

Pharmaceutical Landscape in SOUTH AFRICA & LATAM



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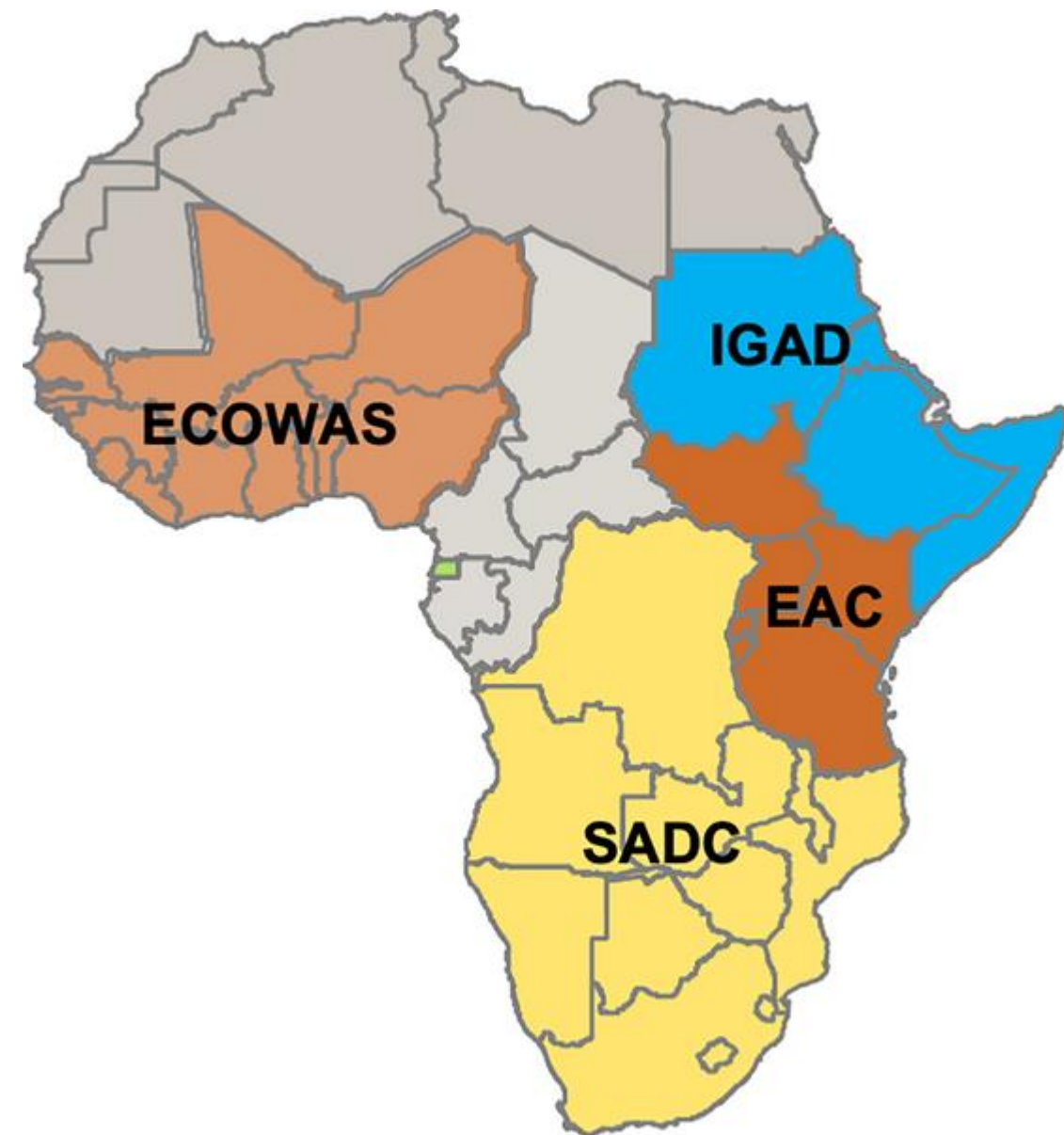
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Introduction

