacity on the continent, which should help to reduce dependence on external buyers.

GAVI, a key procurement agency for African vaccines, is committed to supporting Africa's production capacity. In December 2022, GAVI's board approved a plan for a regionally diverse manufacturing ecosystem, prioritizing "supply security" alongside price in procurement. Subsequently, the African Vaccine Market Accelerator (AVMA) was launched to raise \$1 billion over ten years to help procurement agencies offset the higher cost of buying from African suppliers initially. Experienced African manufacturers such as Vacsera (Egypt), Biovac (South Africa), and Institute Pasteur Senegal are expected to catalyze more biologics production in the region. Their experiences will inform regional policies on funding, capacity building, quality assurance, regulatory compliance, demand management, and the negotiation of AMCs.

The story of the Biovac Institute of South Africa provides important lessons for organizations currently working to extend biomanufacturing networks across Africa and other developing regions in the service of public health. With two decades of experience, and a track record of contract manufacturing as well as R&D and innovation, Biovac manufactures nearly 10 million vaccines each year, some of these with partners, and is both a recipient and provider of biologics tech transfer services.

Biovac: An innovative approach to serving South Africans

Around the turn of the millennium, South Africa explored public-private partnerships (PPPs) for developing its health infrastructure and essential services, establishing a PPP unit and engaging the National Business Initiative to train government personnel in working with the private sector. At the time, the State Vaccine Institute (SVI), founded in 1965, was delivering health products and their components, working across four of the five stages of the pharmaceutical value chain: manufacturing substances, formulating drugs, filling and finishing products, and distributing them to its people. The SVI produced low-tech products; fetal bovine serum, human growth hormone, and dead-virus vaccines derived from cells like those causing rabies and smallpox. While crucial during apartheid sanctions, SVI's low-tech production was no longer competitive once importation grew; along with good manufacturing practices (GMP) challenges, this led to its closure in 2001.

Advised by a multinational accounting firm, a group of organizations known as the Consortium, led by Biovac Holdings, won a competitive bid to form a PPP with the government to rebuild South African vaccine manufacturing and meet national vaccine procurement needs.¹

¹ Initial consortium members included Biovac Holdings (South Africa), Heber Biotec (Cuba), VaxIntel (British Virgin Islands), and the Disability Employment Concerns Trust (DECT). Over 15 years, Heber, Vaxintel, and DECT divested, leaving Kahma Group (formerly Biovac Holdings) as the sole private shareholder.

Figure 1: Responsibilities at Each Stage of the Biopharmaceutical Value Chain

Stage 1	Stage 2	Stage 3	Stage 4	Stage 5
Discover and patent new solutions	Manufacture substances	Formulate products	Package and label products	Distribute and export products
• Research and develop new products. • Complete pre-clinical/ clinical trials. • Secure IP/regulatory approval.	• Produce active drug ingredients (e.g., antigens). • Produce inactive drug ingredients (i.e., excipients).	• Mix and make drugs.	• Fill vials. • Finish packaging for shipment.	• Source products for wholesale or retail. • Warehouse, transport, and distribute products. • Manage cold chain logistics.
Across value chain • Use good manufacturing practices. • Meet all quality and regulatory standards. • Meet all health policy and industry objectives. • Deliver positive value-for-money.				

Value chain adapted from Biovac Institute and Wellcome Trust Emergency Response, "Manufacturers Overview: Biovac," Presentation, Global mRNA Hub, WHO, 20 April 2023, https://cdn.who.int/media/docs/default-source/immunization/mrna-ttp/april-2023/6_biovac.pdf.

Biovac's strategic horizons

In 2003, Biovac was established as a PPP between the Consortium and the South African Department of Health (DOH), with the government initially holding 40 per cent (later increasing to 47.5 per cent for capital through a science and technology agency) and the Consortium the remainder. The PPP aimed to secure vaccine supply at low cost while also building national manufacturing capacity, with Biovac envisioning full integration and novel vaccine development. The government provided access to the outdated SVI facilities, requiring employee training and equipment upgrades.

Biovac adopted a three-horizon "reverse-integration strategy" starting with packaging and distribution, then fill and finish, with progressive movement up the value chain by training talent, upgrading facilities, and acquiring advanced knowledge and capabilities. This approach allowed for the reinvestment of procurement and distribution earnings into manufacturing and basic R&D, in view of reducing import costs while also building expertise and trust with partners. However, the DOH distribution contract alone was insufficient, necessitating external capital.

