Landscape Assessment of the Biopharmaceutical Industry in South Africa

Final Report

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Acronyms

Abbreviation	Description
AI	Artificial Intelligence
AED	Antiepileptic Drug
AIDS	Acquired Immunodeficiency Syndrome
AEEI	African Equity Empowerment Investments
AMA	African Medicines Agency
API	Active Pharmaceutical Ingredients
B2B	Business to Business
BIOVAC	The South African Biologics and Vaccine Institute
BMP	Bone Morphogenetic Protein
BMZ	Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung (*German Federal Ministry for Economic Cooperation and Development)*
CAGR	Compound Annual Growth Rate
CAPEX	Capital Expenditure
CAR-T	Chimeric Antigen Receptor T
CBD	Cannabidiol
CDMO	Contract Development and Manufacturing Organisation
CEPI	Coalition for Epidemic Preparedness Innovations
CEO	Chief Executive Officer
CERI	Centre for Epidemic Response and Innovation
cGMP	current Good Manufacturing Practice
CGT	Cell and Gene Therapies
CHO	Chinese Hamster Ovary
CMC	Chemistry, Manufacturing, and Controls
CMO	Contract Manufacturing Organisations
CSIR	The Council for Scientific and Industrial Research
CSSFF	Chan Soon-Shiong Family Foundation
DCV	Dendritic Cell Vaccines
DNA	Deoxyribonucleic Acid
DoH	Department of Health
DS	Drug Substance
DSTI	Department of Science Technology and Innovation
DTIC	Department of Trade, Industry and Competition
EMA	European Medicines Agency
EPO	Erythropoietin
EU	European Union
FDA	Food and Drug Administration
GCMS	Gas Chromatography-Mass Spectrometry
GAP	Gauteng Accelerator Programme
GAVI	Global Alliance for Vaccines and Immunization
GBS	Group B Streptococcus
GCP	Good Clinical Practice
GDED	Gauteng Department of Economic Development
GDP	Gross Domestic Product

Abbreviation	Description
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit
GCSF	Granulocyte Colony-Stimulating Factor
GMO	Genetically Modified Organism
HIV	Human Immunodeficiency Virus
i3	Investing in Innovation Africa
ICGB	International Centre for Genetic Engineering and Biotechnology
IDC	Industrial Development Corporation
IgG	Immunoglobulin G
IND	Investigational New Drug
IRB	World Trade Organisation
IP	Intellectual Property
iPSC	induced Pluripotent Stem Cell
kDa	Kilodalton
KOL	Key Opinion Leader
LCMS	Liquid Chromatography-Mass Spectrometry
LifeSADX	LifeAssay Diagnostics
LNP	Lipid Nanoparticle
mAb	Monoclonal Antibody
MCEP	Manufacturing Competitiveness Enhancement Programme
ML3	Maturity Level 3
MPP	Medicines Patent Pool
MRL	Market Readiness Level
mRNA	messenger Ribonucleic Acid
MSC	Mesenchymal Stem Cell
NBI	National Bioproducts Institute
NCA	Non-compartmental analysis
NGO	Non-Governmental Organisation
NGS	Next-Generation Sequencing
NHI	National Health Insurance
NHGRI	National Human Genome Research Institute
NHLS	National Health Laboratory Service
OBM	Osteogenic Biomaterials
OBIC	One Bio Innovation Centre
OEM	Original Equipment Manufacturer
OTC	Over-the-counter
PESTLE	Political, Economic, Social, Technological, Legal, and Environmental
PCR	Polymerase Chain Reaction
PPP	Public-Private Partnerships
POC	Proof-of-Concept
PRL	Production Readiness Level
R&D	Research and Development
rHuEPO	recombinant Human Erythropoietin
rHu-GCSF	recombinant Human Granulocyte Colony-Stimulating Factor
RSA/SA	South Africa
SAMRC	South African Medical Research Council
SAPC	South African Pharmacy Council
SEZ	Special Economic Zones

Abbreviation	Description
SME	Small and Medium Enterprise
SAVP	South African Vaccine Producers
SAVAX	Vaccines for Africa: Roll-out and Production in South Africa
SAHPRA	South African Health Products Regulatory Authority
SPII	The Support Programme for Industrial Innovation
SPP	Strategic Partnership Programme
SUN	Stellenbosch University
SWOT	Strengths, Weaknesses, Opportunities and Threats
TB	Tuberculosis
TGF-beta	Transforming Growth Factor beta
THC	Tetrahydrocannabinol
THRIP	Technology and Human Resources for Industry Programme
TIA	Technology Innovation Agency
TIGR	The Institute for Genomic Research

Abbreviation	Description
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TT	Technology Transfer
TRL	Technology Readiness Level
TTO	Technology Transfer Office
UCT	University of Cape Town
UK	United Kingdom
UNICEF	United Nations Children's Fund
UP	University of Pretoria
USA	United States of America
UTF	University Technology Fund
USD	United States Dollar
WHO	World Health Organisation
WTO	World Trade Organisation
ZAR	South African Rand
ZaZiBoNa	Zambia, Zimbabwe, Botswana, & Namibia, the original four countries that initiated the collaborative medicines registration initiative.

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Executive Summary

South Africa's biopharmaceutical industry holds significant promise, but remains underdeveloped, fragmented, and lacking the scale and integration seen in more mature global markets. This report, commissioned by GIZ and prepared by RebelGroup Advisory Southern Africa, assesses the current status of the local biopharmaceutical landscape and presents practical interventions to unlock its potential. The focus is on identifying promising companies for technical support, strengthening enabling systems, and aligning policy with industrial and health goals.

The study was conducted in four phases: (1) defining the research scope and methodology, (2) conducting a comprehensive mapping of the local biopharmaceutical sector, (3) assessing policy and institutional frameworks, and (4) synthesising findings through a validation workshop. The research involved stakeholder interviews, site visits, surveys, and comparative analysis using frameworks such as PESTLE, Porter's Five Forces, SWOT, and the Technological Innovation Systems (TIS) model. These theoretical frameworks provide a general understanding of the sector and facilitate planning interviews, as well as the positioning of data from interviews and site visits.

South Africa's biopharma market, valued at USD 1.1 billion in 2022, is projected to more than double by 2028. [1,2] Growth is driven by rising demand for vaccines, biosimilars, monoclonal antibodies, and recombinant proteins. However, local production remains limited to a few key players, most notably BIOVAC, Afrigen, NBI, and Aspen Pharmacare. While these companies have capacity in vaccine fill-finish and plasma-derived products, full-spectrum biologics and biosimilar manufacturing capabilities are still in early stages. The sector also lacks sufficient GMP-compliant infrastructure, coordinated strategy, and trained workforce.

The vaccine segment dominates the current market, spurred by COVID-19 and renewed interest in pandemic preparedness. South Africa's role as the WHO mRNA hub signals potential for regional leadership, but domestic manufacturing capacity still falls short of demand. Similarly, the biosimilar market is growing rapidly, yet most products are imported, with few local firms able to meet international production and regulatory standards. The report, through case studies like NBI, highlights the critical role biosimilars could play in reducing costs and improving access, particularly for oncology and autoimmune diseases, if appropriate regulatory, manufacturing, and financial support structures are developed.

Policy and regulatory fragmentation across departments (health, science, industry) impedes coherent sector development. Although instruments like the Research Tax incentive, Innovation Agency grants, and procurement frameworks exist, they are often difficult to access and poorly aligned with the needs of biopharmaceutical firms. SAHPRA has improved its processes but remains under-resourced and lacks sufficient in-house expertise for biologics and biosimilars. National strategies, such as the Bioeconomy Strategy, have not been fully operationalised for this sector.

The international case studies (Belgium, Singapore, South Korea, India, Cuba, and Brazil) illustrate how strategic alignment, infrastructure investment, and public-private coordination can catalyse growth. South Africa's TIS assessment, conducted as part of this study, identifies gaps in entrepreneurial activity, translational research, GMP infrastructure, skilled personnel, and market-shaping mechanisms, including pooled procurement and risk-sharing. Without targeted reforms, the country risks missing the current window of opportunity to become a regional hub for biopharmaceuticals.

1 https://www.biospace.com/as-its-domestic-market-grows-south-africa-moves-toward-greater-local-biopharmaceutical-production

2 https://www.arizton.com/market-reports/south-africa-biopharmaceuticals-market

To address the identified limitations and deficiencies, the report recommends interventions at three levels:

System-level recommendations include the development of a national biopharma strategy, improved public procurement alignment, streamlined R&D incentives, and regulatory capacity strengthening (particularly SAHPRA's biologicals unit). Establishing regional procurement platforms, improving intellectual property frameworks, and securing South Africa's role in the African Medicines Agency are also critical.

Sector-level interventions focus on investing in translational and GMP-ready infrastructure, enhancing technology transfer mechanisms, bridging skills gaps (particularly in bioprocessing and GMP), and developing innovation clusters. These efforts require stronger coordination among the Department of Science, Technology, and Innovation, the Department of Trade, Industry, and Competition, and the Department of Health.

Firm-level interventions propose expanding access to innovation finance (especially for clinical trials and market entry), incentivising private investment in Good Manufacturing Practice (GMP) manufacturing, and supporting export readiness through technical assistance and regulatory alignment. The report stresses the need for tailored blended finance mechanisms and strategic co-investment in late-stage product development.

A pipeline maturity assessment and prioritisation matrix were used to identify companies most ready for support. Firms such as NBI, FluoroBiotech, Afrigen, BIOVAC, and Immobazyme were found to have both high viability and strategic relevance. These firms are positioned to deliver near-term impact if provided with appropriate technical assistance, financing, and infrastructure support from GIZ and relevant donor organisations.

In summary, South Africa's biopharmaceutical sector is at a pivotal moment. While global interest and public health imperatives create momentum, the country must act decisively to close policy, capacity, and financing gaps. With coordinated action across government, industry, and development partners, the country can build a more resilient, competitive, and inclusive biopharma sector that contributes to both national health security and regional supply chains.

1. Introduction and Purpose

1.1 Background

The project "Vaccines for Africa: Roll out and Production in South Africa" (SAVax) is part of South Africa's strategic objective to enhance the local production of vaccines, medicines, and health technologies. Co-financed by the German Federal Ministry for Economic Cooperation and Development (BMZ) and the European Union (EU), SAVax aims to strengthen local manufacturing capacity in the biopharmaceutical industry and improve access to essential health products. The initiative aligns with the goals of key South African government partners, including the Department of Science, Technology and Innovation (DSTI), the Department of Health (DoH), and the South African Health Products Regulatory Authority (SAHPRA), to create a sustainable and competitive biopharmaceutical sector.

This landscape assessment focuses on supporting selected South African biopharmaceutical companies with "ready-for-market" products, providing targeted technical assistance to improve their manufacturing capacity, and enhancing market access at national, regional, and continental levels. These companies face challenges such as market intelligence gaps, demand forecasting difficulties, high production costs, and technological transfer obstacles, which impede their ability to meet growing health needs. Addressing these challenges requires long-term strategies, including off-take agreements, purchase guarantees, and investment in technology and skills development.

The project conducted a landscape assessment of South Africa's biopharmaceutical industry, covering the pharmaceutical, biotechnological, and biomanufacturing sectors. This assessment identified companies that need support, thereby enabling them to overcome barriers and capitalise on market opportunities. By addressing supply and demand challenges, the project aims to ensure that health products are available and affordable across African markets.

1.2 Scope of the Study

The study was structured into four phases to address the project's objectives:

i. ***Phase 1: Inception and Research Methodology***
   Drawing directly from the Terms of Reference (ToR), this phase focused on refining the scope, research questions, and methodology. The process involved conducting a comprehensive desk review, identifying key stakeholders, and developing a detailed work plan. This ensured that the foundation is set for a targeted and methodical assessment of the biopharmaceutical landscape.

ii. ***Phase 2: Data Collection and Industry Mapping***
   In this phase, a comprehensive assessment of South Africa's biopharmaceutical industry was conducted. This included detailed industry mapping, profiling key players, and sector analysis using PESTLE, SWOT, and Porter's Five Forces frameworks. As stipulated in the ToR, the deliverables were designed to provide insights into companies' operational capacity and needs.

iii. ***Phase 3: Policy Framework Assessment***
   This phase assessed South Africa's policy, regulatory, and infrastructural environment in accordance with the Terms of Reference (ToR) requirements. The assessment identified actionable recommendations to strengthen the enabling environment for biopharmaceutical development and ensure alignment with the nation's strategic goals.

iv. ***Phase 4: Final Reporting and Validation Workshop***
   This final phase consolidates findings into a comprehensive report, incorporating stakeholder feedback. A validation workshop will be held to ensure alignment with the Terms of Reference

(ToR) objectives, facilitate engagement with key partners, and promote actionable outcomes for the sector's growth.

1.3 Output from the Study

This report summarises the work conducted during the landscape assessment of the biopharmaceutical industry in South Africa and will be presented to stakeholders at a validation workshop. Outputs from the study include:

i. A Sector Analysis was conducted. Using the Porter Five Forces model, we assessed the competitive forces, such as supplier and buyer power, rivalry, barriers to entry, and substitutes, to understand the market's dynamics. We also assessed national comparative advantage using Porter's Diamond model, which considers a country's factor endowments. We also conducted a SWOT Analysis to identify the strengths, weaknesses, opportunities, and threats facing companies within the sector, focusing on both internal capabilities and external challenges (See Strategic Analysis in **ANNEXURE 1**).

ii. The report also summarises data collected through surveys, interviews, and secondary sources to profile private-sector entities operating within the biopharmaceutical industry and identify additional companies operating in this or related sectors (See Stakeholder Identification in **ANNEXURE 1**).

iii. We also comprehensively assessed South Africa's policy framework related to the biopharmaceutical sector, including pharmaceutical, biotechnological, and biomanufacturing industries. This desktop analysis covered national policies, incentives, regulatory frameworks, infrastructure, and procurement systems. The aim was to identify the strengths and gaps within the current policy landscape to inform growth strategies and enhance the competitiveness of the biopharmaceutical sector. We validated the findings through interviews with policymakers, industry experts, and regulatory authorities to ensure that the analysis is well-grounded in current realities and strategic for the future (See Policy Framework in **ANNEXURE 2**).

iv. We also conducted an industry mapping exercise. We mapped stakeholders based on geographic location, sector focus, and role within the value chain. We also developed selection criteria to identify and prioritise companies with high potential for further engagement. Criteria included company maturity, market readiness, public health impact, regulatory compliance, and the ability to scale production. We prioritised companies from this exercise for further engagement. Through follow-up discussions and site visits, we conducted a capacity assessment of the selected companies across key dimensions, including manufacturing capacity, technology transfer, quality assurance, intellectual property management, and workforce skills. Through interviews and selected site visits, we evaluated each company's ability to scale production and address market opportunities. (See Industry Mapping in **ANNEXURE 3**).

v. We then conducted a needs assessment and identified the specific technical, operational, and strategic needs of the prioritised companies. We focused on scaling production, improving access to national and regional markets, and reducing reliance on imported health products. See Needs Assessment in **ANNEXURE 3**.

vi. Finally, this report summarises all findings from this study and critically analyses the data, prioritising companies in need of further technical assistance.

2. The South African Biopharmaceutical Landscape

2.1 Biopharmaceuticals Definition

Biopharmaceuticals are medicinal products derived from biological sources, such as living cells, bacteria, or genetically engineered organisms, rather than chemically synthesised compounds. They encompass a diverse range of therapeutic agents, including monoclonal antibodies, recombinant proteins, vaccines, and gene or cell therapies, which are designed to treat diseases such as cancer, autoimmune disorders, and genetic conditions. Unlike traditional small-molecule drugs, biopharmaceuticals are often larger and more complex molecules that require advanced biotechnological production methods, including recombinant DNA technology and cell culture systems. Their development and manufacture are subject to strict regulatory oversight to ensure safety, efficacy, and consistency.

2.2 Industry Intersections

The biopharmaceutical industry intersects with the pharmaceutical and medical device industries to drive innovation in the healthcare sector. While biopharmaceutical companies develop complex biologics, pharmaceutical companies collaborate in drug formulation, distribution, and regulatory compliance. The medical device industry integrates biopharmaceutical advancements through drug delivery systems (e.g., insulin pumps, biosensors, and implantable drug-eluting devices) and antibody-based technologies, such as diagnostic test kits, biosensors, and targeted drug delivery systems. These industries also share research in personalised medicine, diagnostics, and combination therapies, fostering advancements that improve patient outcomes.

Biomanufacturing is the backbone of the biopharmaceutical industry, enabling the large-scale production of biologics like monoclonal antibodies, vaccines, and cell therapies. It intersects with the pharmaceutical industry by supplying biologic-based drugs that require specialised production processes, such as cell culture and fermentation. Biomanufacturing supports innovations like antibody-coated implants, biosensors, and combination drug-device products in the medical device industry. This ecosystem relies on advanced bioprocessing technologies, strict quality control, and regulatory compliance to ensure safe, effective, and scalable production of cutting-edge medical treatments.

2.3 Biopharmaceuticals Market

The South African biopharmaceutical market is categorised into product segments, including vaccines, monoclonal antibodies, recombinant proteins and hormones, biosimilars, tissue, cell, and gene therapies. Some encouraging developments in local biopharmaceutical production in South Africa highlight a growing commitment to establishing a strong and self-reliant biopharmaceutical industry. With substantial government backing, advancements in research, collaborative partnerships, and a focus on meeting healthcare needs, the country is well-positioned to make significant progress in the biopharmaceutical sector. By promoting local production, South Africa's biopharmaceutical market can enhance access to essential medicines, spur healthcare innovation, and contribute to economic growth, ultimately benefiting the healthcare sector and the overall well-being of its population.

The biopharmaceuticals market in South Africa is projected to grow from USD 1.10 billion in 2022 to USD 2.21 billion by 2028, with a compound annual growth rate (CAGR) of 12.30% during the forecast period[3,4] The South African biopharmaceuticals market has grown substantially in recent years. This progress is driven by the country's focus on advancing healthcare infrastructure, research, and

3 https://www.biospace.com/as-its-domestic-market-grows-south-africa-moves-toward-greater-local-biopharmaceutical-production

4 https://www.arizton.com/market-reports/south-africa-biopharmaceuticals-market

development, as well as supportive regulatory policies, which have facilitated the broader availability and adoption of biologics within the healthcare system.

