

AN EXTENSIVE STUDY OF THE PHARMACEUTICAL ENVIRONMENT IN SOUTH AFRICA AND LATAM

Dissertation Submitted to



The IIHMR University, Jaipur

for the partial fulfilment for the award of the degree of

Master of Business Administration (MBA)

in

Pharmaceutical Management

By

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Under the Supervision and Guidance of

Dr. Sudhinder Singh Chowhan

2024

Completion Certification

CERTIFICATE

This is to certify that **HITESH CHOUDHARI** in partial fulfilment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur has successfully completed Dissertation/ Internship at **Vivimed Labs.** during

May- June 2024.

Place: Hyderabad

Date: 02/07/2024



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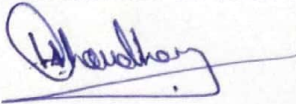
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DECLARATION BY STUDENT

I hereby declare that this dissertation titled "**An extensive study of pharmaceutical environment in South Africa and Latam**". I declare that it has not been shared with any other university or institution for the award of any degree or diploma. Information derived from published or unpublished work from others has been duly acknowledged in the text.

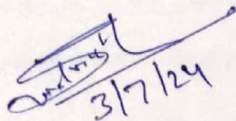
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A handwritten signature in blue ink, appearing to read 'Hitesh Choudhari', with a horizontal line extending to the right.

CERTIFICATE

This is to certify that dissertation titled “**An extensive study of pharmaceutical environment in South Africa and Latam.**” Is a record of the research work undertaken by **Hitesh Choudhari** in partial fulfilment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and her approach to the research study has been sincere, scientific, and analytical.

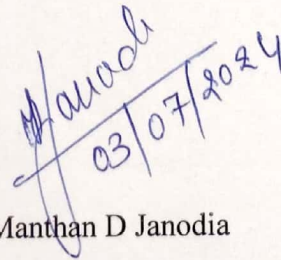


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ACKNOWLEDGEMENT

I would like to express my sincere gratitude and appreciation to all those who have supported me throughout the completion of this dissertation. Without their assistance, encouragement, and guidance, this accomplishment would not have been possible.

First and foremost, I am immensely grateful to my faculty guide, **Dr. Sudhinder Singh Chowhan**, for his unwavering support and invaluable guidance throughout the entire dissertation process and in class. I am truly fortunate to have had their mentorship.

I would like to acknowledge the Dean of Pharmaceutical Management, **Dr. Saurabh Kumar Banerjee**, whose commitment to academic excellence and the pursuit of knowledge has been an inspiration to me throughout my studies.

Lastly, I would like to acknowledge my industry mentor **Mr. Manas Varalwar** who generously dedicated her time and contributed their insights to this study. Their involvement has been fundamental in shaping and enriching the overall quality of this research and I am grateful for the knowledge and skills I have gained under her supervision. I would also like to express my gratitude to the sales officers who worked with me on the field.

Name of the student: **Hitesh Choudhari**

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Abstract

Title: An Extensive Study of the Pharmaceutical Environment in South Africa and Latam

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Advisor Name: Dr. Sudhinder Singh Chowhan

Keyword:

Pharmaceutical industry, healthcare systems, market analysis, regulatory environment, drug approval process, healthcare policies, South African Health Products Regulatory Authority (SAHPRA), National Health Insurance (NHI), pharmaceutical market in South Africa, generic medicines in South Africa, local pharmaceutical manufacturing, access to medicines in South Africa, Latin American pharmaceutical market, ANVISA (Brazilian Health Regulatory Agency), COFEPRIS (Mexican Health Regulatory Agency), pharmaceutical regulations in LATAM, market access in LATAM, generic medicines in LATAM, public health policies in LATAM, pharmaceutical distribution in LATAM, comparative analysis, market trends, regulatory comparisons, healthcare infrastructure, market entry strategies, challenges and opportunities, and investment climate.

Background:

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. This study analyzes market trends, regulatory comparisons, and healthcare infrastructure, highlighting challenges and opportunities for stakeholders. The insights aim to guide strategic market entry and investment decisions in these regions.

Objective:

Analyze Regulatory Frameworks:

- Examine the pharmaceutical regulatory environment in South Africa and Latin America (LATAM), including policies, standards, and compliance requirements.

Market Dynamics and Trends:

- Identify and assess market trends, growth patterns, and competitive landscape in

the pharmaceutical industry within these regions.

Economic Impact:

- Evaluate the economic impact of the pharmaceutical sector on the overall economy of South Africa and LATAM countries, including contributions to GDP and employment.

Healthcare Infrastructure:

- Investigate the state of healthcare infrastructure, access to medicines, and the role of pharmaceuticals in public health systems.

Innovation and Research:

- Explore the level of innovation, research and development activities, and the presence of pharmaceutical research institutions and collaborations.