Each horizon depended on carefully managed "technology transfers" from select partners, which enabled Biovac to acquire knowledge, skills, processes, and equipment. For some projects, the originating company served as the tech transfer partner, providing essential information and inputs. For others, Biovac engaged third-party experts like Merck KGaA to facilitate process improvements and identify bottlenecks, ensuring smoother technology adoption and supporting Biovac as it developed proprietary processes and products.

Figure 2: Biovac's Reverse-Integration Strategy

Horizon 1 2003–2008	Horizon 2 2008–2013	Horizon 3 2013–
Import, package, label, and distribute	Fill, formulate, and manufacture	Innovate new processes and products
• Develop relationships up the value chain. • Develop distribution networks. • Package and label products. • Warehouse, transport and distribute products. • Develop cold chain capabilities.	• Introduce new equipment and facility. • Fill vials, ampoules or syringes, finish products and produce drugs. • Expand production expertise for active and inactive drug ingredients (i.e., antigens and excipients). • Expand logistics expertise.	• Introduce new R&D labs. • Expand bulk production capabilities. • Complete pre-clinical / clinical trials. • Invest in new technology platforms.
Across value chain • Attract partners to transfer technology. • Attract retain talent with advanced degrees. • Use good manufacturing practices. • Leverage technology transfers at every stage. • Train, reskill, and upskill employees. • Meet all quality and regulatory standards. • Meet all health policy and industry objectives. • Deliver positive value-for-money.		

Source: Biovac, "Setting Up Vaccines Human Capital Capacity in South Africa," Presentation, Biovac Institute and Litha Biotech, 30 Nov. 2011, https://www.who.int/phi/Session3B_Retention_local_workforce_Makhoana.pdf.

Horizon 1: Vaccine Supply

As part of its PPP, Biovac's initial focus (Horizon 1) was supplying South Africa's Expanded Program on Immunization (EPI) with imported vaccines for diphtheria, tetanus, pertussis (DTP), measles, inactivated polio (IPV), oral polio (OPV), bacillus Calmette–Guerin (BCG), and hepatitis B virus (HBsAg). This required building expertise in procurement, supplier and distribution network management, quality control, and cold chain capabilities—essential for future partnerships. Biovac assumed the risk of procuring, storing, and distributing these vaccines for the EPI. Initial expectations of Biovac's first chief executive officer, Selwyn Kahanovitz, to produce a generic tetanus toxoids vaccine within 18 months proved overly optimistic, requiring more financial and human resources than anticipated.

From its inception, Biovac actively sought partnerships. It signed MoUs for manufacturing with the South African AIDS Vaccine Initiative and the Italian National Institute of Health for their respective HIV vaccine candidates. In 2005, it received funding from the Dutch government to study bird flu vaccine manufacturing feasibility, and in 2006, it mobilized to supply Namibia with polio vaccines during an outbreak.

In 2007, Biovac invested ZAR 54 million to upgrade its facilities for a technology transfer from its Cuban partner, Heber. Following staff training in Cuba, Biovac's initial attempt at formulating Heber's hepatitis B vaccine faced challenges due to inexperience. Consequently, Biovac prioritized developing its vaccine packaging and labeling capabilities. In September 2010, African participants at the International Vaccine Technology Workshop (Inida) launched the African Vaccine Manufacturing Initiative (AVMI) to advocate for sustainable vaccine manufacturing in Africa. AVMI aimed to coordinate advocacy, celebrate partnerships, promote capacity building, and attract investment in the African biopharmaceutical sector.

Biovac's Chief Science and Innovation Officer, Patrick Tippoo, a founding member and executive director of AVMI, recognized the need for demand certainty, procurement support for new producers, and IP sharing on commercial terms. Mr. Tippoo was instrumental in AVMI's formation, with Biovac hosting the secretariat. Biovac was also a member of the WHO-initiated Developing Countries Vaccine Manufacturers Network (DCVMN), a platform for sharing manufacturing expertise. As DCVMN vice president (2019–2022), Mr. Tippoo influenced COVID-19 vaccine manufacturing expansion policies through tireless advocacy.