Biopharmaceuticals, also known as biologics, represent cutting-edge medical treatments derived from living organisms or their components. These innovative therapies have revolutionised healthcare by offering targeted and personalised treatments for chronic and complex diseases. As a result, the biopharmaceuticals market in South Africa is gaining prominence and becoming a critical element in modern healthcare, aimed at addressing unmet medical needs and improving patient outcomes.

With the region facing a growing burden of chronic and infectious diseases, as well as an ageing population, the biopharmaceuticals market in South Africa presents new opportunities for more effective treatments, improved disease management, and enhanced quality of life. Understanding the role of biologics in the country's healthcare system is crucial for policymakers, healthcare professionals, and patients as they continue to seek innovative approaches to achieve better health outcomes and patient care.

The industry is characterised by intense competition among multinational biopharmaceutical companies striving to capture a share of this market. Key players operating in South Africa include AbbVie, F. Hoffmann-La Roche, GSK, Johnson & Johnson, Merck & Co., Novartis, Novo Nordisk, Pfizer, and Sanofi.[5]

South Africa is demonstrating promising signs of local biopharmaceutical production, reflecting a growing interest in developing a robust and self-sufficient pharmaceutical industry. Additionally, the country has established an mRNA vaccine technology transfer hub to produce mRNA vaccines for African nations, supported by the World Health Organisation and other global health entities.[6]

2.3.1 Vaccines

In the overall biopharmaceuticals market, the vaccines segment holds the largest share. Vaccines play a crucial role in public health by preventing and controlling infectious diseases that pose a significant threat to communities globally. In South Africa, vaccines are a cornerstone of the biopharmaceutical market, providing vital protection against infectious diseases and supporting the country's efforts to enhance healthcare outcomes. Government initiatives, alongside partnerships with international organisations, have been pivotal in advancing vaccine development and distribution throughout the country. Immunisation programs led by the South African government, the World Health Organisation (WHO), and other global health entities focus on various age groups and high-risk populations to strengthen disease prevention efforts.

Africa produces less than 1% of its yearly vaccine needs, rendering the continent vulnerable. This was evident during the COVID-19 pandemic when governments faced challenges in procuring essential vaccines to save lives. The pandemic underscored the need for the continent to boost investments in vaccine development and manufacturing capabilities to achieve the ambitious goal of producing 60% of the vaccines consumed in Africa. Enhancing local vaccine manufacturing capacity bolsters national health security and decreases reliance on foreign suppliers for timely access to essential vaccines, emphasising the crucial role of companies like BIOVAC.

Public health needs primarily motivate Africa's ambition to manufacture vaccines. While vaccine manufacturers share this motivation, they must also consider economic factors to establish successful businesses.

5 https://www.researchandmarkets.com/reports/5860487/south-africa-biopharmaceuticals-market

6 https://www.biospace.com/as-its-domestic-market-grows-south-africa-moves-toward-greater-local-biopharmaceutical-production

In South Africa, the vaccine market is expected to experience substantial revenue growth, with projections indicating that it will reach USD 171.60 million in 2024. This growth is expected to continue at a steady annual rate of 5.71% from 2024 to 2028, resulting in a market volume of USD 214.30m by the end of the forecast period. South Africa is experiencing a growing demand for vaccines as the government focuses on improving public health.[7] However, most of this will come from importation due to a lack of manufacturing capacity in South Africa and the region.

2.3.2 Biosimilars

Biosimilars, another subsection of the biopharmaceutical market, hold the potential to transform healthcare in South Africa by improving access, reducing costs, and enhancing health outcomes nationwide. Biosimilars are biologic medicines that are highly similar to an existing FDA- or EMA-approved reference biopharmaceutical or biologic product. While they are not exact copies (due to the complexity of biological drugs derived from living organisms), biosimilars have no clinically meaningful differences in safety, purity, or efficacy compared to their reference products. Biologics, including biosimilars, are used to treat various diseases, such as cancer, autoimmune disorders (like rheumatoid arthritis), and chronic conditions like diabetes.

Many innovative biologics are expensive, limiting access for patients in low- and middle-income countries, such as South Africa. Biosimilars are more affordable alternatives, making life-saving treatments accessible to a larger population. Introducing biosimilars reduces healthcare costs by increasing market competition and driving down prices for biologics. This is critical in South Africa, where healthcare budgets are often constrained.

South Africa faces a high prevalence of diseases that require biological therapies, such as cancer and autoimmune disorders. Biosimilars provide an effective way to meet the growing demand for these treatments. The biosimilar market creates opportunities for local manufacturing, fostering economic growth and reducing dependency on imported medicines.

The global biosimilar market has been experiencing significant growth and is projected to continue expanding in the years to come. According to Grand View Research, the market was valued at approximately USD 21.8 billion in 2022 and is expected to reach USD 76.20 billion by 2030, exhibiting a compound annual growth rate (CAGR) of 15.9% during the forecast period. Similarly, Fortune Business Insights projects the market to grow from USD 23.96 billion in 2023 to USD 73.03 billion by 2030, with a compound annual growth rate (CAGR) of 17.3%.[8]

In South Africa, the biosimilar market is also on an upward trajectory. Insights10 reports that the market was valued at approximately USD 189 million in 2022 and is projected to reach USD 982.2 million by 2030, representing a compound annual growth rate (CAGR) of 22.88% during the forecast period. This growth is driven by factors such as the increasing prevalence of chronic diseases, the need for cost-effective therapeutic options, and supportive regulatory frameworks.[9]

Expanding the biosimilar market in South Africa is expected to enhance access to affordable biologic therapies, thereby improving healthcare outcomes and contributing to the sustainability of the healthcare system.

Leveraging the biosimilar market in South Africa to enhance access to affordable biologic therapies is a long-term goal. However, optimising existing capacity and regulatory frameworks can make some

7 https://www.statista.com/outlook/hmo/pharmaceuticals/vaccines/south-africa

8 https://www.fortunebusinessinsights.com/biosimilars-market-108928

9 https://www.insights10.com/report/south-africa-biosimilars-market-analysis/

progress in the mid-term. A holistic approach encompassing regulatory reforms, investment in manufacturing infrastructure, market incentives, and the adoption of technology will be essential.

South Africa has some biologics manufacturing infrastructure, but it primarily focuses on vaccine production and limited-scale biopharmaceutical manufacturing. Some facilities, such as BIOVAC (for vaccines), Aspen Pharmacare (for sterile injectables and limited biologics), and NBI (blood plasma products), could be repurposed or expanded to accommodate biosimilar production. However, to become a significant player in biosimilars, South Africa must invest in new biomanufacturing capabilities, including upstream and downstream processing, cell line development, and analytical characterisation. This could involve public-private partnerships to establish large-scale current Good Manufacturing Practice (cGMP) facilities and technology transfer agreements with global biosimilar manufacturers, thereby accelerating the development of local expertise. Collaboration with universities and research institutions to develop bioprocessing talent will also be essential.

Government policies, such as tax incentives, procurement preferences for locally produced biosimilars, and price regulations, can encourage the production of biosimilars. The National Health Insurance (NHI) initiative could be a significant driver of biosimilar uptake, with bulk purchasing agreements enhancing cost-effectiveness. However, healthcare professionals often resist the adoption of biosimilars due to concerns about their efficacy and safety. Targeted education and incentive programs are essential for increasing the confidence of both physicians and patients.

South Africa could position itself as a regional hub for biosimilar production by offering investment incentives, regulatory clarity, and partnerships with global biotech companies. Developing a skilled workforce in bioprocessing, quality control, and bioanalytics is critical. Industry-academia partnerships and specialised training programs should be expanded. Beyond local supply, South Africa can export biosimilars to African markets, where there is high demand but limited access to biologics.

2.4 Biopharmaceutical Industry Value Chain

At a high level, the biopharmaceutical industry value chain encompasses six key stages involved in biopharmaceutical product discovery, development, manufacturing, and distribution. It is essential to evaluate companies within the industry to determine their position in the value chain. These are summarised below and graphically illustrated in **Figure 1** below.

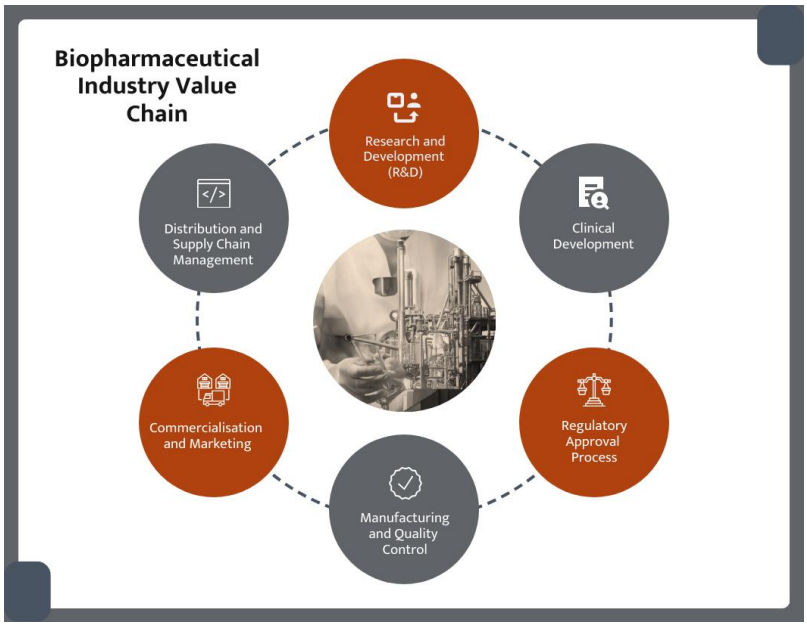

Figure 1: High-Level Biopharmaceutical Industry Value Chain

The biopharmaceutical value chain is a complex, multi-phase process integrating upstream suppliers, innovation, regulatory oversight, manufacturing, diagnostics, and end-user delivery. It begins with raw material and technology providers supplying cell lines, reagents, bioreactors, and other inputs essential for drug development. A more detailed view of the biopharmaceutical value chain is graphically depicted in

Figure 2**.**

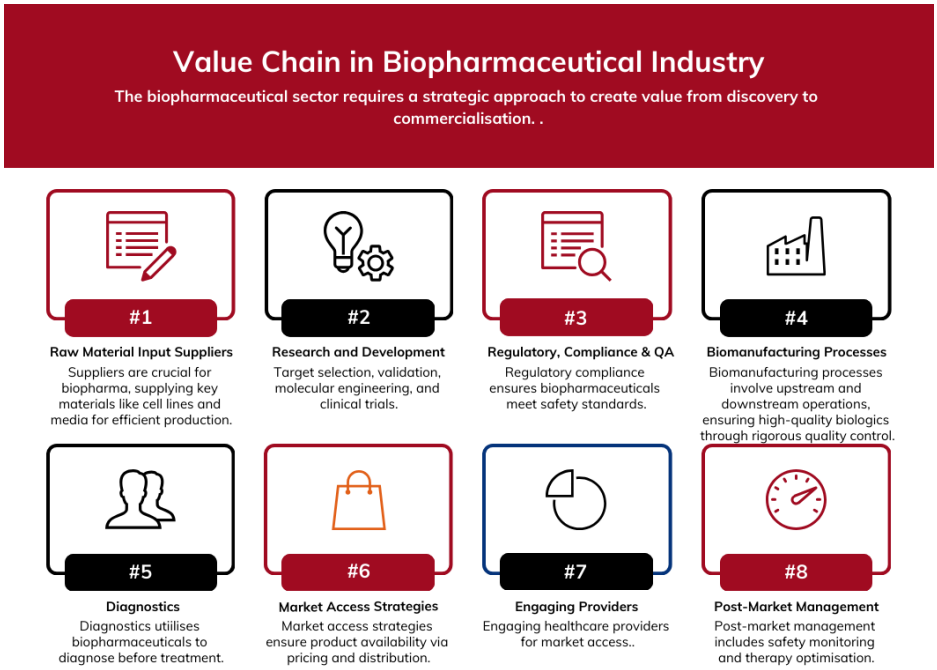

Figure 2: Expanded Biopharmaceutical Industry Value Chain

3. Strategic Analysis

3.1 PESTLE Analysis

A PESTLE analysis was conducted to assess external factors affecting the sustainability of South Africa's biopharmaceutical industry.

Political: Government initiatives, such as the Bio-economy Strategy and Pharmaceutical Master Plan, support the sector; however, policy fragmentation and shifting procurement rules create uncertainty. While SAHPRA has achieved WHO Maturity Level 3, local firms still face delays in product approvals. Regulatory reliance mechanisms and regional harmonisation efforts are positive but need further strengthening.

Economic: Access to funding remains limited, particularly for early-stage and scale-up activities. Local capital is scarce, and international donors play a significant role. Currency volatility and reliance on imported inputs affect cost competitiveness. Existing initiatives are helpful but insufficient to close the financing gap.

Social: The country has a strong base of scientific talent, though emigration and low diversity remain challenges. Public awareness of biopharma products is uneven, with issues such as vaccine hesitancy affecting uptake.

Technological: Progress has been made in mRNA and recombinant platforms, but gaps remain in monoclonal antibodies, cell and gene therapies, and analytical services. A shortage of cGMP-compliant facilities and limited bioprocessing capacity slow development. Technology transfer efforts require better coordination, particularly for small and medium-sized enterprises (SMEs).

Legal: The legal framework aligns with global standards, but regulatory delays and limited guidance on emerging technologies hinder progress. The TRIPS agreement governs intellectual property rules, although debates continue regarding the balance between access and innovation.

Environmental: Energy and water supply constraints pose risks to biomanufacturing. Load shedding and high resource demands pose a threat to compliance and operational stability. Some firms are adopting renewable and recycling solutions, but uptake is constrained by cost.

The detailed analysis is provided in **ANNEXURE 1,** and the graphic is presented in **Figure 3 below**.

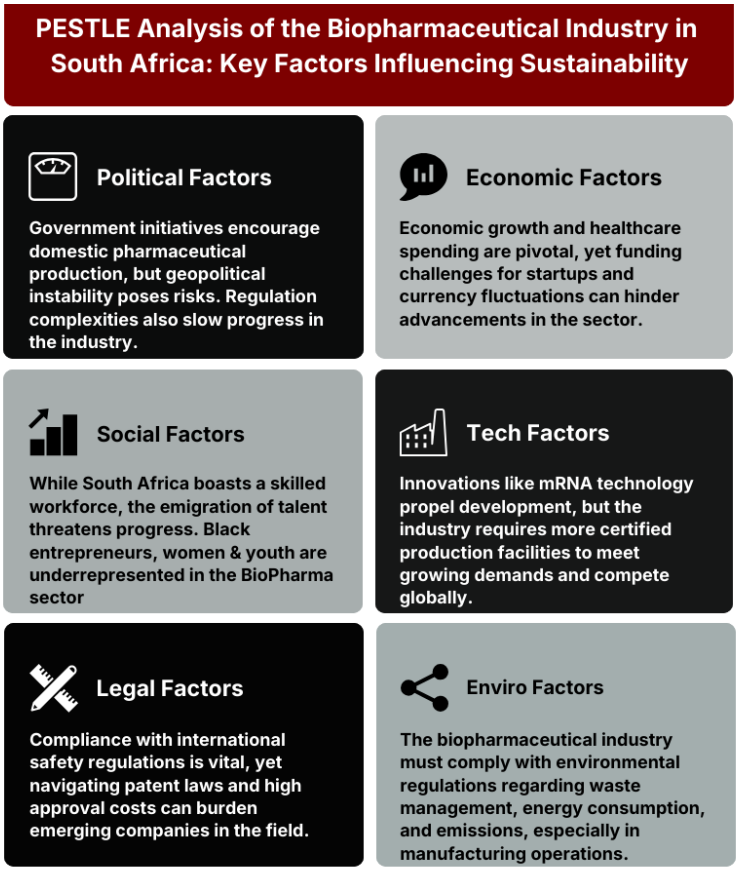

Figure 3: PESTLE Analysis of the SA Biopharmaceutical Landscape

3.2 Porter's Five Forces

Porter's Five Forces is a framework developed by Michael Porter to analyse the competitive structure of an industry. It helps assess the external pressures that influence profitability and long-term viability by examining five key forces shaping industry dynamics.

Threat of New Entrants: Barriers to entry are high due to the capital intensity of manufacturing, lengthy regulatory processes, and limited access to skilled personnel. However, government support and initiatives, such as the mRNA technology transfer program, have encouraged some new activity, especially in vaccines and biologics.

Bargaining Power of Suppliers: Suppliers of specialised inputs and equipment hold considerable power, as most materials are imported and subject to currency fluctuations. Local supply chains for critical inputs remain underdeveloped.

Bargaining Power of Buyers: The public sector is the dominant purchaser through centralised procurement, which puts downward pressure on prices. Private buyers are more fragmented but limited in size, reducing the overall bargaining power of firms.

Threat of Substitutes: For many products, particularly generics and biosimilars, substitution is possible. Imported products often present a cost-competitive alternative, particularly where local capacity is limited or pricing is not aligned.

Industry Rivalry: Competition is limited by the small number of local manufacturers. However, rivalry is increasing in segments such as vaccine fill-finish and contract development and manufacturing. Imported products dominate most therapeutic areas.

Companies operating in this environment must navigate these forces strategically to maintain and enhance their market positions. This analysis is provided in detail in **ANNEXURE 1**, and graphically summarised below in **Figure 4**:

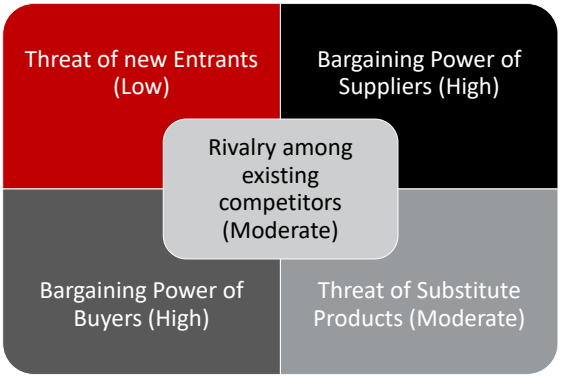

Figure 4: Porter's Five Forces Analysis of the SA Biopharmaceutical Industry

3.3 SWOT Analysis

The SWOT analysis summarises internal strengths and weaknesses, as well as external opportunities and threats affecting the biopharmaceutical sector in South Africa.