Challenges and Opportunities:

- Identify key challenges faced by the pharmaceutical industry in these regions, such as supply chain issues, pricing, and regulatory hurdles, and explore potential opportunities for growth and improvement.

Comparative Analysis:

- Conduct a comparative analysis of the pharmaceutical environments in South Africa and LATAM to highlight similarities, differences, and unique regional characteristics.

Impact of Global Trends:

- Assess the influence of global pharmaceutical trends, such as the rise of generics, biosimilars, and the impact of COVID-19, on the South African and LATAM markets.

Public and Private Sector Roles:

- Examine the roles and contributions of both public and private sectors in the development and distribution of pharmaceuticals in these regions.

Policy Recommendations:

- Provide policy recommendations to enhance the pharmaceutical environment, improve regulatory efficiency, and support sustainable growth in the pharmaceutical sectors of South Africa and LATAM.

Methodology:

The methodology for the extensive study of the pharmaceutical environment in South Africa and LATAM involves conducting a comprehensive literature review of academic journals, industry reports, government publications, and market analyses. Secondary sources such as databases, online repositories, and relevant websites will be systematically searched to gather data on regulatory frameworks, market dynamics, key players, and challenges in the pharmaceutical sectors of these regions. Comparative analysis will be performed to identify similarities and differences in the pharmaceutical landscapes. The findings will be synthesized to provide a detailed understanding of the pharmaceutical environments in South Africa and LATAM.

Results/Findings:

The pharmaceutical environments in South Africa and Latin America (LATAM) show significant variability. South Africa faces challenges such as regulatory complexities and market access issues, but it benefits from a growing generic drug market and government healthcare initiatives. In LATAM, the pharmaceutical market is expanding due to increasing healthcare demands, but it is hindered by economic instability and regulatory diversity across countries. Both regions are experiencing growth in local production and innovation, driven by government policies and increasing healthcare needs.

Conclusions:

The study concludes with recommendations for enhancing educational programs and marketing strategies to promote the broader adoption of RCR technology. It also advocates for ongoing comparative research to continuously evaluate and improve Cardiac Health. By bridging the knowledge gap and providing a thorough comparative analysis, this dissertation aims to support the integration of advanced technologies, ultimately improving patient care and clinical outcomes.

Abbreviation Full form

WHO	World Health Organization
FDA	Food and Drug Administration
EMA	European Medicines Agency
GMP	Good Manufacturing Practice
API	Active Pharmaceutical Ingredient
OTC	Over-the-Counter
BLA	Biologics License Application
ANDA	Abbreviated New Drug Application
NDA	New Drug Application
MHRA	Medicines and Healthcare products Regulatory Agency
GMP	Good Manufacturing Practice
M&A	Mergers and Acquisitions
CAGR	Compound Annual Growth Rate
QMS	Quality Management System
GCP	Good Clinical Practice
GDP (pharma)	Good Distribution Practice
CRO	Contract Research Organization
CTD	Common Technical Document
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
PDUFA	Prescription Drug User Fee Act
PBM	Pharmacy Benefit Manager

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South African Pharma Market

Understanding the South African Pharma Market in-depth by conducting secondary research. This was the first project assigned to me which was aimed to gauge my understanding about the dynamics of a regulated market such as South Africa. I used various research articles, blogs, and various other online sources to make a presentation on the same.

Methodology:

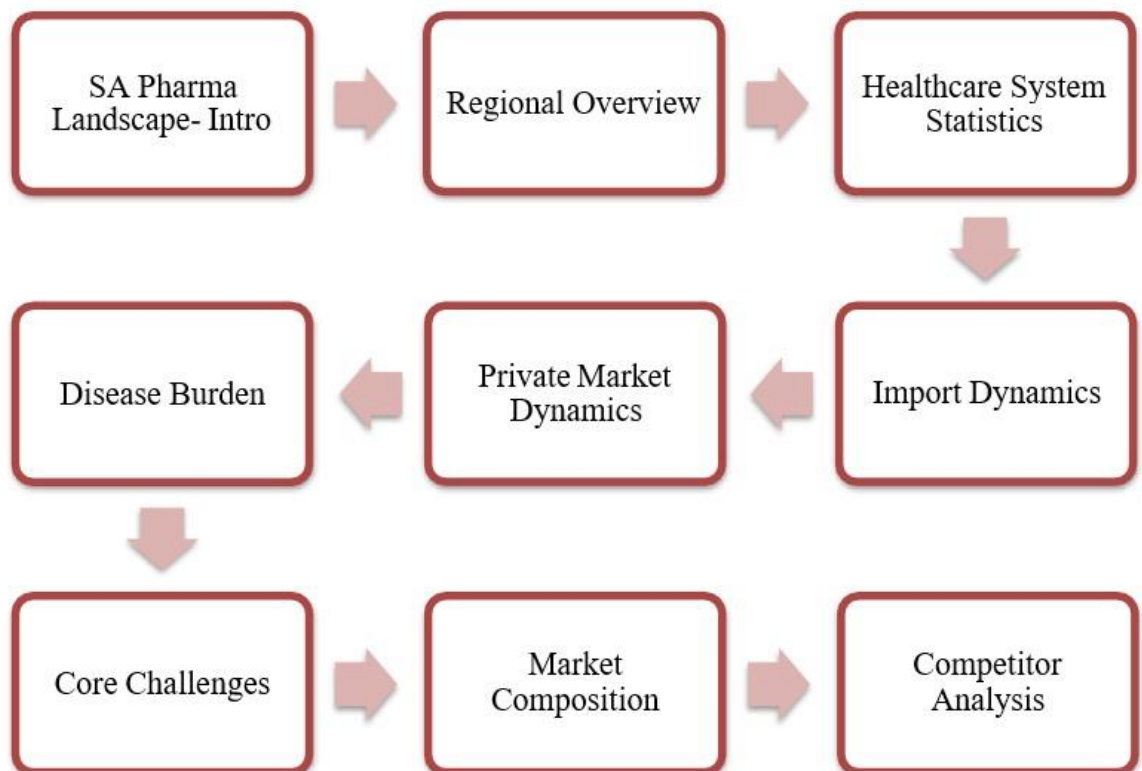


Figure 1: Topics Covered – Order Wise

1.1 South Africa Pharma Landscape

- In 2021, the pharmaceutical industry in South Africa was worth \$ 4.6 billion.
- The fundamentals for pharmaceutical players in South Africa have always been in place: increasing disposable income, diverse demographics, an ageing population, and a variety of illness burdens.