Another key figure in revolutionizing the biopharmaceutical industry in Africa through his work at Biovac is Dr. Morena Makhoana, Biovac's CEO, known for his focus on collaboration and trust-building to achieve mutually beneficial agreements. He has led Biovac's plant and operational transformation by aligning infrastructure upgrades with technology transfer deals. Together, Dr. Makhoana, Mr. Tippoo, and their colleagues have shaped the discourse on local vaccine manufacturing, emphasizing achievable goals while managing investment expectations by acknowledging the statistical realities of venture success and failure, both in Africa and globally.

Horizon 2: Tech Transfer and Vaccine Manufacturing

In 2004, Biovac's initial R&D aimed to produce a local pentavalent vaccine (DTP–HepB–Hib), intending to develop its own import-difficult Hib antigen while importing others, including whole-cell pertussis, for formulation and finishing. This project built Biovac's end-to-end conjugate vaccine competency, including bacterial fermentation, antigen purification, and conjugation, alongside investment in BSL-3 facilities and quality assessment methods.

However, a 2009 South African policy shift to acellular pertussis (aP) rendered Biovac's whole-cell pertussis-based pentavalent unsellable to the EPI and unsuitable for local pediatric trials, leading to the project's termination. Biovac then strategically pivoted to partnering for mid-term commercial viability while refining its R&D strategy.

Leveraging its pentavalent development knowledge, Biovac licensed its Hib technology package to two international manufacturers, one successfully commercializing a whole-cell pertussis-based pentavalent and the other an acellular version. Biovac also applied its Hib expertise to develop other conjugate vaccines, like a pneumococcal vaccine with PATH and Sinopharm's Chengdu Institute. Beyond technology transfer, Biovac provided training in recombinant vaccine technology through HIV/AIDS and TB vaccine partnerships. Finally, in 2017, Biovac initiated a proof-of-concept for a novel group B streptococcus (GBS) conjugate vaccine with funding from the Gates Foundation and expertise from PATH and Merck, demonstrating its capability to develop a product from inception to market. Although the pentavalent vaccine wasn't completed, it yielded crucial scientific knowledge for Biovac's subsequent successes.

Contracting and expanding

In early 2010, Biovac set an ambitious goal to increase its annual capacity sevenfold within three years, aiming for 35 million doses by 2013, with 70 per cent for South Africa. Facing limited local venture capital and biotech infrastructure, Biovac strategically partnered with multinational corporations for technology transfers of leading vaccines to accelerate capacity building for manufacturing and the development of novel products.

Contracts with Sanofi Pasteur, Pfizer's Wyeth, and others helped Biovac secure ZAR 130 million from South Africa's Industrial Development Corporation (IDC) for plant expansion, intended to enhance pandemic response capabilities, including against swine flu (H1N1). In 2011, a proposal for a medical technology park adjacent to Biovac's offices in Pinelands was approved with an initial investment of ZAR 110 million, envisioning a local biotechnology ecosystem.

In mid-2012, Sanofi agreed to transfer technology for its Hexaxim six-in-one vaccine (DTaP–hepB–IPV–Hib) to Biovac for local manufacturing. This multi-year process involved training, process simulations, testing, and regulatory approvals. Biovac modernized its plant to produce four million Hexaxim doses annually, with potential for expansion in the Southern Africa Development Community region.

These efforts culminated in a second multi-year technology transfer agreement worth \$20 million with Pfizer in November 2015 for the pediatric Prevenar-13 conjugate vaccine, which constituted a significant portion of the national vaccine budget. This partnership further established Biovac's reliability, introducing advanced equipment and consumables. By the end of 2019, Biovac was producing Sanofi's Hexaxim with a four-million-dose target and projected three million doses of Pfizer's Prevenar-13 in the first half of 2021. Pfizer's first deal in the region, it facilitated the implementation of Pfizer's latest formulation system at Biovac, enhancing staff expertise.

Demonstrating higher-value capabilities

Researchers at the Hague and the Vrije University in the Netherlands highlighted fill-and-finish capacity as a key bottleneck in scaling COVID-19 vaccine manufacturing. In July 2021, Pfizer and BioNTech signed a letter of intent with Biovac to manufacture their BNT162b2 COVID-19 vaccine for distribution within the African Union. This deal acknowledged Biovac's quality, compliance, technical and project management skills, capacity, trained workforce, positive relationships, and agility.

Building on Biovac's Prevenar-13 work, Pfizer pledged ZAR 255 million (\$14.7 million) in March 2022 to enhance Biovac's pandemic readiness, including ultra-cold storage. The technology transfer involved on-site development and equipment installation, integrating Biovac into Pfizer's global manufacturing network. Sourcing drug substances from Europe, Biovac formulated and released its first mRNA vaccine batch within a year, targeting 100 million annual doses for the African Union by 2023.