Strengths: South Africa boasts a robust scientific foundation, featuring established research institutions and highly skilled professionals. Local firms, such as Biovac, Afrigen, and Aspen, have experience in manufacturing and established partnerships with global companies. SAHPRA's recognition at WHO Maturity Level 3 enhances regulatory credibility.

Weaknesses: The sector faces limited local funding, long regulatory lead times, and insufficient manufacturing infrastructure, particularly for biologics. Fragmentation among public actors and gaps in support for early-stage companies hinder growth.

Opportunities: Global interest in regional manufacturing, especially for vaccines and biologics, creates prospects for investment and technology transfer. Initiatives like the WHO mRNA Hub and African Medicines Agency offer platforms to build capacity and access new markets.

Threats: Dependence on imported inputs, exposure to currency risks, and infrastructural constraints such as load shedding, which pose operational challenges. Policy uncertainty and competition from lower-cost imports continue to affect market stability and investor confidence.

This SWOT analysis reveals that while the South African biopharmaceutical industry is well-positioned, with strong research capabilities and growing local demand, addressing funding, talent retention, and regulatory challenges is crucial for capitalising on emerging opportunities and mitigating external threats.

More details on the SWOT analysis are provided in **ANNEXURE 1,** and a graphic summary is provided in **Figure 5** below.

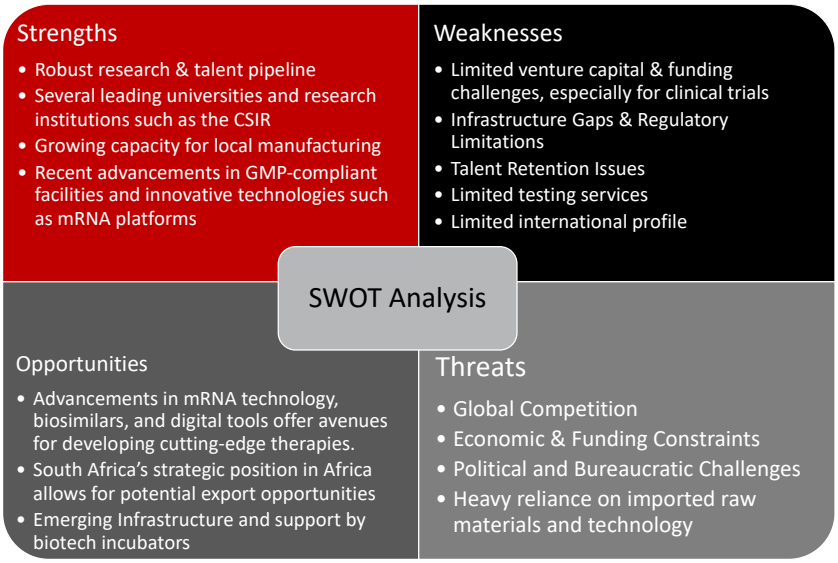

Figure 5: SWOT analysis of the South African Biopharmaceutical Industry

3.4 Porter's Diamond – National Comparative Advantage

Porter's Diamond is a framework developed by Michael Porter to examine how the conditions in a country influence the competitiveness of firms in a specific industry. It is named for the diamond-shaped diagram used to represent four interrelated factors: factor conditions, demand conditions, related and supporting industries, and firm strategy, structure, and rivalry. The model also takes into account the role of government and external events.

Factor Conditions: South Africa has a strong base of scientific and technical expertise, supported by leading universities and public research institutions. However, there are infrastructure gaps, particularly in biomanufacturing, and a shortage of specialised skills for biologics production.

Demand Conditions: Health needs are significant, with high demand for vaccines and essential medicines in the public sector. However, demand for advanced therapies remains limited, and cost containment in public procurement restricts the market for new entrants.

Related and Supporting Industries: Although there is some upstream research capacity, the local supply of biopharmaceutical inputs and manufacturing services is limited. This weakens the overall ecosystem and increases dependence on imported components and technologies.

Firm Strategy, Structure, and Rivalry: The number of local firms is small, but includes established players with global partnerships. Competitive pressure is moderate, though interest in biologics and vaccine manufacturing is increasing.

Government and Chance: Government policy recognises the sector's potential, and programmes such as the Pharmaceutical Master Plan aim to build local capacity. Events such as the COVID-19 pandemic have accelerated efforts to localise production and attract investment.

The detailed analysis is presented in **ANNEXURE 1** and graphically depicted below in **Figure 6.**

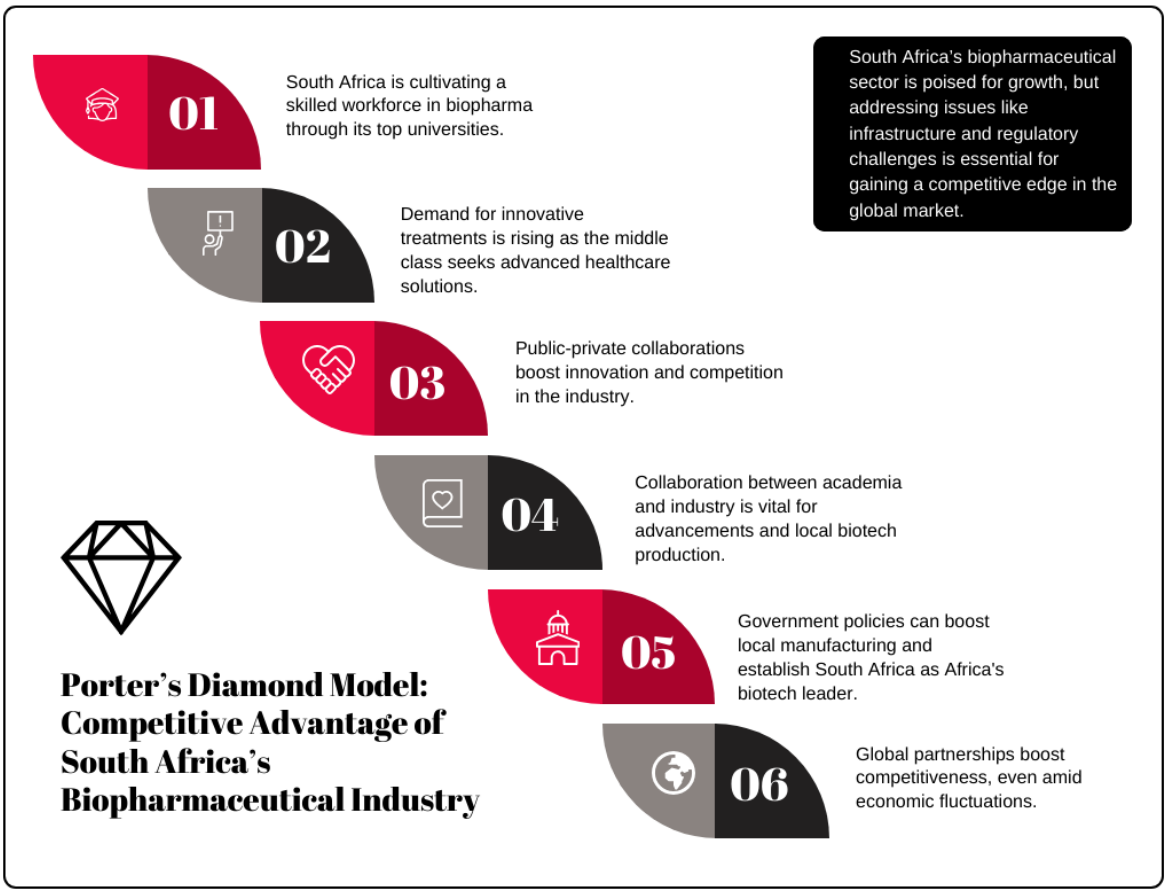

Figure 6: National Comparative Advantage – Porter's Diamond

4. POLICY FRAMEWORK ASSESSMENT

A detailed Policy Framework Assessment is provided in **ANNEXURE 2**

4.1 Role of Policy and Regulation in Shaping Competitiveness

The biopharmaceutical sector is highly regulated, capital-intensive, and dependent on scientific and technical expertise. Countries that have successfully developed biopharmaceutical capabilities, such as Singapore and South Korea, have typically done so through deliberate policy choices that are coordinated across science, industry, and health portfolios. Key enablers include:

- **Long-term strategic vision**, often articulated through national strategies or industrial roadmaps;
- **Regulatory agility**, including reliance frameworks, fast-track pathways, and early engagement with innovators[10];
- **Investment in enabling infrastructure**, such as GMP-compliant manufacturing zones, technology parks, and clinical trial platforms;
- **Support for translational research**, bridging the gap between academic science and commercial development;

[10] International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). (2023). Advancing regulatory reliance on a global scale. Retrieved from https://www.ifpma.org/insights/advancing-regulatory-reliance-on-a-global-scale/

- **Human capital development**, with specialised training in bioprocessing, regulatory affairs, and quality systems;
- **Market-shaping mechanisms**, such as public procurement, pricing frameworks, and international technology partnerships,[11].

This is graphically summarised in **Figure 7** below. These examples are explored in more detail in the case studies presented in **Section 4.6**.

Figure 7: Role of Policy and Regulation in Shaping Competitiveness

Significantly, international regulatory convergence, facilitated through platforms such as the International Council for Harmonisation (ICH) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S), has helped streamline compliance and facilitate the globalisation of production[12]. Participation in these frameworks enhances a country's credibility and reduces barriers to export, particularly in the case of vaccines and biosimilars[13].

In recent years, there has also been growing attention to regional diversification and health sovereignty, with global initiatives, including the WHO mRNA Technology Transfer Hub and the African Medicines Agency (AMA), seeking to expand local production and strengthen regulatory capacity in developing regions. For example, the WHO mRNA Technology Transfer Hub aims to enable low- and middle-income countries to produce their own mRNA vaccines, therapeutics, and diagnostics through training programs and technology sharing, thereby reducing reliance on external suppliers and fostering local innovation. Similarly, the African Medicines Agency (AMA) aims to harmonise medicine regulation across Africa, promote the quality of medical products, and combat substandard and

11 Mazzucato, M., & Li, H. L. (2021). A Market Shaping Approach for the Biopharmaceutical Industry: Governing Innovation Towards the Public Interest. Journal of Law, Medicine & Ethics, 49(2), 317–330. Retrieved from https://www.cambridge.org/core/journals/journal-of-law-medicine-and-ethics/article/market-shaping-approach-for-the-biopharmaceutical-industry-governing-innovation-towards-the-public-interest/AF2ED4004E59F92D4AD0A68CE5C50D78

12 International Council for Harmonisation (ICH). (2022). ICH Members and Observers. https://www.ich.org/page/members-observers

13 Pharmaceutical Inspection Co-operation Scheme (PIC/S). (2023). About PIC/S. https://picscheme.org/en/about

falsified medicines, thereby strengthening regulatory capacity, facilitating cross-border trade, and enhancing access to safe and effective treatments.

4.2 Key Challenges and Opportunities

Despite these building blocks, the sector faces several well-documented constraints:

- **Fragmented and uncoordinated policy support** across science, health, and industrial portfolios[14];
- **Limited GMP-compliant infrastructure** for upstream and downstream biologics production, outside of donor-supported platforms[15];
- **Capacity constraints within SAHPRA** are limiting the speed and scope of biologics registration and clinical trial approval.[16]
- **Weak industry–science linkages**, particularly in translational research and scale-up[17,18,19];
- **High production costs and a small domestic market** limit the commercial viability of large-scale local manufacturing without pooled demand[20].

Nonetheless, recent developments offer promising opportunities:

- The establishment of the **mRNA hub** and associated tech transfer efforts has positioned South Africa as a potential regional knowledge leader[21];
- Increased attention from the **African Union**, **African Medicines Agency (AMA)**, and initiatives such as the **Partnership for African Vaccine Manufacturing (PAVM)** has created momentum for regional collaboration[22];
- Government interest in local production for **health security and economic development** has revived policy attention on the sector[23].

This is graphically illustrated below in **Figure 8**.

14 U.S. Department of Commerce. (2024). South Africa - Healthcare: Medical Devices and Pharmaceuticals. Retrieved from https://www.trade.gov/country-commercial-guides/south-africa-healthcare-medical-devices-and-pharmaceuticals

15 Makenga, G., et al. (2025). Building vaccine and biotherapeutics manufacturing capacity in Africa: a practical approach. Journal of Pharmaceutical Policy and Practice, 18(1), 13. Retrieved from https://link.springer.com/article/10.1007/s44337-025-00313-w

16 RebelGroup Industry Interviews, GIZ Biopharmaceutical Landscape, 2025

17 Weiner, B. J., et al. (2012). Translational research in South Africa: evaluating implementation and scale-up of a health systems intervention. Implementation Science, 7, 110. Retrieved from https://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-7-110

18 Olatunji et al. (2023). "Enhancing clinical and translational research in Africa: a comprehensive exploration of challenges and opportunities for advancement." Journal of Clinical and Translational Research, 9(5): 357–368

19 Singh et al. (2025). "Building vaccine and biotherapeutics manufacturing capacity in Africa: translating university discoveries into commercial-scale production." Global Health Innovation, 12(1).

20 Nattrass, N., & Seekings, J. (2021). Global value chains, import orientation, and the state: South Africa's pharmaceutical industry. Review of African Political Economy, 48(167), 1-18. Retrieved from https://www.tandfonline.com/doi/full/10.1080/03056244.2020.1865902

21 The mRNA vaccine technology transfer hub. Retrieved from https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub

22 Africa Centres for Disease Control and Prevention. (2021). African Union and Africa CDC launch Partnerships for African Vaccine Manufacturing (PAVM). Retrieved from https://africacdc.org/news-item/african-union-and-africa-cdc-launches-partnerships-for-african-vaccine-manufacturing-pavm-framework-to-achieve-it-and-signs-2-mous/

23 Department of Science and Innovation. (2023). Boosting local vaccine manufacturing capacity. Retrieved from https://www.dsti.gov.za/index.php/media-room/latest-news/4149-boosting-local-vaccine-manufacturing-capacity

Figure 8: Key Regulatory and Policy Challenges and Opportunities

4.3 Overview of Relevant National Strategies and Policies

Several national policies and strategies influence the development of the biopharmaceutical sector, although they have historically lacked integration (see **ANNEXURE 2** for details).

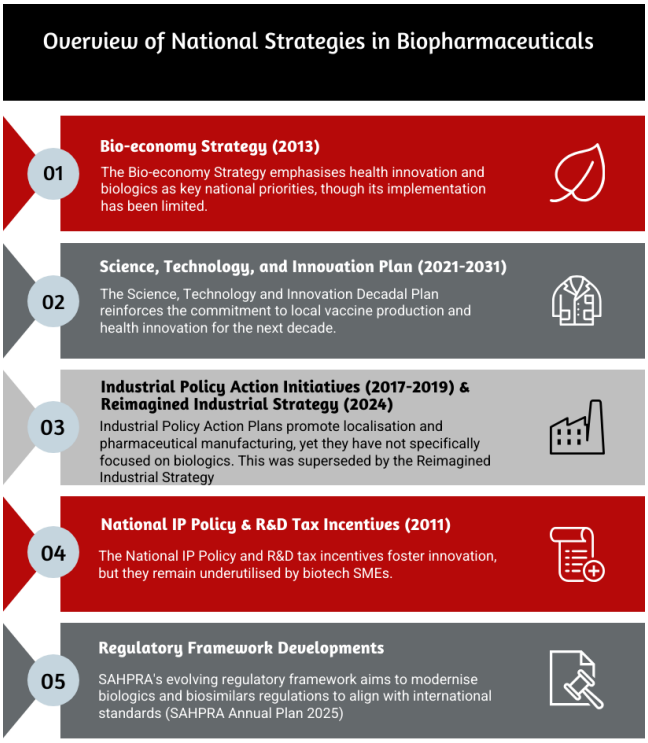

Figure 9: Relevant National Strategies and Policies

4.4 Public Instruments Relevant to Innovation and Technology Development

South Africa has a range of government instruments covering different stages of innovation, technology development, and commercialisation. While not dedicated to the biopharmaceutical sector, many of these instruments are potentially applicable to firms and initiatives in the field.

Figure 10 below illustrates these public support instruments across the innovation and commercialisation value chain. While these instruments are not sector-specific, they span various stages of activity, from basic research and technology development to market entry and business growth, and may be applicable to biopharmaceutical initiatives. The diagram maps each programme to its corresponding phase in the innovation lifecycle. It highlights the roles of different implementing agencies, including the Department of Science, Technology and Innovation (DSTI), the Industrial Development Corporation (IDC), the Technology Innovation Agency (TIA), and the Department of Trade, Industry and Competition (dtic).

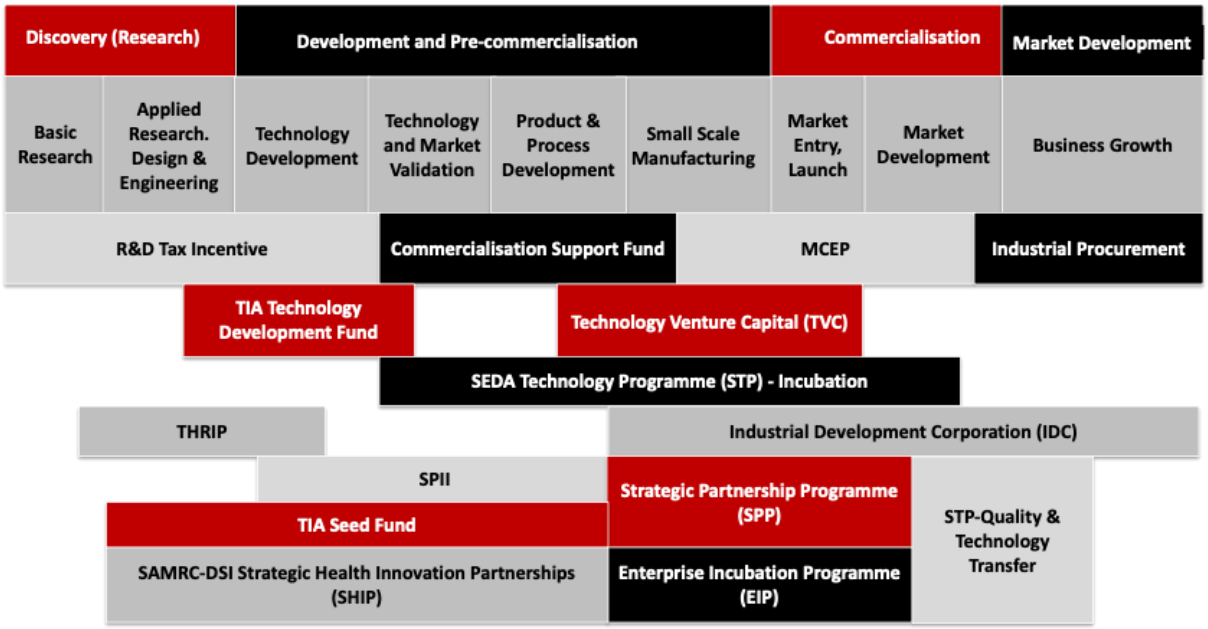

Figure 10: Mapping of Innovation and Technology Funding Instruments

4.5 Policy and Strategic Gaps

In addition to these funding instruments, South Africa supports its technology-based sectors through a range of complementary institutions, infrastructure initiatives, regulatory mechanisms, and export assistance programmes. These instruments span the entire value chain, from research to manufacturing and global market entry. These are detailed in **ANNEXURE 2** and summarised below in **Figure 11**.