The pharmaceutical environments in South Africa and Latin America (LATAM) are shaped by diverse regulatory frameworks, healthcare policies, and market dynamics. South Africa's industry is influenced by the South African Health Products Regulatory Authority (SAHPRA) and the National Health Insurance (NHI) scheme, promoting access to medicines and local manufacturing. In LATAM, regulatory bodies like ANVISA and COFEPRIS govern markets with a focus on improving healthcare access and promoting generic medicines



Regulatory bodies of SOUTH AFRICA



SAHPRA
South African
Health Products
Regulatory Authority

Regulatory Landscape in South Africa



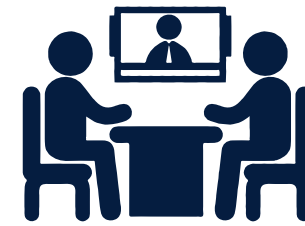
Stringent Regulations

SA regulatory landscape is known for its strictness, with the Medicines and Related Substances Act (1965) governing the pharmaceutical industry.



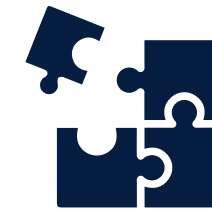
Medicines Control Council

The Medicines Control Council (MCC), now the South African Health Products Regulatory Authority (SAHPRA), plays a vital role in ensuring the safety and efficacy of medicines.



Emphasis on Quality

The regulatory framework emphasizes adherence to Good Manufacturing Practices (GMP), prioritizing product quality and patient safety.



Strict Registration Process

The registration process for new drugs is comprehensive, requiring rigorous testing and approval procedures.

Pharmaceutical Market Trends in SA

- **Growing Demand** : The South African pharmaceutical market is characterized by rising demand for rising demand for both essential and specialty medicines, driven by factors like population growth population growth and an aging demographic.
- **Generic Competition** : Generic drug manufacturers have increased their market share, leading to share, leading to price competition and affordability improvements.
- **Focus on Non-Communicable Diseases** : The South African healthcare system is prioritizing the prioritizing the management of non-communicable diseases like diabetes, heart disease, and disease, and cancer.
- **Digital Transformation** : The pharmaceutical industry in South Africa is embracing digital digital technologies, including e-commerce and telehealth, to improve patient access and care. access and care.

Pharmaceutical Manufacturing Capabilities in South Africa

Established Industry

South Africa boasts a mature pharmaceutical manufacturing sector, with numerous local companies producing a wide range of medicines.

Global Partnerships

Several multinational pharmaceutical companies have established manufacturing facilities in South Africa, fostering partnerships and knowledge transfer.

Focus on Generics

A significant portion of South Africa's pharmaceutical manufacturing capacity is dedicated to the production of generic medicines, supporting affordability and access.

Regulatory Landscape in LATAM

Diverse Regulations

Latin America comprises a diverse region with varying regulatory frameworks across different countries, leading to complexities in navigating the pharmaceutical landscape.

National Agencies

Each country within LATAM has its own national agency responsible for regulating the pharmaceutical industry, with varying levels of stringency and oversight.

Harmonization Efforts

Efforts are underway to harmonize regulatory processes across LATAM countries, streamlining drug approval procedures and facilitating regional trade.

Regional Challenges

Challenges remain in ensuring consistent regulatory practices, addressing counterfeit drugs, and promoting ethical standards across the region.

Pharmaceutical Market Trends in LATAM

01

Growing Middle Class

The expanding middle class in LATAM is driving increased demand for healthcare services and pharmaceuticals, fueling market growth.

02

Rise of Chronic Diseases

Non-communicable diseases are becoming increasingly prevalent in LATAM, leading to greater demand for treatment and prevention strategies.

03

Evolving Healthcare Systems

LATAM countries are investing in healthcare infrastructure and implementing reforms to improve access and quality of care.