By March 2023, Biovac and Pfizer unveiled their "Freezer Farm" in Cape Town, with Pfizer's total investment in Biovac's infrastructure, training, and skills development reaching ZAR 855 million across two projects. Biovac's collaborations with Sanofi and Pfizer provided a model for its own product manufacturing. Simultaneously, Biovac announced a ZAR 2.3 billion (\$150 million) collaboration with nine development partners to expand its manufacturing plant for increased vaccine output.²

Horizon 3: Innovation and Biomanufacturing Leadership

Despite some NGO criticism focusing on "only" fill-and-finish work, this is a common starting point for successful biopharmaceutical manufacturers, with strong capacity building requiring years of partnerships and technology transfer learning. Biovac's stepwise approach to skill acquisition, relationship building, and target achievement has strengthened its reputation and technical foundations. Biovac is engaged in mRNA COVID-19 vaccine fill-and-finish with Pfizer, achieving its first demonstration batch and regulatory approval for production. Biovac has carefully managed the IP and know-how exchange in this and a complementary mRNA technology partnership.

In June 2021, a WHO-backed consortium of seven organizations formed a technology transfer "hub" in South Africa to develop an mRNA vaccine candidate and provide multilateral technology transfer (data, research, know-how, IP access, training) to its "spokes" seeking to enhance vaccine manufacturing and reduce import reliance. Spokes receive comprehensive resources to implement and validate their manufacturing processes.

Merck collaborated with Afrigen, the hub host, on process development. Biovac is tasked with the critical task of upscaling the hub-received technology, including in-house testing, CPP development, process industrialization and optimization, and ultimately transferring this industrialized process, with Afrigen, to the designated spokes. Merck emphasized its ability to provide seamless service for efficient and rapid robust process development. In March 2022, PAHO conducted its first training at Afrigen for scientists from mRNA hub spokes in Argentina and Brazil, covering the entire manufacturing process to facilitate future process optimization and technology transfer.

By April 2023, Afrigen had established an mRNA COVID-19 vaccine manufacturing process and began GMP-standard scaling for clinical trials, supported by Merck KGaA. Afrigen also organized training for

² Development partners were the African Development Bank, British International Investment, European Investment Bank, European Union Delegation to South Africa, Proparco, German Investment and Development Society, Industrial Development Corporation of South Africa, International Finance Corporation and the International Development Finance Corporation.

hub spokes, including Biovac, for future technology transfer. Spokes poised to benefit from Biovac's mRNA hub contributions included entities in Egypt, Brazil, Nigeria, Senegal, Tunisia, Bangladesh, Indonesia, India, Pakistan, Serbia, Argentina, Ukraine, and Vietnam.

Figure 3: Participants in the mRNA Vaccine Technology Transfer Hub

Organization	Mandate within the Hub
World Health Organization	Coordinates resources, monitors implementation
Afrigen Biologics and Vaccines (Avacare Health and IDC)	Establishes mRNA vaccine production process, produces materials for phase 1 clinical trials, and transfers laboratory scale technology to Biovac
South African Medical Research Council	Conducts and delivers research, supports clinical development
Biologicals and Vaccines (Biovac) Institute of South Africa	Receives technology from Afrigen, manufactures vaccine, and transfers industrial scale production back to Afrigen for distribution to the spokes
African Union	Coordinates resources
Africa Centres for Disease Control and Prevention	Provides regional insight, oversight and expertise
Medicines Patent Pool	Drafts agreements and monitors their implementation
Access to COVID-19 Tools Accelerator	Fast-tracks the development, production, and equitable access to COVID-19 tests, treatments, and vaccines
South African Government	Ensures government buy-in

Source: PAHO, "Latin American Manufacturers Complete First Training in mRNA Technology in Bid To Improve Regional Vaccine Production," News, Pan American Health Organization, 11 March 2023, <https://www.paho.org/en/news/24-3-2022-latin-american-manufacturers-complete-first-training-mrna-technology-bid-improve>.