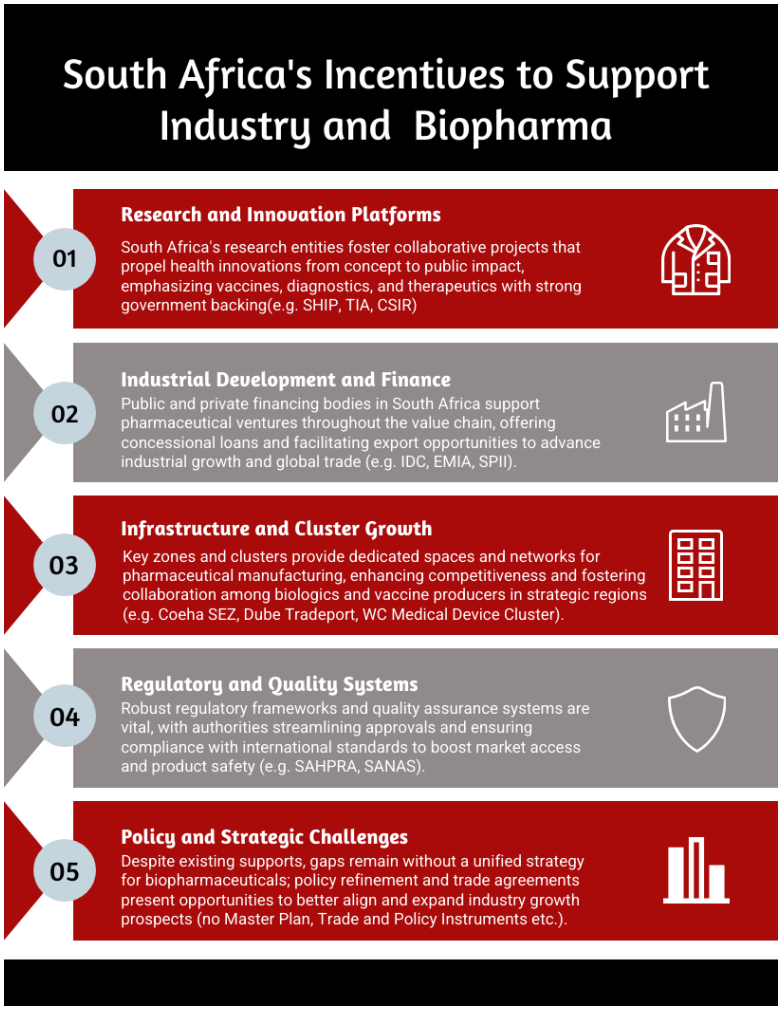

Figure 11: Relevant National Incentives to Support Industry

South Africa's biopharmaceutical sector is influenced not only by domestic policy but also by a growing array of continental and regional initiatives aimed at strengthening Africa's capacity for health products manufacturing. These frameworks offer potential alignment opportunities for national actors and shape the broader enabling environment for investment and collaboration. These are summarised below in **Figure 12** and also detailed in **ANNEXURE 2**.

Figure 12: Relevant Continental and Regional Initiatives

4.6 International Case Studies

Case studies were conducted in six countries: Belgium, South Korea, Singapore, Brazil, Cuba, and India. Each of these countries has successfully developed a competitive biopharmaceutical sector through a distinct combination of policy, regulatory, and institutional instruments. These countries also represent a mix of developing and developed countries, with various enabling factor conditions, demonstrating different approaches to developing a new industry. The case studies examine how countries at

different levels of development and with varying governance models have promoted innovation, manufacturing, and market access in biopharmaceuticals, particularly biologics, biosimilars, and advanced therapies. This is detailed in **ANNEXURE 2.**

This comparative framing helps identify how countries balance public health goals with industrial competitiveness, and provides a reference for South Africa as it shapes its own biopharma development path. This is summarised below in **Figure 13**.

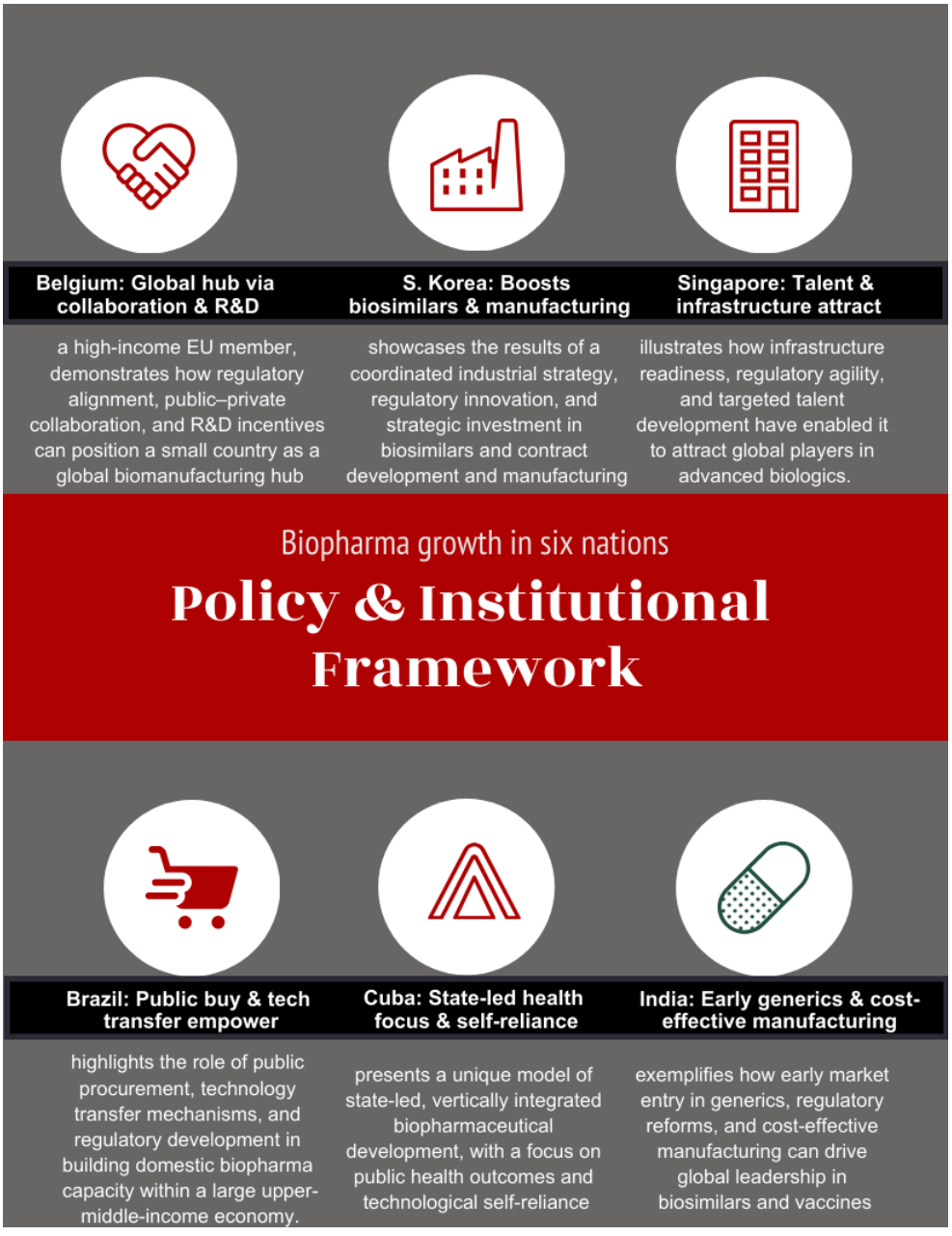

Figure 13: International Case Studies

4.7 Cross-Country Comparison Using the TIS Framework

The Technological Innovation Systems (TIS) framework provides a structured approach to analysing the factors that support or constrain the emergence of a new technology or industrial sector.[24] In this report, the TIS framework is employed to compare the support provided by Belgium, South Korea, Singapore, Brazil, Cuba, and India for the development of their biopharmaceutical sectors and to draw insights that may be relevant to South Africa.
The TIS framework identifies seven key functions required for innovation system performance:
F1 – Entrepreneurial Activity: Presence of new ventures, technology-based firms, and innovation projects.
F2 – Knowledge Development: Scientific research, R&D spending, and technological advancement.
F3 – Knowledge Diffusion: Collaborative networks, cluster organisations, and inter-institutional learning.
F4 – Guidance of the Search: Strategic vision, roadmaps, policy signals, and public priorities.
F5 – Market Formation: Demand creation through procurement, incentives, standards, or regulation.
F6 – Resource Mobilisation: Availability of financial, human, and infrastructural inputs.
F7 – Creation of Legitimacy: Regulatory credibility, political support, and societal trust.

The radar chart in **Figure 14** visualises the relative strengths of the seven countries across the TIS functions. The scores are based on our assessment in Error! Reference source not found., which is d erived from the detailed country case studies (See the following section for an assessment of South Africa using the TIS framework).

In interpreting the chart:

- A score of 4–5 indicates strong performance in that function.
- A score of 2–3 indicates moderate performance or areas where gaps remain.

24 Hekkert, M. P., Suurs, R. A., Negro, S. O., Kuhlmann, S. & Smits, R. E. 2007. Functions of innovation systems: A new approach for analysing technological change. Technological forecasting and social change, 74(4), pp 413-432.

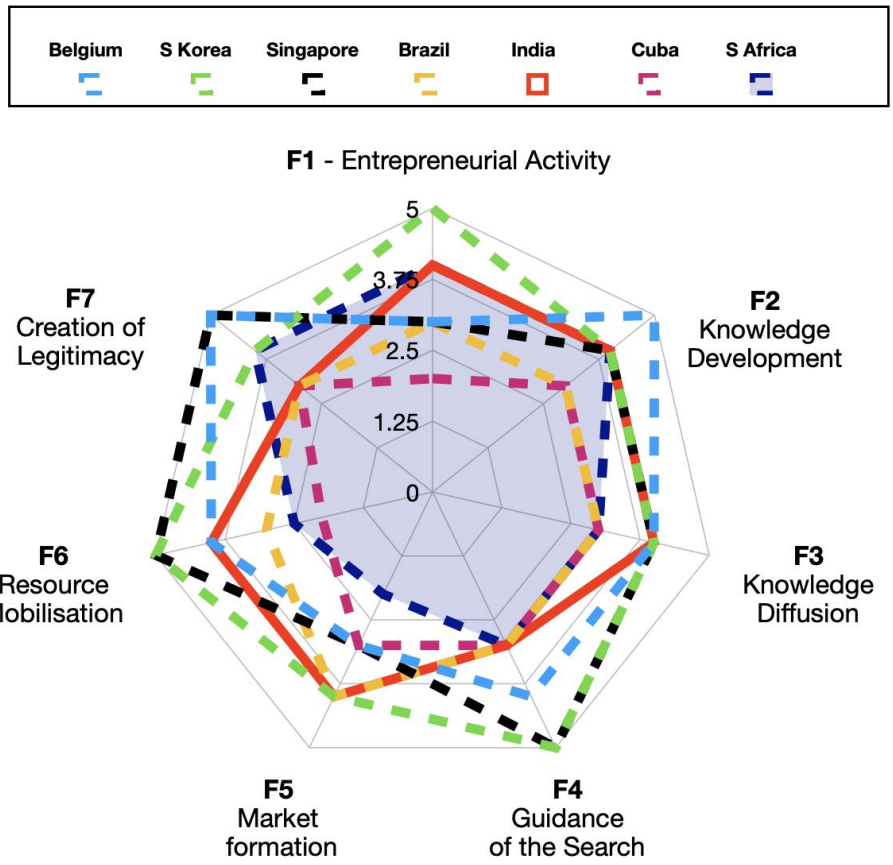

Figure 14: TIS comparison for International Case Studies vs SA

Table 1: TIS Scores for case study countries and South Africa

TIS FUNCTION	BEL-GIUM	SOUTH KOREA	SINGA-PORE	BRAZIL	INDIA	CUBA	SOUTH AFRICA
F1: Entrepreneurial Activity	3	5	3	3	4	2	3
F2: Knowledge Development	5	4	4	3	4	3	4
F3: Knowledge Diffusion	4	4	4	3	3	3	3
F4: Guidance of the Search	4	5	5	3	4	3	3
F5: Market Formation	3	4	3	4	4	3	2
F6: Resource Mobilisation	4	5	4	3	4	2	2,5
F7: Creation of Legitimacy	5	4	5	3	3	3	4

This analysis reinforces the observation that:

- **Belgium** scores strongly on **knowledge development (F2 = 5)**, **knowledge diffusion (F3 = 4)**, and **regulatory legitimacy (F7 = 5)**, supported by strong networks and embeddedness in the European regulatory ecosystem.
- **South Korea** demonstrates strong **entrepreneurial activity (F1 = 5)**, **guidance of the search (F4 = 5)**, and **resource mobilisation (F6 = 5)**, reflecting its focused industrial policy and public investment.
- **Singapore** shows high scores for **regulatory legitimacy (F7 = 5)**, **knowledge diffusion (F3 = 4)**, and **resource mobilisation (F6 = 4)**, in line with its strategy as a trusted hub for advanced manufacturing.
- **India** stands out for **entrepreneurial activity (F1 = 4)**, **market formation (F5 = 4)**, and **knowledge development (F2 = 4)**, reflecting its large domestic market and vibrant generics and biosimilars industry.
- **Brazil** shows strengths in **market formation (F5 = 4)** and **guidance of the search (F4 = 3)**, supported by recent industrial policies and growing investment in public R&D.
- **Cuba** presents a relatively balanced profile with moderate scores across functions (**mostly 2–3**), reflecting its centralised coordination, strong public research, and human capital investments.
- **South Africa** shows emerging strengths in **knowledge development (F2 = 4)** and **regulatory legitimacy (F7 = 4)**, with moderate performance in other functions and notable gaps in **resource mobilisation (F6 = 2.5)** and **market formation (F5 = 2)**.

The comparative analysis of TIS functions and country case studies provides the following insights.

These are drawn from the combined functional profiles and qualitative evidence in the case studies. Countries that perform well across multiple TIS functions generally demonstrate stronger sector outcomes and more resilient biopharma ecosystems:

- **High-performing countries invest in multiple TIS functions**, not just science or regulation. Belgium, South Korea and Singapore, for example, score strongly across F2 (knowledge development), F4 (guidance), F6 (resource mobilisation), and F7 (legitimacy).
- **A coherent strategic vision (F4)**, such as South Korea's K-Bio 2030 or Singapore's Biomedical Sciences Initiative, provides direction for stakeholders and justifies investment.
- **Countries that succeed create platforms for translation and commercialisation**, such as VIB (Belgium), A*STAR (Singapore), and KHIDI (South Korea), supporting F2 and F3 functions.
- **Engagement in international regulatory frameworks (F7)** (ICH, PIC/S, WHO recognition) enhances trust and enables exports, as seen in Belgium, Singapore, and increasingly India and Brazil.
- **Government plays a central role in de-risking early investment**, especially in GMP infrastructure (linked to F6), regulatory capacity (F7), and human capital (part of F6), as shown in Singapore and South Korea.
- **Public procurement systems can be leveraged to stimulate local production**, as demonstrated by Brazil's SUS and PDPs, and Cuba's state-led health sovereignty model, contributing to F5 (market formation) despite resource constraints.
- **State-led or mixed models** (e.g. Cuba, Brazil) demonstrate that biopharmaceutical development is possible even in constrained environments, provided there is policy coherence, long-term planning, and investment in local capabilities (spanning F2, F4, F5, F6)

This section applies the Technological Innovation Systems (TIS) framework to assess the strengths and weaknesses of South Africa's biopharmaceutical sector. Drawing on the functional framework introduced in Section 6, it identifies gaps across the innovation system. It considers how development cooperation actors, such as GIZ, can contribute to addressing these issues, as shown in **Table 2** below.

Table 2: TIS Analysis of the SA Biopharmaceutical Sector

TIS FUNCTION	ASSESSMENT IN SOUTH AFRICA
F1: Entrepreneurial Activity	The number of active biopharma SMEs is limited. Key initiatives (e.g. Afrigen, BIOVAC) are heavily donor-supported, and private venture creation is weak.
F2: Knowledge Development	Scientific research is strong in certain fields (e.g. immunology, molecular biology), but underfunded and poorly linked to commercialisation pathways.
F3: Knowledge Diffusion	Collaboration between academia, public research, and firms is ad hoc. Platforms like the mRNA Hub are emerging but not yet systemic.
F4: Guidance of the Search	Policy intent is present across DSTI, dtic, and NDoH, but fragmented. No unified biopharma strategy or coordinated roadmap exists.
F5: Market Formation	Procurement incentives are limited; high cost of local production and absence of pooled regional demand hinder scale.
F6: Resource Mobilisation	Human capital gaps (in specific areas such as bioprocessing, GMP, regulatory affairs) are severe. Infrastructure is improving but still thin outside donor-funded platforms.
F7: Creation of Legitimacy	SAHPRA is respected but resource-constrained. Public trust in local production is improving but needs further consolidation.