Regulatory bodies of LATAM



Healthcare System – Core Challenges

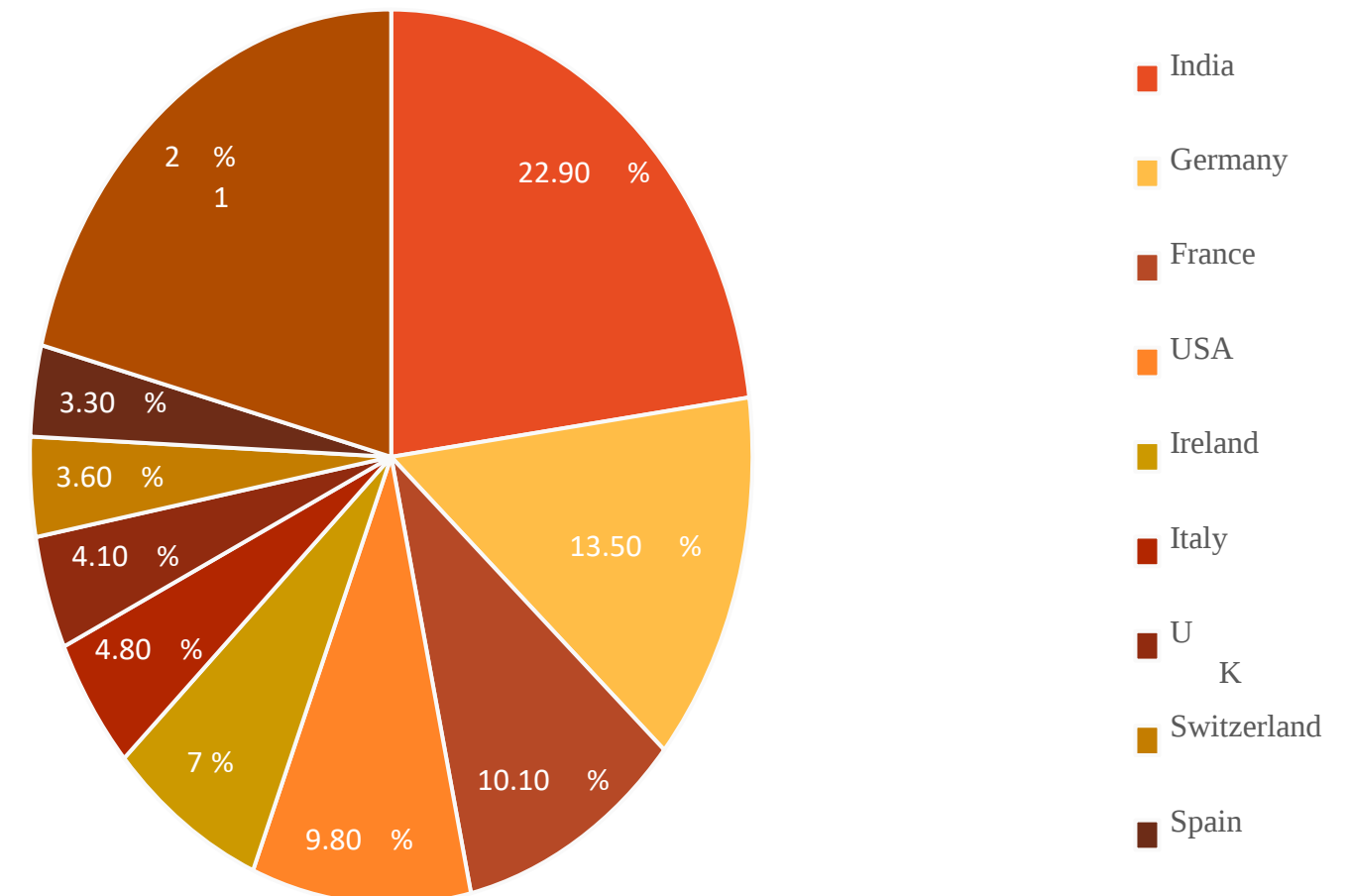
Unequal Distribution of Resources

Single Exit Price

Slow Progress of Restructuring

Increased Litigation

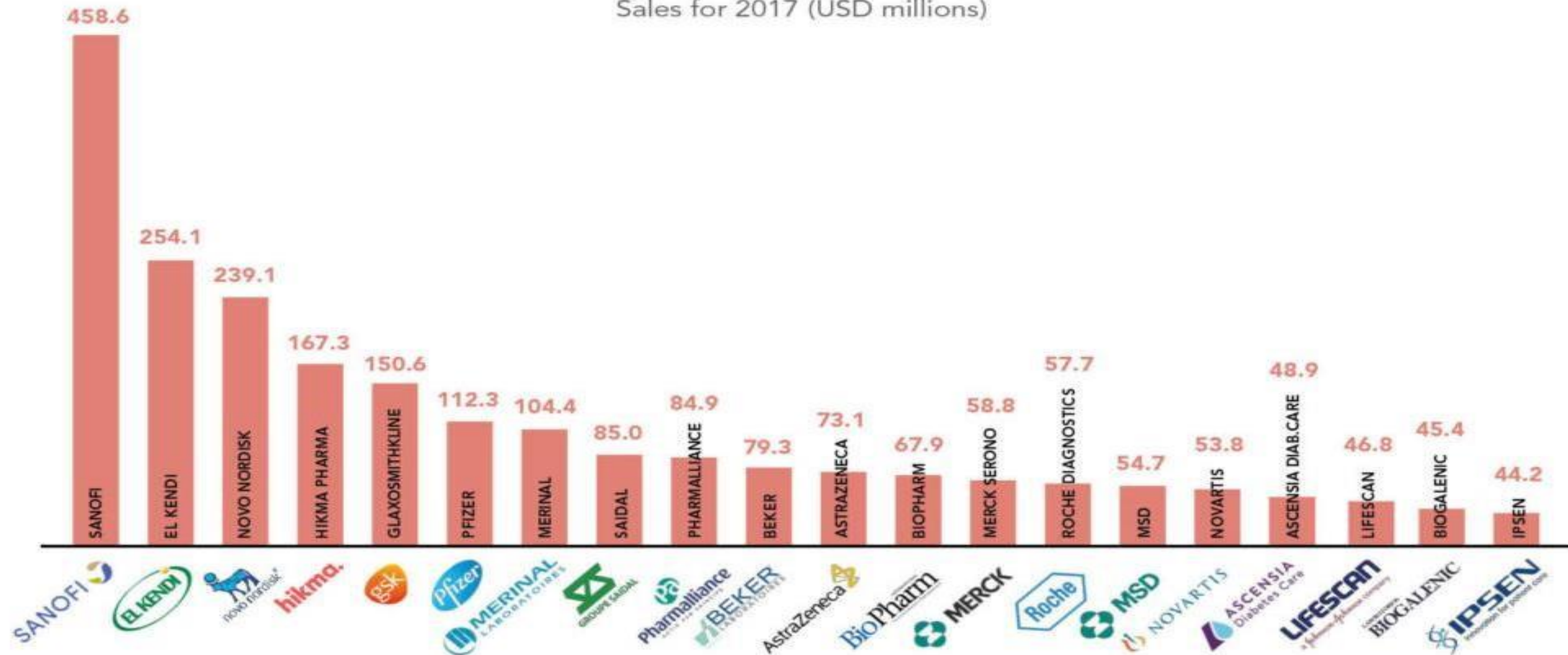
Import Market Share, 2023



Major Players in Algeria

TOP 20 PHARMA COMPANIES IN ALGERIA

Sales for 2017 (USD millions)



Conclusion and Key Takeaways



Growth Potential

Both South Africa and LATAM offer significant growth potential for the pharmaceutical industry, driven by population growth, rising healthcare spending, and a growing demand for medicines.



Regulatory Considerations

Navigating the regulatory landscape is crucial for success in both regions, requiring adherence to stringent guidelines and navigating complex approval processes.



Innovation & Digitalization

The pharmaceutical industry in both regions is embracing innovation and digitalization, creating opportunities for advanced technologies and patient-centric solutions.



Strategic Partnerships

Establishing strategic partnerships with local companies and stakeholders is vital for success, facilitating knowledge transfer and market access.