Separately, in November 2022, Biovac partnered with the International Vaccine Institute (IVI) for a licensing and technology transfer agreement to produce an oral cholera vaccine (OCV), encompassing end-to-end production in Africa. This collaboration offers Biovac the opportunity to establish and scale OCV manufacturing in a GMP environment for clinical trials and global distribution. The Wellcome Trust and the Gates Foundation funded the initial phase of facility expansion across the biopharma value chain. This expanded facility will enable Biovac to demonstrate full-cycle vaccine manufacturing excellence. Biovac anticipates its first clinical trial batches in 2024 and regulatory approval in 2026.

While still supplying approximately 80 per cent of South Africa's routine childhood vaccines, Biovac anticipated a decrease due to import competition. In December 2023, the IFC loaned Biovac \$7 million for current vaccine production and agreed to support a new multi-vaccine plant, increasing capacity from 150 million to 560 million doses. Biovac's years of collaboration have enabled it to offer upstream and downstream processing, formulation, filling (licensed and owned), inspection/labeling/packaging (licensed), and quality control (licensed).

Figure 4: Technology Transfer Partners along Biovac's Value Chain

Stage 1	Stage 2	Stage 3	Stage 4	Stage 5
Discover and patent solutions (preclinical)	Manufacture substances	Formulate products	Fill and finish products	Package and label products
• Bill & Melinda Gates Foundation • PATH • Wellcome Trust • International Vaccine Institute • mRNA Hub Programme	• Biovac Hib antigen • Oral cholera vaccine	• Pfizer Prevenar-13.	• Sanofi hexavalent • Pfizer Prevenar-13 • Pfizer BioNTech COVID-19	• AJVaccines • Centro de Ingeniería Genética y Biotecnología (CIGB).
• Merck KGaA, Darmstadt, Germany				

Adapted from Biovac Institute and Wellcome Trust Emergency Response, "Manufacturers Overview: Biovac," Presentation, Global mRNA Hub, WHO, 20 April 2023, https://cdn.who.int/media/docs/default-source/immunization/mrna-ttp/april-2023/6_biovac.pdf.

To develop a world-class workforce, Biovac has cultivated strong relationships with local universities (CPUT, Stellenbosch, UCT, UWC), regularly hosting students and deploying interns. These universities have also assisted in product development. Biovac provides scholarships to disadvantaged biotech scholars and offers internship and mentorship programs. Its ongoing training program includes customized courses, train-the-trainer initiatives, site visits, training on technology transfers, and equipment supplier training. Biovac has also partnered with professional firms such as the African Management Services Company and the German Society for International Cooperation (GIZ) to recruit experienced talent.

Of Biovac's 350 employees, a significant majority are Black and over half are women, with a substantial portion holding degrees or diplomas. It has created 8,500 job opportunities. Biovac's female leaders received a commendation at the 2023 Standard Bank Top Women Awards, and Biovac achieved Level 1 B-BBEE status, highlighting its economic and employment significance in its community and its contribution to public health.

Enabling policy environment

The COVID-19 pandemic highlighted the role of industrial and other policies in the management of health crises, including subsidizing vaccine R&D and manufacturing, accelerating approvals, and creating purchasing mechanisms. Post-pandemic, governments are increasingly focused on policies supporting sustainable local vaccine production for improved healthcare and pandemic preparedness. They are applying lessons from the pandemic.

Policies must effect structural change

However, public policy can falter, as seen in South Africa, when short-term political goals outweigh long-term economic structural changes. Despite government bodies promoting biopharmaceuticals and helping Biovac attract partners like Sanofi and Pfizer, the Department of Health's 2023 decision to procure pediatric pneumococcal vaccines from Cipla over Biovac, citing ZAR 2.4 billion in savings, jeopardized jobs, goodwill, and investment, with Biovac disputing the claimed savings.

South African biomanufacturing experts have emphasized that vaccine production relies on economies of scale, which requires alignment between public health and economic imperatives, especially given the public sector's dominant demand. The government's short-term (two-year) tender cycle can hinder local manufacturers' ability to project revenue, allocate capital, and scale operations effectively, and contract losses can render such investments unproductive.

Policies must create stability in demand

Policymakers should balance short-term cost savings with long-term economic prosperity, ensuring procurement policies across departments send a unified message to investors. Longer-term procurement commitments and policies stimulating demand are crucial. While global vaccine purchasing mechanisms have increased global protection by procuring low-cost vaccines, they often disadvantage higher-cost local manufacturers in their own markets.

PHARMISA (the trade association Pharmaceuticals Made in South Africa) has advocated for policies that balance trading conditions, noting that local policies can favor importers subsidized by export destinations, making the South African pharma market vulnerable to import substitution. Policymakers must consider the impact of trade and education policies on local manufacturers' business cases and tech transfer potential.