The TIS assessment reveals four main systemic issues:

1. **Fragmented Policy and Institutional Landscape**: Despite the presence of relevant strategies and actors, there is no overarching framework to align and coordinate efforts across government departments, funders, and industry.
2. **Limited Translational Capacity**: The "valley of death" between academic research and industrial production remains wide. Platforms for scale-up, clinical validation, and regulatory engagement are few and under-resourced.
3. **Constrained Regulatory Throughput**: SAHPRA is making progress on biologics and biosimilars; however, capacity constraints and complex legacy processes limit its responsiveness to innovation.
4. **Market and Investment Risk**: Without pooled demand, technology transfer incentives, or reliable procurement signals, private investment in biologics manufacturing remains commercially unviable for most firms.

These weaknesses reinforce each other; for example, the lack of scale leads to underinvestment, which in turn hinders the development of regulatory experience and trust-building. These are graphically illustrated below in **Figure 15**.

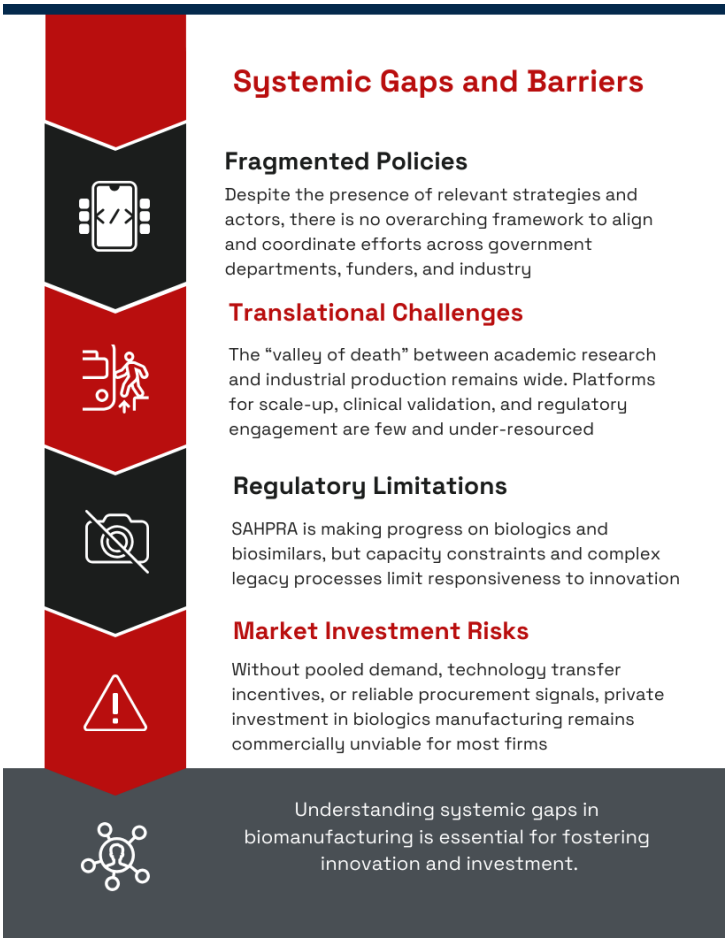

Figure 15: Systemic Gaps and Barriers

4.8 Policy Recommendations

Based on the above, the following policy recommendations are made, which align with the Technological Innovation Systems (TIS) framework. This section presents policy recommendations aligned with the Technological Innovation Systems (TIS) framework and structured across three levels: (1) System-level interventions to shape the national enabling environment; (2) Sector-level interventions to build shared capabilities and institutions; and (3) Firm-level interventions to catalyse investment and innovation. Each recommendation identifies the responsible actor(s) and next steps.

4.8.1 System-Level Support Interventions

These interventions aim to create an enabling policy, regulatory, and institutional environment that supports long-term sector development.

4.8.1.1 Establish a National Biopharma Strategy (F4)

A coherent national strategy is needed to align the fragmented policy landscape and ensure cross-departmental collaboration in biopharmaceutical development. This will strengthen coordination, build investor confidence, and enhance long-term planning.

The biopharmaceutical sector intersects multiple policy domains, as follows: science, technology and innovation (DSTI), industrial development and localisation (dtic), and health policy and regulation (Department of Health, SAHPRA). So, without a unified strategy, efforts risk duplication, misalignment, and missed opportunities for synergies. A unified approach will strengthen coordination, build investor

confidence, and enhance long-term planning. A useful precedent is the 2007 ARV Task Team, which showed how coordinated action across departments with a clear mandate can accelerate implementation and deliver measurable public health and industrial outcomes.

In the strategy, a phased approach could begin with a virtual coordination mechanism among key stakeholders, such as DSTI, dtic, DoH, SAHPRA, and leading research institutions, prior to committing to significant infrastructure investments like a physical biopark.

i. *Lead Actor(s):* Department of Science, Technology and Innovation (DSTI), in collaboration with the Presidency
ii. *Supporting Actors:* Department of Health, dtic, CSIR, SAMRC, SAHPRA and private sector stakeholders
iii. *Next Steps / Actions:* Convene an interdepartmental task team; develop a Green Paper on the biopharma strategy
iv. *Existing Instruments / Initiatives:* Bio-economy Strategy (2013); Science, Technology and Innovation Decadal Plan

4.8.1.2 Align Public Procurement and Industrial Development (F5)

With the Public Procurement Act (2023), South Africa can align health procurement with industrial policy goals. Strategic procurement instruments can be leveraged to support the local production of biologics and vaccines.

i. *Lead Actor(s):* National Treasury, dtic
ii. *Supporting Actors:* Department of Health, CSIR, GIZ
iii. *Next Steps / Actions:* Issue guidance note on strategic health procurement under the Public Procurement Act; identify candidate products for risk-sharing mechanisms
iv. *Existing Instruments / Initiatives:* Public Procurement Act (2023); existing Department of Health tenders

4.8.1.3 Improve IP Regime and R&D Incentives (F4, F6)

Simplified access to R&D tax incentives and a fit-for-purpose IP regime are critical to unlocking private investment in biologics and biosimilars. Improvements will help incentivise early-stage innovation and ensure protection of novel products.

i. *Lead Actor(s):* Department of Trade, Industry and Competition (dtic), Department of Health, CIPC
ii. *Supporting Actors:* South African Revenue Service (SARS), DSTI, National Treasury, Innovation Hub
iii. *Next Steps / Actions*: Review and revise biotech eligibility under R&D tax incentive; consult stakeholders on IP policy reform
iv. *Existing Instruments / Initiatives*: R&D Tax Incentive (Section 11D); National IP Policy Phase 1

4.8.1.4 Strengthen SAHPRA and Regulatory Partnerships (F7)

Reliable and efficient health product regulation is vital for public safety and health outcomes, and is also a key enabler of innovation and industrial development. SAHPRA has made significant progress in recent years, including digitalisation, international engagement, and improved performance on registration timelines. This recommendation supports the continuation and scaling of those efforts.

Government action—such as increased funding, formal ratification of the African Medicines Agency (AMA) treaty, and strengthened interdepartmental coordination—will enable SAHPRA to expand its capacity and deepen its international role.

SAHPRA is actively participating in regional and continental harmonisation platforms, including the African Regulatory Harmonisation (AMRH) initiative and WHO collaborative registration procedures. Strengthening SAHPRA and building international partnerships will accelerate access to markets and attract investors.

i. *Lead Actor(s):* South African Health Products Regulatory Authority (SAHPRA)
ii. *Supporting Actors:* Department of Health, DSTI, WHO, African Medicines Agency, GIZ
iii. *Next Steps / Actions:* Secure budget for digital systems upgrade and staff training; engage in formal ICH and AMA pathways
iv. *Existing Instruments / Initiatives:* WHO-listed authority roadmap; SAHPRA digitalisation strategy; African Medicines Regulatory Harmonisation (AMRH); existing GIZ technical support project

4.8.1.5 Support Regional Market Development and Procurement Collaboration (F5)

The African Continental Free Trade Area and platforms like RCCCN offer opportunities to aggregate demand and shape markets. South Africa can help anchor regional procurement models that benefit domestic producers.

To do this, legal and structural changes may be needed to enable mechanisms such as advance market commitments (AMCs) or regional volume guarantees.

The design of such instruments should align with emerging insights from the Genesis Analytics study on procurement reform and make strategic use of the Public Procurement Act (2023) to support localisation.

i. *Lead Actor(s):* Department of Health, AUDA-NEPAD
ii. *Supporting Actors:* Africa CDC, dtic, CSIR, GIZ, WHO
iii. *Next Steps / Actions:* Engage in Africa CDC RCCCN forums; draft concept for pooled procurement mechanism, support ratification of AMA treat; analyse legal feasibility of AMCs; support integration of industry development goals in procurement frameworks; coordinate with Genesis Analytics study team
iv. *Existing Instruments / Initiatives:* RCCCN platform (Africa CDC); AU Pharmaceutical Manufacturing Plan for Africa; Public Procurement Act (2023)

4.8.2 Sector-Level Support Interventions

These interventions aim to strengthen the institutions, infrastructure, and capabilities that support the sector as a whole.

4.8.2.1 Invest in Translational and GMP-Ready Infrastructure (F2, F6)

South Africa lacks sufficient (late-stage translational infrastructure and) pilot-scale GMP facilities to support commercialisation and regulatory approval. Where clinical trial materials or commercialisation-readiness is the goal, GMP compliance is necessary even at pilot scale. Investing in these capabilities will strengthen the commercialisation pathway, attract industry partners, and enable local firms to meet international quality standards.

Priority areas should be identified through the national biopharma strategy and linked to market opportunities and public health needs, for example, biosimilars for oncology or vaccines for regional use. Infrastructure investments should be closely tied to entrepreneurial activity and innovation financing mechanisms to ensure that facilities are demand-driven and fully utilised.

i. *Lead Actor(s):* Department of Science, Technology and Innovation (DSTI)
ii. *Supporting Actors:* CSIR, TIA, SAMRC, private developers
iii. *Next Steps / Actions:* Map current assets and gaps; design co-investment facility; identify use cases for pilot-scale production, identify priority product areas; align infrastructure support with national biopharma strategy and entrepreneurial pipeline
iv. *Existing Instruments / Initiatives:* SAMRC SHIP; CSIR BioManufacturing Unit, existing private sector facilities and expertise

4.8.2.2 Enhance Technology Transfer Access and Implementation (F3, F6)

Effective technology transfer (TT) remains a significant challenge, particularly for biopharma small and medium-sized enterprises (SMEs) with limited capacity to absorb and scale technologies. South Africa has TT platforms, such as ICGEB and TIA, but support is needed both to access these and to implement the transferred technologies, especially for smaller firms.

i. *Lead Actor(s):* DSTI, TIA
ii. *Supporting Actors:* ICGEB, CSIR, universities, incubators
iii. *Next Steps / Actions:* Evaluate TT performance (e.g., ICGEB experiences); Develop TT facilitation model with differentiated support for SMEs vs. larger firms; Co-finance technology absorption projects and follow-on development
iv. *Existing Instruments:* TIA TT funds, ICGEB projects, university incubators

4.8.2.3 Address Skills Gaps and Institutional Capabilities (F6)

Specialised skills in bioprocessing, GMP, and regulatory science are in short supply. Developing human capital is critical to building a resilient ecosystem and meeting domestic and export regulatory standards.

In particular, practical hands-on GMP experience is limited across academia and industry, and gaps exist in areas such as process validation, quality systems, and biomanufacturing operations.

To address this, South Africa should consider establishing a dedicated "School for GMP" as a national focal point for high-quality, practice-oriented training. This could be located within or closely linked to the RCCCN Workforce Development Hub hosted by CSIR.

Skills development should be aligned with the needs of the broader biopharma strategy and prioritised areas such as biosimilars, vaccines, and fill-finish operations.

i. *Lead Actor(s):* Department of Higher Education and Training (DHET), DSTI
ii. *Supporting Actors:* Universities, SAHPRA, Africa CDC, RCCCN, GIZ
iii. *Next Steps / Actions:* Expand postgraduate funding schemes; update curriculum; operationalise RCCCN training hub; establish feasibility study for a "School for GMP"; strengthen operationalisation of RCCCN training hub
iv. *Existing Instruments / Initiatives:* NRF scholarships; RCCCN Workforce Development Hub (CSIR-led), existing postgraduate programmes in pharmaceutical sciences and biotechnology

4.8.2.4 Establih Cluster Coordination and Innovation Platforms (F3)

South Africa's innovation system is fragmented. Dedicated cluster platforms can catalyse coordination, build supplier networks, and enable public-private partnerships.

i. *Lead Actor(s):* dtic, DSTI
ii. *Supporting Actors:* Innovation Hub, Bioentrepreneurs' associations, regional SEZs, GIZ
iii. *Next Steps / Actions:* Launch call for pilot cluster initiatives; identify host institutions for coordination platforms, provide technical assistance and peer support
iv. *Existing Instruments / Initiatives:* Innovation Support Programme; Bio-economy Strategy hubs

4.8.2.5 Strengthen Sector Data and Foresight Capabilities (F2, F4)

Strategic decision-making is hampered by limited sector intelligence. Developing foresight and data capabilities will enable better policy, investment planning, and response to technological change.

i. *Lead Actor(s):* DSTI, HSRC
ii. *Supporting Actors:* Department of Health, CSIR, TIA, GIZ
iii. *Next Steps / Actions:* Develop terms of reference for observatory; pilot foresight exercise with key sector stakeholders
iv. *Existing Instruments / Initiatives:* Foresight exercises under the Decadal Plan; CSIR analytics platforms

4.8.3 Firm-Level Support Interventions

These recommendations focus on unlocking firm-level investment and growth in biopharmaceuticals.

4.8.3.1 Expand Access to Innovation Finance (F1, F6)

Biopharma entrepreneurs face barriers in accessing appropriate finance across the innovation chain—from seed funding to costly clinical trials. Existing support schemes are fragmented and difficult to navigate, making it challenging for firms to identify the right instrument at the right stage. Improved transparency, better coordination, and the use of blended finance mechanisms will enable more firms to grow and bring products to market.

In addition to early-stage capital, biopharma firms often require significant funding for feasibility studies, regulatory market assessments, and technical trials. Public instruments must bridge these gaps while exploring innovative trial designs and cost-efficiency strategies.

Particular attention is needed to ensure sufficient funding for later-stage development, such as clinical trials for biosimilars, which often require large cohorts and the costly procurement of reference biologics.

Lessons from Brazil and other contexts show that innovation finance must be tailored to sector needs and actively shaped by public instruments. South Africa's landscape includes promising initiatives, such as the Stellenbosch Launch Lab, that could be unified or scaled to serve the specific needs of biopharma innovators.

i. *Lead Actor(s)*: DSTI, Department of Trade, Industry and Competition (dtic)
ii. *Supporting Actors:* IDC, TIA, NRF, SAMRC, private investors, GIZ
iii. *Next Steps / Actions*:
    - Map existing instruments across the innovation chain; improve visibility through a public guidance tool or portal; develop tailored blended finance instruments for clinical trials and scale-up; map and benchmark local incubator and innovation support programmes;

design tailored support instruments for biopharma ventures (including scale-up, GMP readiness, and regulatory navigation);
- Clarify roles of public funders (e.g., IDC, SAMRC, DSTI) for supporting technical trials and feasibility studies. Explore funding for adaptive trial designs or international partnerships to share costs and reduce duplication

iv. *Existing Instruments / Initiatives*: THRIP; TIA funding, IDC healthcare funding; Innovation Support Programme; SAMRC SHIP; Black Industrialists Scheme

4.8.3.2 Incentivise Private Investment in Biomanufacturing (F6)

Biomanufacturing is capital-intensive and high-risk. Fiscal incentives, concessional finance, and de-risking tools such as public guarantees or milestone-based grants can attract private investment in GMP-compliant production. Such mechanisms are required to close the viability gap, particularly for firms with limited access to global value chains.

i. *Lead Actor(s)*: dtic, National Treasury
ii. *Supporting Actors*: IDC, SARS, SAHPRA, industry associations
iii. *Next Steps / Actions*: Review effectiveness of current incentives; develop a strategic project pipeline; pilot tailored support packages for biomanufacturing
iv. *Existing Instruments / Initiatives*: MCEP; Section 12L Energy Efficiency Incentive; Strategic Integrated Projects framework

4.8.3.3 Support Export Readiness and Standards Compliance (F7)

Export competitiveness depends on quality assurance and international regulatory alignment. Many firms struggle to meet stringent standards for biologics and biosimilars. Technical assistance, targeted funding, and regulatory cooperation can help close this gap and build a pipeline of export-ready firms.

i. *Lead Actor(s)*: dtic, Department of Health
ii. *Supporting Actors*: SAHPRA, ECIC, GIZ, South African Bureau of Standards (SABS)
iii. *Next Steps / Actions*: Launch a support facility for export compliance and certification; link trade promotion tools with regulatory advisory services
iv. *Existing Instruments / Initiatives*: EMIA Scheme; SAHPRA reliance pathways; GIZ regulatory capacity-building support

The recommendations outlined above are intended to complement South Africa's existing efforts and enable GIZ to play a catalytic role in supporting system-wide reforms, strengthening sector-level capabilities, and enabling tangible firm-level outcomes. They respond to specific gaps identified in the national innovation system and draw on international experience with biopharmaceutical development.

OECD analysis highlights that effective industrial policy requires coordination across public and private actors, long-term investment in enabling systems, and strategic support for innovation. In the context of biopharmaceuticals, this includes regulatory capacity, translational infrastructure, human capital, and access to finance.

South Africa already possesses a number of relevant institutions and instruments. The focus now should be on improving coordination, strengthening implementation, and ensuring these resources are applied in a more targeted and strategic manner to advance health outcomes, local innovation, and regional value creation.

4.8.4 Sector Profile: Capabilities, Companies, and Institutions

South Africa has a long history of vaccine development and biologics manufacturing, but today's biopharmaceutical sector remains small and fragmented. Despite the presence of leading research institutions and some industrial capacity, the country has struggled to establish a competitive and integrated biopharmaceutical value chain. Recent initiatives, including renewed political interest, donor-funded technology transfer, and regional health security commitments, offer a new window of opportunity to strengthen the sector.