Policies must ensure resilience

Mr. Tippoo of Biovac has proposed a "resilience premium" on vaccine purchases to fund African vaccine manufacturing infrastructure, enabling their integration into the global supply chain. Government policies significantly shape the vaccine sector, with newcomers facing shifting EPI guidelines, funding uncertainties, and evolving regulations that deter entrepreneurs and investors. Regulatory coordination, harmonization, and stabilization within and across borders are crucial for local manufacturers to access global markets.

An organization like the African Medicines Agency, tasked with harmonizing legislation and developing common standards, could complement regional and national regulatory bodies, potentially becoming a continent-wide hub for approving medicines and health technologies.

Ultimately, decision-makers in both the public and private sectors will need to consider how to maintain readily available manufacturing capacity, rather than seeking to rapidly increase it during crises. Policymakers must adopt a global perspective on health, expertise, and supply chains to effectively leverage resources during health emergencies, recognizing that surge capacity requires ongoing readiness with updated equipment, a skilled workforce, and compliant facilities.

"Vaccines and biological technology transfer are much more complex than standard pharmaceutical products, therefore, we at Biovac are pleased that we have been able to develop and demonstrate our capability in this industry." **Says CEO, Morena Makhoana.³**

Key takeaways

Big-picture strategy front and center. Biovac's leadership consistently prioritized its reverse-integration strategy, guiding project selection and sequencing to build staff capabilities. A baseline income from procurement, distribution, and fill-and-finish provided resilience against policy and market shifts while long-term R&D and manufacturing capacity were developed. Leaders maintained a clear long-term vision despite interim challenges.

Strong business case for every project. Biovac meticulously evaluated each project by considering local and export market size and demand, determining the manufacturing modality and molecule type, assessing necessary human resources and retention strategies, and articulating a compelling overarching goal with motivating milestones.

³ See <https://biovac.co.za/>

Partnerships to accelerate capacity building. Biovac leveraged its biological and scientific expertise to attract partners and investments, capitalizing on their extensive experience and knowledge. Partnerships and technology transfers significantly reduce uncertainties and trial-and-error, accelerating the development of biomanufacturing and R&D capabilities compared to organic growth.

Public-private support for workforce development. Biovac's leadership recognized the critical need for a qualified workforce and invested in its people. Attracting talent requires a shared public-private vision for the local biotech sector, with governments supporting long-term workforce development and retention plans, as exemplified by Vacsera's approach in Egypt.

Building trust as a priority. Trust in the global partner's expertise, the quality of transferred products and services, and mutual respect among team members were paramount. Biovac prioritized these elements, alongside talent and relationships, as essential for commercial success. Transparency, even during setbacks, was central to Biovac's brand, fostering growth.

Technology transfer on mutually agreed terms. Government, intergovernmental, and NGO policies should facilitate developing countries' transition from procurement to local production through mutually agreed technology transfers and the growth of local biologics manufacturers. This requires a predictable business environment with appropriate trade policies and IP protection frameworks. Collaborative models like hubs and voluntary transfers are more effective than coercive approaches.

Biovac's distinguishing characteristics as a tech transfer partner include: (1) proven collaborations with leading innovators and NGOs, (2) leadership in reshaping global perceptions of African-made biologics, (3) access to world-class talent at the forefront of innovation, and (4) a commitment to serving Africa with quality biologics consistently.

Figure 5: Vaccines Supplied by Biovac in 2023

Vaccine	Pathogen
Hepatitis B	Hepatitis B (Hep B) virus
Measles	Measles virus
Pneumococcal conjugate	Streptococcus pneumoniae bacterium
Bacillus Calmette–Guérin	Mycobacterium tuberculosis
Tetanus toxoid	Clostridium tetani bacterium
Hexavalent containing: • Diphtheria • Tetanus • Pertussis • Poliomyelitis • Hib • Hep B	• Corynebacterium diphtheriae • Clostridium tetani bacterium • Bordetella pertussis bacterium (whooping cough) • Polio virus • Haemophilus influenza b bacterium • Hepatitis B virus

Source: Biovac products, as of 10 February 2024, <https://www.biovac.co.za/products/>.

For the full research paper with references refer to the unabridged report [Spotlight on Biovac: Building Local Biomanufacturing Capacity in South Africa](#).