South Africa's current biopharmaceutical capabilities are concentrated in a small number of firms and public-private platforms. Key industrial actors include:

- **BIOVAC**: Biovac was initially established in 2003 as a Public Private Partnership (PPP). Biovac now exists as a joint venture between its government shareholders-the Department of Science and Innovation and the Technology Innovation Agency and its private partner. BIOVAC is responsible for vaccine formulation, fill-finish, and distribution for South Africa's Expanded Programme on Immunisation. BIOVAC is expanding into full manufacturing and mRNA capability through the WHO's technology transfer programme[25].
- **Afrigen Biologics**: A Cape Town-based company hosting the WHO mRNA technology hub, focusing on technology transfer, formulation, and process development for mRNA vaccines[26].
- **Aspen Pharmacare**: South Africa's largest pharmaceutical manufacturer, involved in fill-finish operations for COVID-19 vaccines, and with potential to expand into biologics if market conditions improve[27].
- **National Bioproducts Institute (NBI):** NBI is strategically positioned to expand into biosimilars production, leveraging its existing cGMP-compliant infrastructure and expertise in plasma-derived therapies[28].
- **Start-up companies:** A small number of firms are engaged in monoclonal antibody or biosimilar development, although activity remains limited and fragmented[29].

In addition to industry actors, several public institutions play critical roles in shaping the policy and regulatory environment for the sector:

- **Department of Science, Technology and Innovation (DSTI):** DSTI sets national research and innovation policy and provides funding through instruments such as the Technology Innovation Agency (TIA) and the National Research Foundation (NRF). It is the primary policy owner of the Bio-economy Strategy and the Science, Technology and Innovation Decadal Plan, both of which prioritise health innovation, vaccine production, and local biomanufacturing capacity[30]. DSTI also oversees strategic initiatives such as the mRNA Hub, the Biomanufacturing Innovation Partnership Programme, and health-related Centres of Competence.

25 BIOVAC. (2023). About BIOVAC. https://www.biovac.co.za

26 Afrigen Biologics and Vaccines. (2023). mRNA Hub. Retrieved from https://www.afrigen.co.za/mrna-hub/

27 Aspen Pharmacare. (2023). Aspen COVID-19 Vaccine Production Update. https://www.aspenpharma.com

28 National Bioproducts Institute (NBI). (2023). About Us. https://www.nbi.ac.za

29 SAMRC. (2023). Strategic Health Innovation Partnerships. Retrieved from https://www.samrc.ac.za/innovation/strategic-health-innovation-partnerships

30 Department of Science, Technology and Innovation (DSTI). (2021). Science, Technology and Innovation Decadal Plan 2021–2031. DSTI. (2021). Science, Technology and Innovation Decadal Plan 2021–2031. Retrieved from https://static.pmg.org.za/220202STI_Decadal_Plan.pdf

- **Department of Trade, Industry and Competition (dtic):** dtic is responsible for South Africa's industrial development strategy, including localisation, investment promotion, and support for manufacturing firms. It administers financial incentives (e.g., SPII, Manufacturing Competitiveness Enhancement Programme) and coordinates sectoral master plans, although biologics have not yet been fully integrated into these frameworks. dtic also engages with global partners around localisation and technology transfer initiatives.
- **South African Health Products Regulatory Authority (SAHPRA):** SAHPRA is the national regulatory authority responsible for approving medicines, including vaccines, biologics, and biosimilars. It is in the process of strengthening its internal capacity for evaluating biopharmaceuticals and aligning its regulatory framework with international standards[31,32]. SAHPRA is also participating in regional harmonisation efforts and exploring regulatory reliance mechanisms, though it remains resource-constrained and faces a large approval backlog.
- **National Department of Health (NDoH):** The NDoH plays a dual role — as a major purchaser of vaccines and therapeutics for the public sector, and as a stakeholder in domestic production initiatives. Its procurement policies (e.g. via the National Treasury's transversal contracts) have important implications for the viability of local manufacturing. The department is also involved in regional initiatives on pooled procurement and pandemic preparedness[33].
- **South African Medical Research Council (SAMRC)** - The SAMRC funds and conducts health research, including product development and clinical trials. Its Strategic Health Innovation Partnerships (SHIP) programme provides grant funding to advance candidate biologics and diagnostic tools through preclinical and early clinical stages[34]. SAMRC also supports capacity development for regulatory science and biostatistics.
- **Technology Innovation Agency (TIA)** - TIA is a public entity under the oversight of the Department of Science, Technology and Innovation (DSTI) that supports technology development and commercialisation. It provides seed funding, development grants, and platform infrastructure to biotech small and medium-sized enterprises (SMEs) and public research teams. Its Biomanufacturing Innovation Platform has supported projects relevant to vaccines, recombinant proteins, and enzyme production[35].
- **Council for Scientific and Industrial Research (CSIR)** – The CSIR undertakes applied research and offers platform services for the development of biologics and diagnostics. While its health focus has historically been modest, it is involved in pilot-scale production, cell line development, and analytical method development for biologics and vaccines[36].

31 United Nations Industrial Development Organization (UNIDO)
UNIDO. (2016). Pharmaceutical Manufacturing Plan for Africa. Retrieved from https://www.unido.org/sites/default/files/2016-01/Pharmaceutical_manufacturing_plan_for_Africa-English_0.pdf

32 South African Health Products Regulatory Authority (SAHPRA), 2025/26 – 2029/30 Strategic Plan. Available at: www.sahpra.org.za

33 National Department of Health. (2024). Expanded Programme on Immunisation in South Africa. Retrieved from https://knowledgehub.health.gov.za/elibrary/vaccinators-manual-expanded-programme-immunisation-south-africa-epi

34 SAMRC. (2023). Strategic Health Innovation Partnerships. Retrieved from https://www.samrc.ac.za/innovation/strategic-health-innovation-partnerships

35 TIA. (2023). Bioprocessing Platform Brochure. Retrieved from https://www.tia.org.za/core/uploads/2023/09/bioprocessing-brochure.pdf

36 Council for Scientific and Industrial Research (CSIR). (2022). Biomanufacturing and Health Technologies. https://www.csir.co.za/biomanufacturing-industry-development-centre

These public institutions form the backbone of South Africa's biopharmaceutical policy and regulatory system. However, coordination among them is uneven, mandates sometimes overlap, and long-term funding remains insufficient to fully operationalise the policy intent around local biomanufacturing.

5. Industry Data Collection

The process for prioritising companies for technical assistance is summarised below in **Figure 16**.

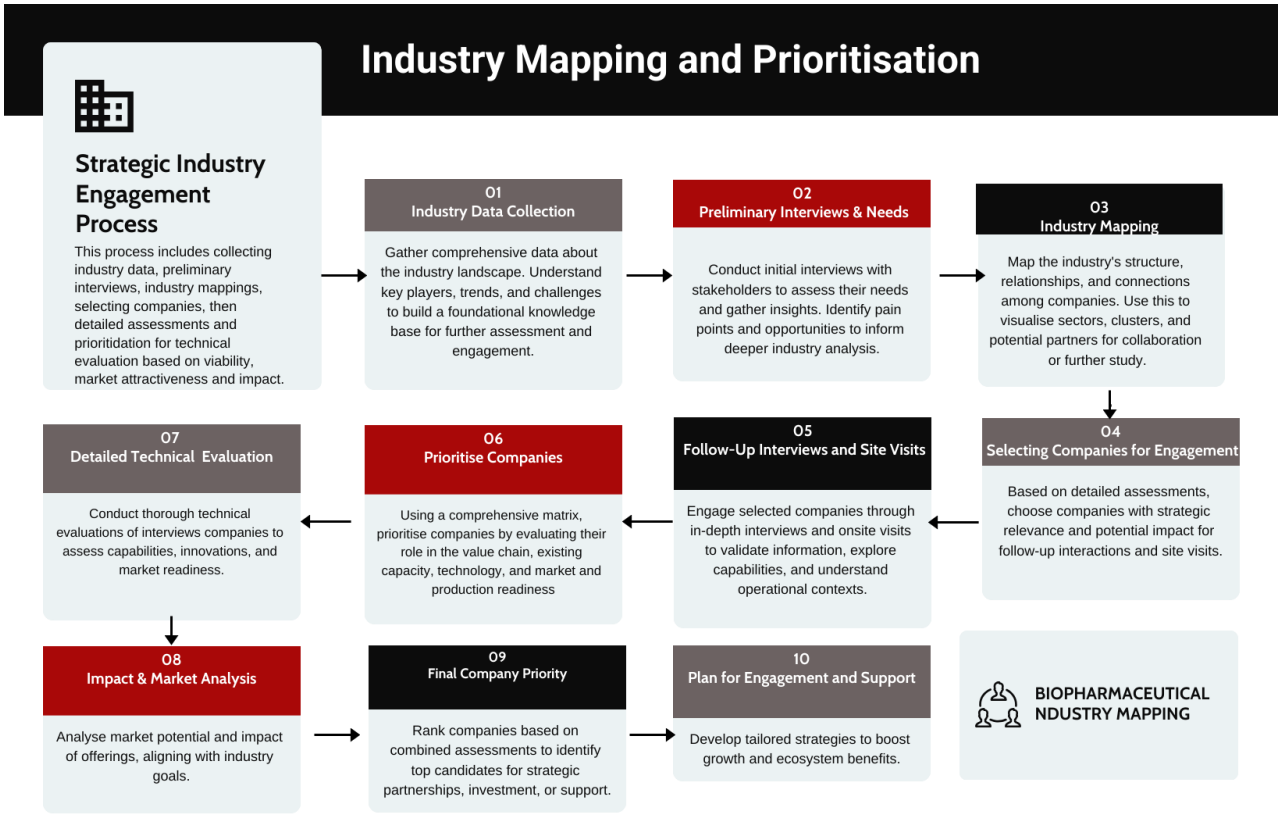

Figure 16: Flow Chart for Prioritisation of Companies for Technical Assistance

A summary of some of the most prominent biotech business incubators and technology accelerators in South Africa, as well as other supporting institutions, is given in **ANNEXURE 1.**

In **ANNEXURE 1,** we also list biopharmaceutical companies and others we could identify in the value chain. This summarises the publicly available information on the companies, and we supplemented it with additional information received from our initial interviews for some of the companies. Stakeholder Interviews

5.1 Stakeholders Interviewed

Below is the complete list of interviews conducted. We have also highlighted the agencies we interviewed in **Figure 17** below.

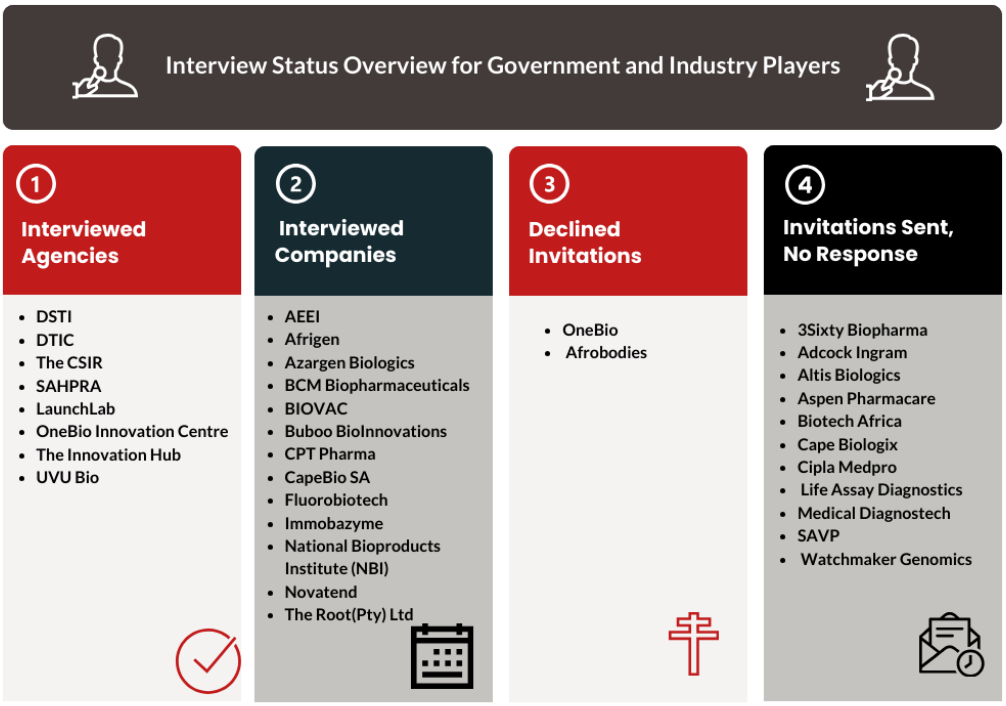

Figure 17: Interviews Conducted

5.2 Biopharmaceutical Industry Players' Input: Perceived Constraints on Industry Growth

Key insights have been gathered from industry interviews. The South African biopharmaceutical industry has significant growth potential but faces major constraints, including regulatory delays, infrastructure gaps, financial barriers, and workforce shortages. Targeted interventions, such as regulatory reforms, expanded Good Manufacturing Practice (GMP) manufacturing, increased investment support, local biosimilar development, and stronger industry collaboration, are crucial to fostering a globally competitive sector. Some of the inputs received from industry are summarised in **ANNEXURE 3,** and these challenges are summarised in **Figure 18** below.

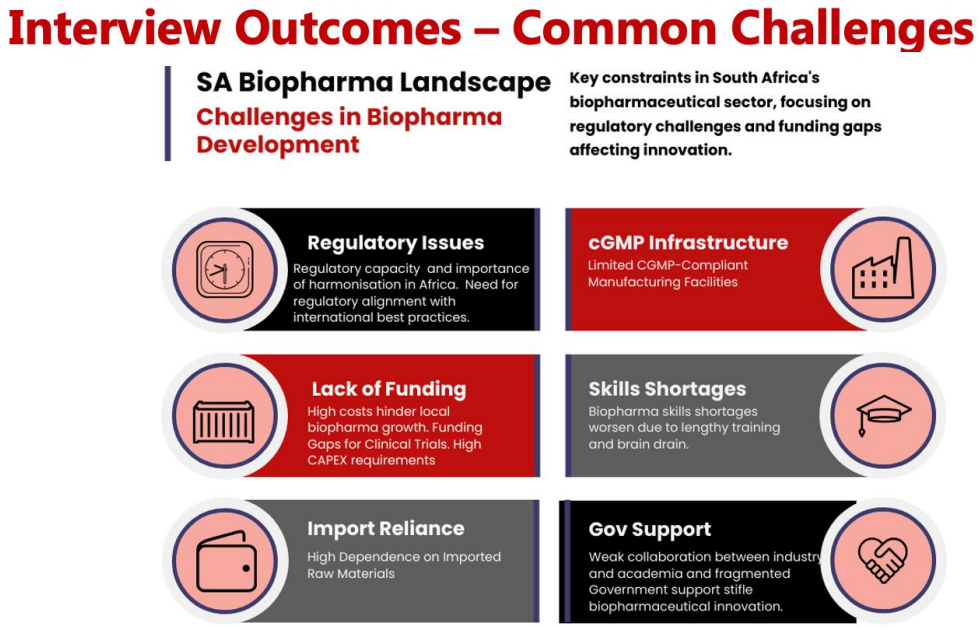

Figure 18: Industry's Perceptions of Constraints

5.3 Industry's Proposed Interventions for Strengthening the Industry

In general, despite having strong teams and promising technologies, the interviewed companies all noted gaps in infrastructure, skills development, and coordinated government support as important challenges hindering their growth. Recommendations across the board point to the need for funding mechanisms, shared Good Manufacturing Practice (GMP) infrastructure, regulatory harmonisation, and workforce training programs to unlock the sector's full potential. Additional details are outlined in **ANNEXURE 3** and illustrated in **Figure 19**.

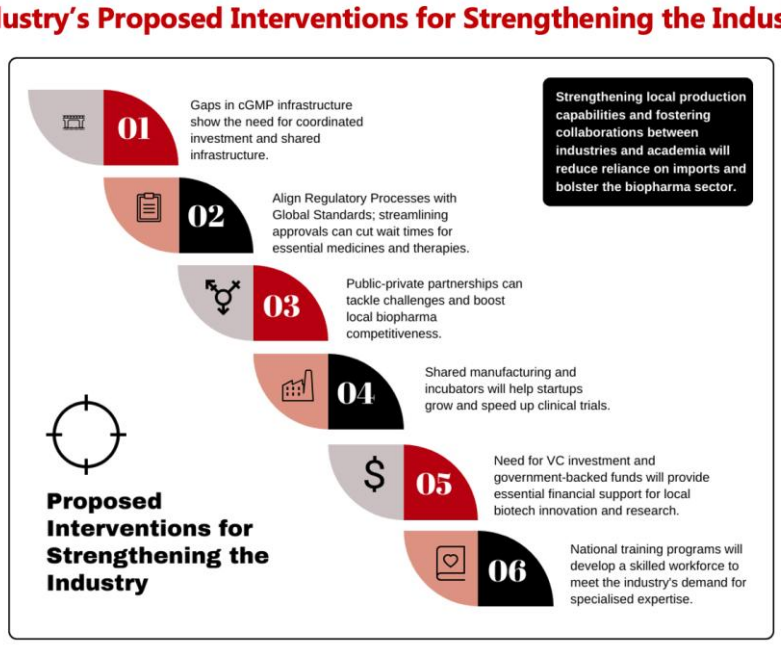

Figure 19: Proposed Interventions for Strengthening the Industry

6. Industry Mapping and Technical Needs Assessment

6.1 Biopharmaceutical Industry Mapping

The industry mapping exercise aims to comprehensively describe South Africa's private biopharmaceutical sector, including companies, start-ups, and small to medium-sized enterprises (SMEs), by cataloguing their capabilities, geographic presence, and positions within the value chain. This aim was further strengthened through engagement with key stakeholders, including DTIC, DSTI, Incubators, and university technology transfer offices. The mapping aims to achieve a detailed sector analysis and support, identifying and prioritising high-potential companies for further engagement, based on criteria such as market readiness, scalability, regulatory compliance, and public health impact.

In the first instance, the mapping exercise specifically targeted the companies' existing capacity, technology, and market readiness as they pertain to the biopharmaceutical industry. Therefore, if a company is not yet in the market, this would be reflected in a lower score. We developed a set of selection criteria to prioritise biopharmaceutical companies in South Africa that operate in the Biopharmaceutical sector for further engagement. Each company was scored against the criteria. The overall score for each company was then plotted from high to low, with the highest score indicating the most mature company (see **Figure 20).**

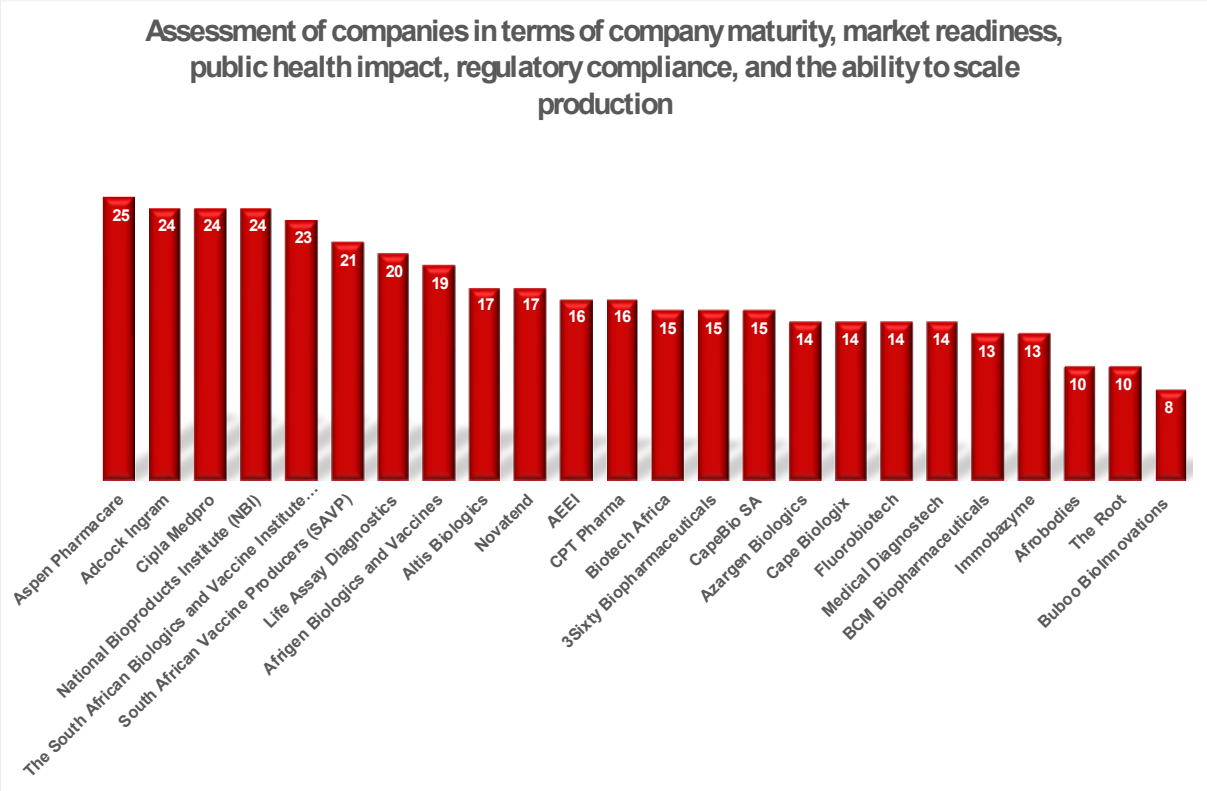

Figure 20: Assessment of Companies at a High Level

We then conducted a more detailed assessment of companies based on additional information obtained through our preliminary interviews. This was achieved in terms of Technology Readiness Levels (TRLs), Market Readiness Levels (MRLs), and Production Readiness Levels (PRLs). The detailed industry mapping is provided in **ANNEXURE 3**.

We categorised companies in the following three subsets (fully defined in **ANNEXURE 3**).

- Start-ups
- SMEs (Small & Medium Enterprises)
- Commercial Biopharma Companies

The geographic distribution of all identified companies is provided below. It lists the primary operations, although some companies may have offices in Cape Town and Gauteng. From this, it is clear that the highest concentration of companies is in the Western Cape and Gauteng (see **Figure 21** below).

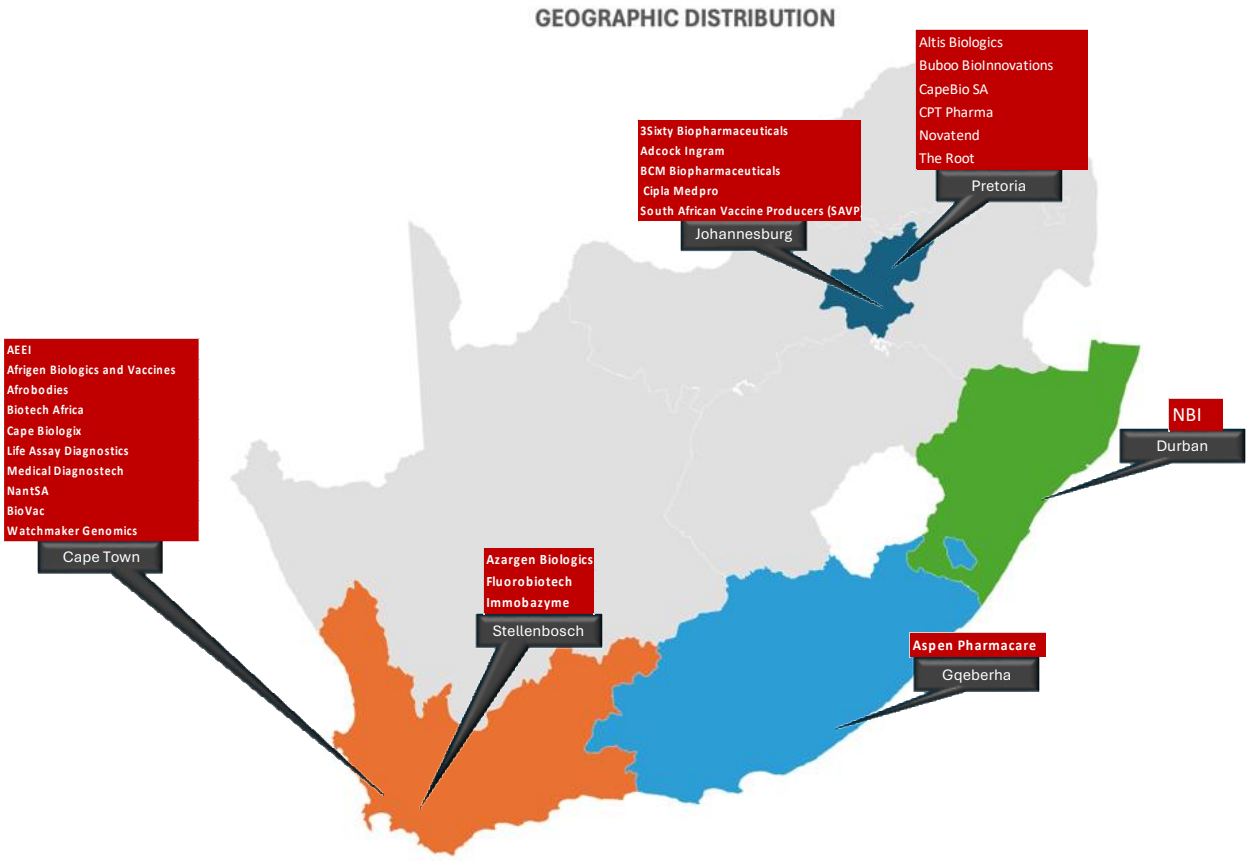

Figure 21: Geographic Distribution of the Biopharmaceutical Sector in SA

We also conducted a value chain analysis and plotted the companies' activities across the value chain, categorising them in terms of their size.

Table 3: Value Chain Analysis

Companies	Type	Raw material and Input Suppliers	Research, Development & Innovation	Manufacturing and Quality Control	Commercialisation and Marketing	Distribution and Supply Chain Management	Post-Market Surveillance and Lifecycle Management
National Bioproducts Ir	Commercial Biopharma		✖	✖	✖	✖	✖
South African Vaccine I	Commercial Biopharma		✖	✖	✖	✖	✖
Adcock Ingram	Commercial Biopharma		✖	✖	✖	✖	✖
Aspen Pharmacare	Commercial Biopharma		✖	✖	✖	✖	✖
Cipla Medpro	Commercial Biopharma			✖	✖	✖	✖
The South African Biolo	Commercial Biopharma		✖	✖	✖	✖	✖
CapeBio SA	SME		✖	✖	✖	✖	✖
Life Assay Diagnostics	SME		✖	✖	✖	✖	✖
Medical Diagnostech	SME		✖	✖	✖	✖	✖
3Sixty Biopharmaceuti	SME				✖	✖	✖
Afrigen Biologics and V	SME		✖	✖			
CPT Pharma	SME	✖	✖	✖	✖	✖	
Biotech Africa	SME	✖	✖	✖	✖	✖	✖
The Root	Start-up		✖				
AEEI	Start-up		✖	✖			
Afrobodies	Start-up		✖	✖	✖		
Azargen Biologics	Start-up		✖				
BCM Biopharmaceutic	Start-up		✖	*IN-LICENSED TECHNOLOGY, AND PLANT DESIGNS NO FACILITY YET*			
Cape Biologix	Start-up	✖	✖	✖	✖		
Immobazyme	Start-up	✖	✖	✖	✖		
Altis Biologics	Start-up		✖	✖	✖		
Novatend	Start-up		✖	✖	✖	✖	
Watchmaker Genomic	Start-up		✖	✖	✖	✖	
Fluorobiotech	Start-up	✖	✖				
Buboo BioInnovations	Start-up	✖					

6.2 Company Capacity and Needs Assessment

We conducted some targeted site visits and follow-ups, where we did the following:

- **Capacity Assessment:** Evaluate the selected companies across key dimensions, including manufacturing capacity, technology transfer, quality assurance, intellectual property management, and workforce skills. We evaluated each company's ability to scale production and address market opportunities.
- **Needs Assessment:** Identified the prioritised companies' specific technical, operational, and strategic needs. We focused on scaling production, improving access to national and regional markets, and reducing reliance on imported health products.

The technical assistance needs of companies interviewed are summarised graphically below in **Figure 22**. We provide a detailed assessment in **ANNEXURE 3**

Figure 22: Technical Assistance Needs for Companies

Companies also expressed other needs, beyond technical assistance. A summary of these needs has been aggregated and is provided below in **Figure 23** and **Figure 24.**

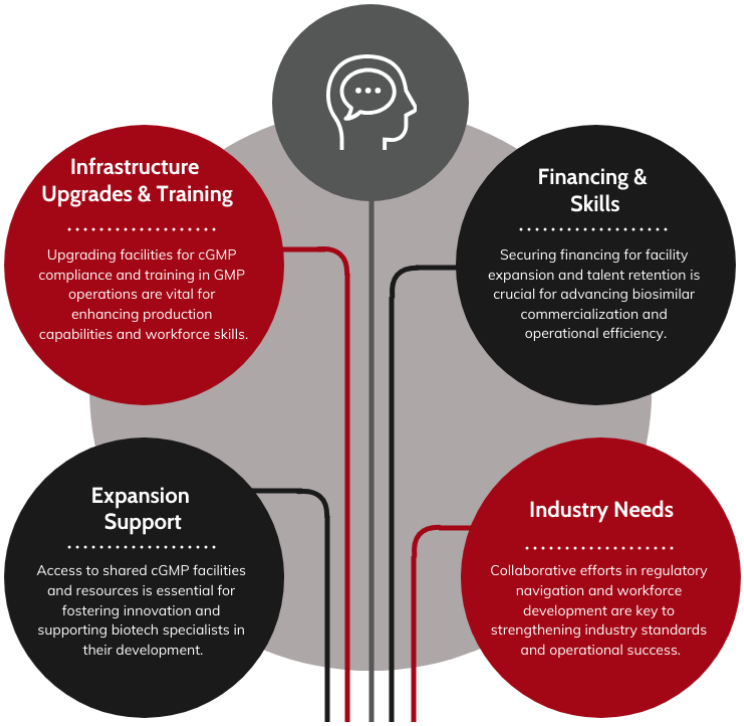

Figure 23: Companies' Needs Assessment – General

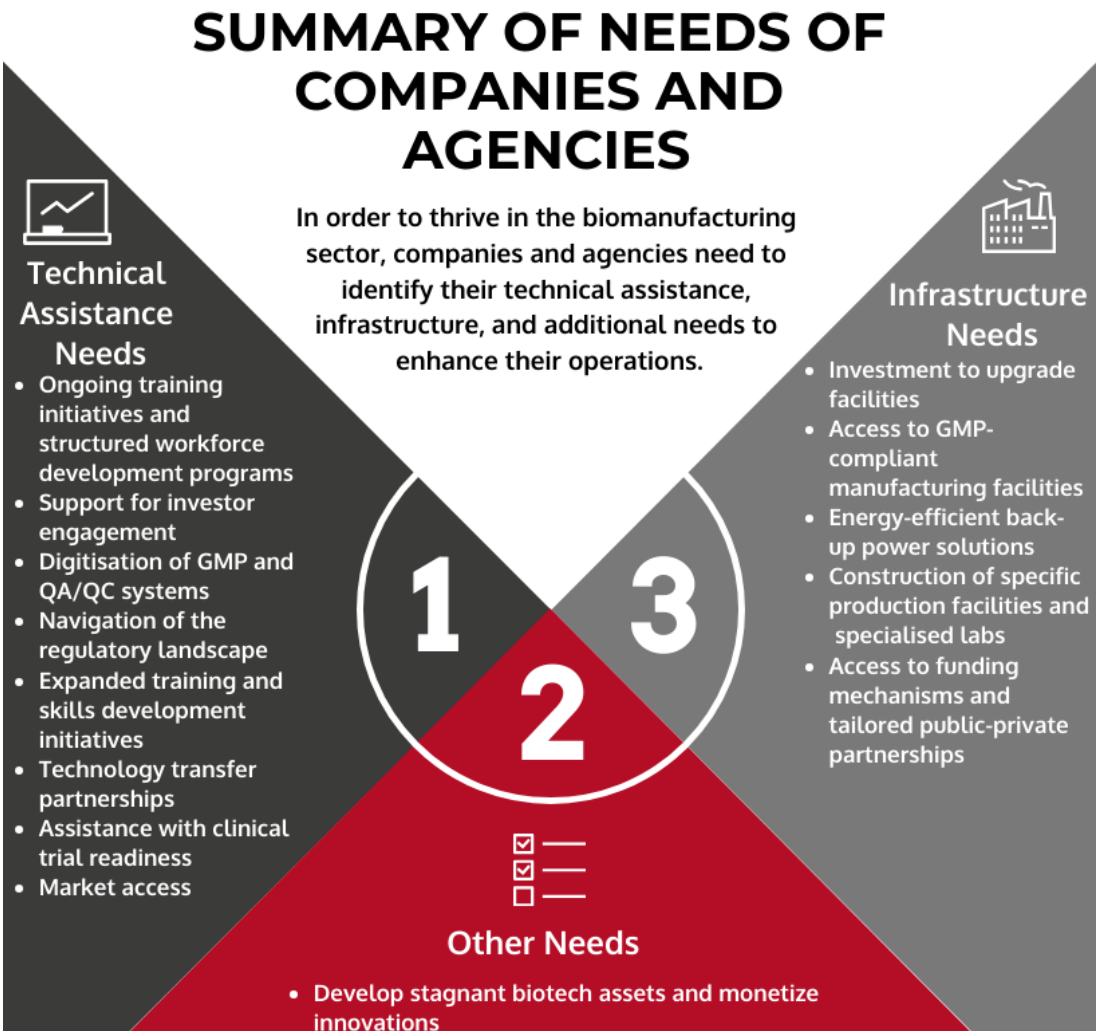

Figure 24: Companies' Needs, Categorised

In **Figure 25** below, the technical assistance needs are also summarised at an aggregate level.

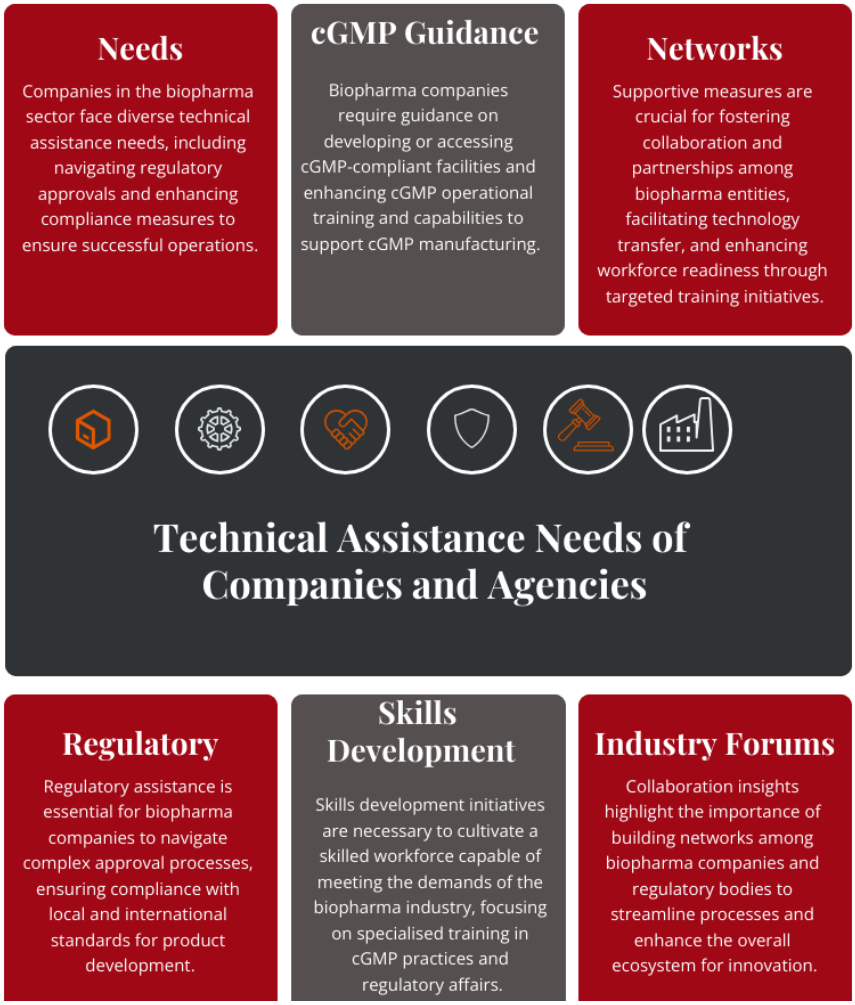

Figure 25: Technical Assistance Needs of Companies

6.3 Prioritising Technical Assessment Needs of Companies

Following the site visits and subsequent interviews, we created a prioritisation matrix to guide the recommendation of technical assistance. This framework considered each company's specific product portfolio as well as the respective Technology Readiness Levels (TRLs) of individual products. In addition, we aligned our analysis with standard development timelines to ensure that support needs were assessed in both a strategic and time-sensitive manner.

Assessing the maturity of a company's product pipeline is essential for understanding its innovation trajectory, commercial potential, and risk profile. Pipeline maturity refers to the stage of development each product or asset has reached, ranging from early research and manufacturing readiness through to access to cGMP infrastructure, clinical trials, regulatory approval, and market launch. This evaluation provides insight into how close products are to generating revenue, the timeframes involved, and the level of technical or regulatory risk that still needs to be overcome.

A mature pipeline, particularly one with late-stage or commercially launched products, signals a company's readiness to generate near-term value and may be more attractive to investors and partners. In contrast, a pipeline dominated by early-stage assets often indicates higher uncertainty and

longer timelines, but may offer greater innovation potential. Strategically, understanding pipeline maturity enables stakeholders to forecast revenue, allocate resources effectively, assess risk-reward balances, and benchmark progress against industry peers.

We assessed each company at the product level in terms of these criteria, as shown below in **Figure 26**.

Companies	Products	Technology Development	Product and Process Development	Small Scale Manufacturing	cGMP manufacture	Clinical Trial Ready	SAHPRA approved Products	Products in Market
Technology Readiness Levels		TRL4	TRL5	TRL5/6	TRL6	TRL6/7	TRL8	TRL9
AEEI	Infrastructure	✗	✗	✗	✓	✗	✗	✗
	Hematopoietic growth factors - Biosimilars	✓	✓	✓	✗	✓	✓	✗
	Cell-Based Immunotherapy	✓	✓	✓	✗	✓	✗	✗
Afrigen Biologics and Vaccines	mRNA Vaccines	✓	✓	✓	✗	✗	✗	✗
	mRNA Therapeutics	✓	✗	✗	✗	✗	✗	✗
Azargen Biologics	Peptide - based Biopharmaceuticals	✓	✓	✓	✗	✗	✗	✗
	Vaccines	✓	✓	✗	✗	✗	✗	✗
	Diagnostics	✓	✓	✗	✗	✗	✗	✗
BCM Biopharmaceuticals	Monoclonal antibodies - Biosimilars	IN-LICENSED TECHNOLOGY, AND PLANT DESIGNS NO FACILITY YET						
CapeBio SA	Enzymes	✓	✓	✓	✗	✗	✗	✓
	Diagnostics	✓	✓	✗	✗	✗	✗	✗
CPT Pharma	Raw Materials for use in biopharmaceutical manufacture	✓	✓	✗	✗	✗	✗	✗
Fluorobiotech	Enzymes form mRNA vaccine manufacture	✓	✓	✓	✗	✗	✗	✗
	Enzymes for medical use	✓	✓	✓	✗	✗	✗	✗
Immobazyme	Recombinant proteins therapeutic - Growth factors	✓	✓	✓	✗	✗	✗	✗
	Other Recombinant Proteins	✓	✓	✓	✗	✗	✗	✗
National Bioproducts Institute (NBI)	Hematopoietic growth factors - Biosimilars	✓	✓	✓	✗	✗	✗	✗
	Monoclonal antibodies - Diagnostics	✓	✓	✓	✓	✓	✓	✓
	Monoclonal antibodies - Biosimilars	✓	✓	✗	✗	✗	✗	✗
	Diagnostics	✓	✓	✓	✓	✓	✓	✓
	Plasma-derived medicinal products (PDMPs).	✓	✓	✓	✓	✓	✓	✓
Novatend	Tissue-engineered biomaterials	✓	✓	✓	✓	✓	✓	✓
	Naturally Derived Growth Factor-Enriched Biologics	✓	✓	✓	✗	✗	✗	✗
BIOVAC	Vaccine Biopharmaceuticals	✓	✓	✓	✓	✓	✓	✓
	mRNA Vaccines	✓	✓	✓	✗	✗	✗	✗

Figure 26: Analysis of Product Pipelines in terms of Maturity

We subsequently established formal prioritisation criteria. The primary criterion was to include only those companies that explicitly articulated a need for technical assistance at the product level. This served as the initial screening filter. Based on this initial filtering, we proceeded with the subset of companies that had clearly expressed a need for technical assistance. For these companies, we conducted a more detailed assessment of their product development efforts, focusing on two key dimensions: Technical Viability and Probability of Commercial Success. The combined scores from these dimensions were used to derive an Overall Viability rating.

In parallel, we evaluated the Strategic Relevance of each product and its Market Attractiveness. These factors were aggregated to determine the Overall Attractiveness score. Finally, each product line was assigned an Impact Score, reflecting its potential contribution to the broader South African and African biopharmaceutical landscape (see **Table 4** below and a detailed methodology in **ANNEXURE 3**).

Table 4: Viability and Attractiveness of All Product Pipelines

Companies	Products	Viability	Attractiveness	Impact
AEEI	AEEI Infrastructure	7	7	5
Afrigen Biologics and Vaccines	Afrigen mRNA Vaccines	9	9	10
Afrigen Biologics and Vaccines	Afrigen mRNA Therapeutics	6	6	5
Azargen Biologics	Azargen Biopharmaceuticals	6	7	1
CapeBioSA	CapeBioSA Diagnostics	6	6	5
CPT Pharma	CPT Raw Materials	8	8	5
Fluorobiotech	Fluorobiotech mRNA Enzymes	9	9	5
Fluorobiotech	Fluorobioteh other enzymes	8	7	5
Immobazyme	Immobazyme Growth factors	9	8	5
Immobazyme	Immobazyme Other Recombinant Proteins	7	7	5
NBI	NBI Protein Biosimilars	9	9	10
NBI	NBI Monoclonal antibodies	9	10	10
Novatend	Novatend Naturally derived GFs	7	5	1
BIOVAC	BIOVAC vaccines Vaccines	9	8	5
BIOVAC	BIOVAC mRNA Vaccines	9	9	10

The bubble chart entitled *"Viability vs Attractiveness (Bubble size Impact)"* visually represents the outcome of the prioritisation exercise undertaken following site visits and company interviews. Each bubble corresponds to a specific product line or platform, plotted according to its assessed Overall Viability (x-axis) and Overall Attractiveness (y-axis). Viability reflects a combination of technical feasibility and probability of commercial success, while Attractiveness captures the product's strategic relevance and market potential. In addition, the size of each bubble indicates the expected impact of the product on the South African and broader African biopharmaceutical landscape, with larger bubbles representing higher potential system-level influence (see **Figure 27**).

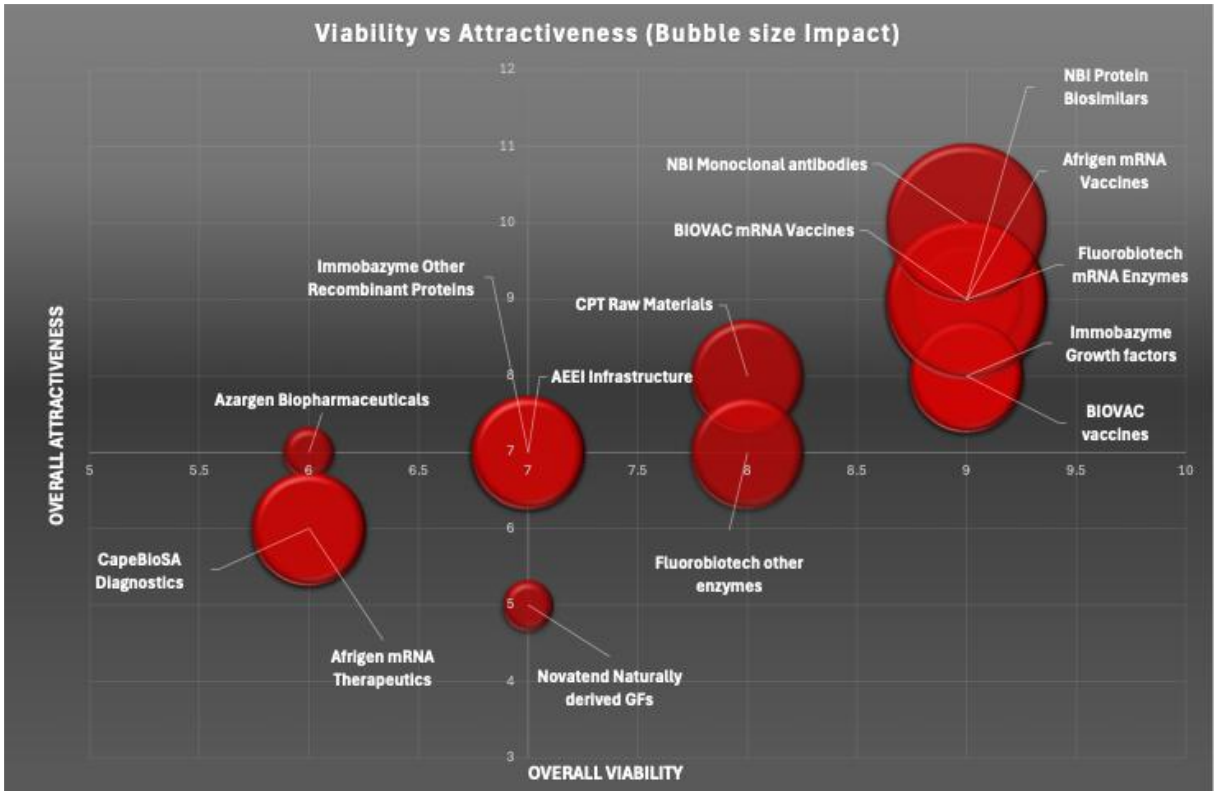

Figure 27: Product Pipeline Viability vs Overall Attractiveness

This is graphically depicted in a graph with two axes, where the bubble size corresponds to the Potential Impact, as shown in **Figure 27** above.

The chart is divided into four quadrants, each conveying a different strategic interpretation. The top right quadrant contains the "stars", products that are both highly viable and highly attractive. These include, for example, NBI's protein biosimilars and BIOVAC's mRNA vaccines, which combine strong technical readiness with significant market and strategic relevance. These represent the most compelling opportunities for support and investment. In the top left quadrant, we find products that are attractive from a market or strategic standpoint but are currently less technically developed or commercially de-risked, such as CPT Raw Materials and Immobazyme's recombinant proteins. These "strategic bets" may warrant targeted technical assistance to help them progress toward viability.

The bottom right quadrant includes products that score well in terms of viability but are less attractive from a market or policy perspective. These "quick wins," such as Fluorobiotech's other enzyme platforms, may yield short-term returns but are not likely to transform the sector. Lastly, the bottom left quadrant contains products that are currently low in both viability and attractiveness, such as CapeBioSA Diagnostics and Novatend's naturally derived growth factors. These are considered lower-priority interventions, requiring significant development effort with limited strategic payoff. Overall, the chart offers a comprehensive tool for evidence-based decision-making, ensuring that technical assistance and ecosystem support are directed where they can deliver the most significant impact.

To further refine our prioritisation process, we aggregated the analysis to the company level by selecting the highest-ranking product from each company's pipeline. This approach enabled us to focus on the lead opportunity within each firm and allowed for a consistent comparison across entities.

Using the same scoring framework, Overall Viability (based on technical feasibility and commercial potential), Overall Attractiveness (based on strategic alignment and market opportunity), and Impact Score (represented by bubble size), we generated a company-level matrix to identify those with the greatest need and potential benefit from technical assistance.

The updated bubble chart visualises this refined analysis. Companies positioned in the top right quadrant (e.g., NBI, Fluorobiotech, Afrigen, and BIOVAC) exhibit high scores in both viability and attractiveness, indicating strong technical and commercial readiness as well as alignment with strategic market needs. These are considered the most promising candidates for targeted support, as they combine robust innovation capacity with significant potential to shape the biopharmaceutical landscape.

Companies located in the middle band, such as CPT Pharma and AEEI, demonstrate moderate viability and attractiveness. They may benefit from specific, targeted interventions to enhance the maturity or market positioning of their leading products. Meanwhile, entities in the lower left quadrant, such as CapeBioSA, Azargen, and Novatend, show relatively low scores across both dimensions, suggesting early-stage development, limited commercial readiness, or weaker alignment with national and continental priorities. These companies may require more fundamental capacity-building support or reconsideration of strategic direction. This is illustrated in **Figure 28 below**.

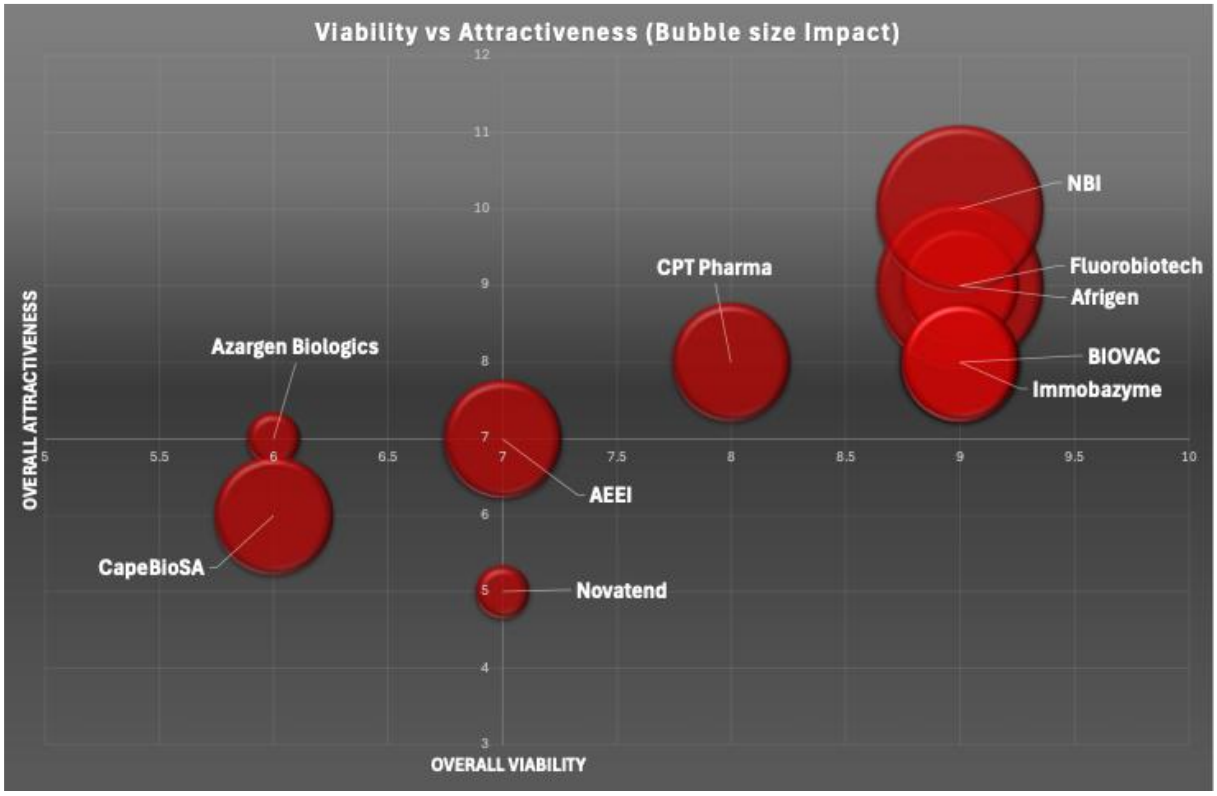

Figure 28: Overall Ranking of Companies in Need of Technical Assistance

Based on this refined analysis, the companies positioned in the upper-right quadrant of the matrix were prioritised for technical assistance. These firms demonstrated a combination of high product viability, strategic relevance, and potential impact, making them strong candidates for targeted support. The prioritised companies include:

- National Bioproducts Institute (NBI)
- FluoroBiotech
- Afrigen Biologics
- BIOVAC
- Immobazyme
- CPT Pharma
- AEEI, specifically concerning the potential utilisation of their currently idle cGMP-compliant

7. Conclusion and Recommendations

South Africa stands at a critical juncture in developing its biopharmaceutical sector. The country possesses strong research capabilities, emerging industrial actors, and growing political commitment to local production. However, its biopharmaceutical industry remains fragmented, under-capitalised, and largely dependent on imported biologics. Despite encouraging steps, such as the establishment of the WHO mRNA technology hub and recent policy attention, progress has been uneven, with persistent gaps in GMP manufacturing infrastructure, regulatory readiness, technical skills, and cross-sector coordination. Key players, such as BIOVAC, Afrigen, and the National Bioproducts Institute, offer promising foundations; however, without systemic reforms and targeted investment, their impact will remain limited. The current landscape reflects a disconnect between public health needs, industrial development goals, and the institutional support required to realise both.

To address these gaps, a set of coordinated interventions is needed across system, sector, and firm levels. At the system level, the immediate priority should be to establish a National Biopharma Strategy that aligns health, industrial, and innovation policies under a unified framework. This strategy should be backed by reforms to the public procurement system, linking purchasing power to local production goals, and improvements to the R&D incentive and intellectual property regimes. Regulatory capacity, particularly within SAHPRA, must be strengthened to expedite approvals for biologics and biosimilars. At the sector level, investment in translational research facilities, pilot-scale GMP infrastructure, and practical skills training will be essential to strengthen South Africa's value chain. Lack of access to GMP infrastructure has been highlighted across the board, from companies near the finish line (concerning some products), such as NBI, to promising companies early in the value chain, like Immobazyme.

Dedicated platforms for technology transfer, cluster development, and market foresight can help bridge the divide between research and commercialisation. At the firm level, tailored innovation finance instruments should support companies through the critical early and mid-stages of product development, especially for high-impact therapeutic areas such as oncology, infectious diseases, and autoimmune disorders. Blended finance, export readiness support, and regulatory guidance will further de-risk private sector investment.

In short, South Africa's biopharmaceutical industry has the potential to enhance national health resilience, reduce reliance on imports, and contribute to the continent's supply chains. Realising this potential will require coordinated leadership, sustained public investment, and partnerships that link science, industry, and regulation in pursuit of common goals. With targeted reforms and strategic support, the country can position itself as a credible regional hub for biopharmaceutical innovation and manufacturing.

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