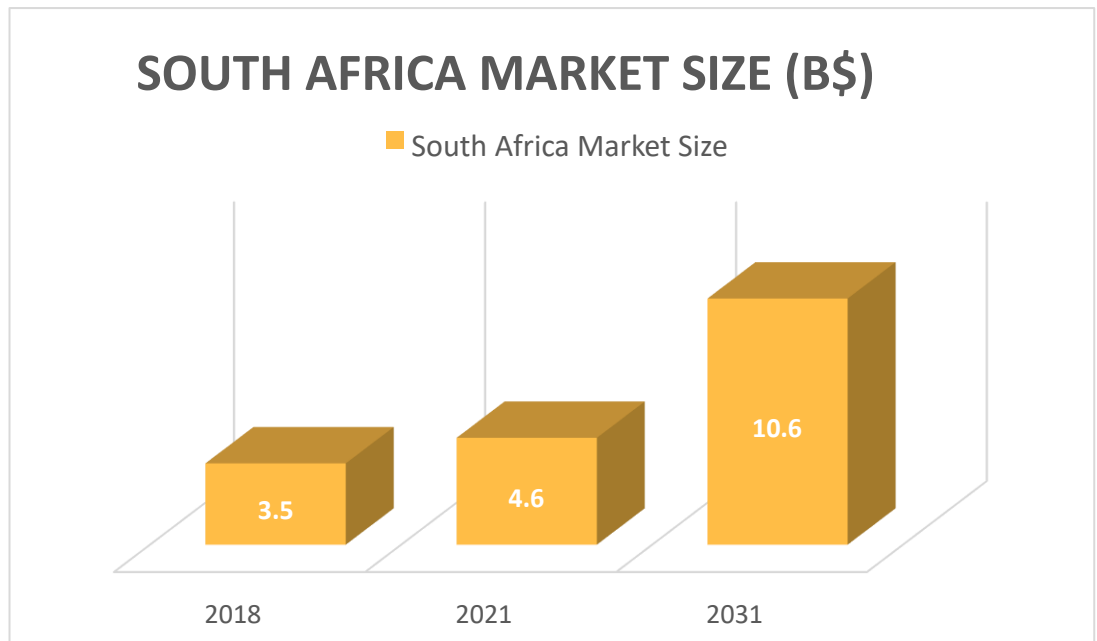


Figure 2: South Africa market evolution

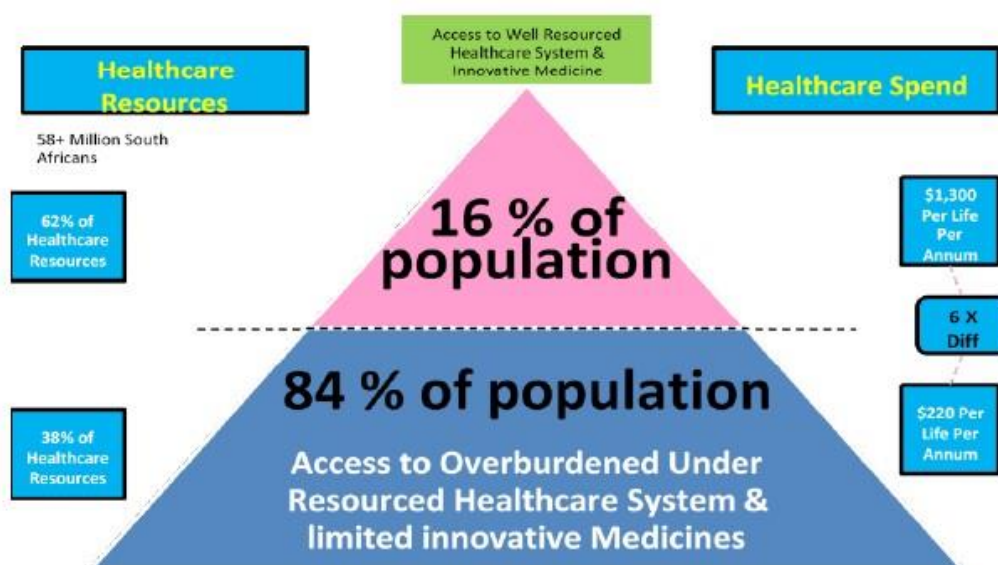


Figure 3: Pyramid of Healthcare system disparity

- Figure 3 shows the underlying issues existing in the healthcare industry of South Africa. Only 16% of the population gets access to well resourced healthcare system and innovative medicines due to their subscriptions with medical aids, whereas the remaining 84% of the population must make do with overburdened and under resourced healthcare system
- The average healthcare expenditure for the top 16% (1300\$ per life/per annum) is 6x more than the annual healthcare spend of the rest of the population (220\$ per life/per annum).
- Another major disparity that can be seen in South Africa is that almost 62% of the healthcare resources in the country cater to the top 16%, whereas the remaining 84% of the population gets access to only 38% of the national healthcare resources.

South Africa Pharmaceutical Industry – Background

1850 to 1993

- Market was run by retail pharmacists – Local agents of MNC's (Aspen – Lennon (1850), Adcock Pharmacy (1890))
- MNC's setup manufacturing units (Mid -20th century)
- Focus on formulations stage was the major problem.
- Only 13% of API's in the market were made locally.

Post Apartheid

- Manufacturing value in GDP dropped from 22% (1990) to 11.8% (2018)
- Manufacturing units – downgraded or discontinued (30%)
- Failed as center of excellence and no economies of scale.
- Local products - 40% domestic (labor, utilities etc) and 60% International (API, packaging, excipients etc).

Import Orientation

- Rise of Indian generics in the SA market – 25-30% of the import market.
- Local companies also have most of their products sourced from India
- More cost-effective: Input costs like water, electricity and labor + high volumes and backward integration of API facilities.

1.2 Regional Overview



Figure 4 : South Africa Provincial Map

- **Gauteng:** Economic and financial center (largest population). Maximum number of hospitals. More non-communicable diseases.
- **Limpopo:** The highest level of poverty, with 78.9% of the population living below the national poverty line.
- **Mpumalanga:** Since 2009, Mpumalanga has seen positive changes in health indicators, with an increase in the number of health professionals and the number of beds.
- **KwaZulu-Natal:** Second most populous state. The lowest life expectancy.
- **Free State:** Births in the Free State continue to fall and stillbirth rates are low. Poor health care for pregnant women.
- **Eastern Cape:** A relatively poor standard of living, with a lower crude birth rate and a higher death rate than the US average.

1.3 Healthcare Statistics

Province	Population (Million)	Hospitals (Public and Private)	Hospital Beds	Medical Practitioners per 1000	Life Expectancy	Crude Death Rate per 1000
Gauteng	14.3	134	36538	0.7	60.7	7
Kwazulu-Natal	11.3	94	22881	0.5	54.1	7.6
Western Cape	6.5	103	20970	0.9	64.4	7.6
Eastern Cape	6.51	108	20970	0.4	56	10.2
Limpopo	5.74	54	8728	0.2	62.7	8
Mpumalanga	4.45	47	5880	0.3	62.7	5.7
North West	3.9	38	7091	0.3	58.5	9.2
Free State	2.94	51	7384	0.4	56.8	10.9
Northern Cape	1.2	20	1810	0.4	61.4	11.6

Table 1: Healthcare Statistics Region-wise

Key Inputs from Table-1:

Category	Highest	Lowest
Total Number of Hospitals	Gauteng	Northern Cape
Hospital Beds	Gauteng	Northern Cape
Medical Practitioners per 1000	Western Cape	Limpopo
Life Expectancy	KwaZulu-Natal	Western Cape
Crude Death Rate per 1000	Gauteng	Northern Cape

Table 2: Highest and Lowest performing regions –Healthcare

1.4 Import Dynamics

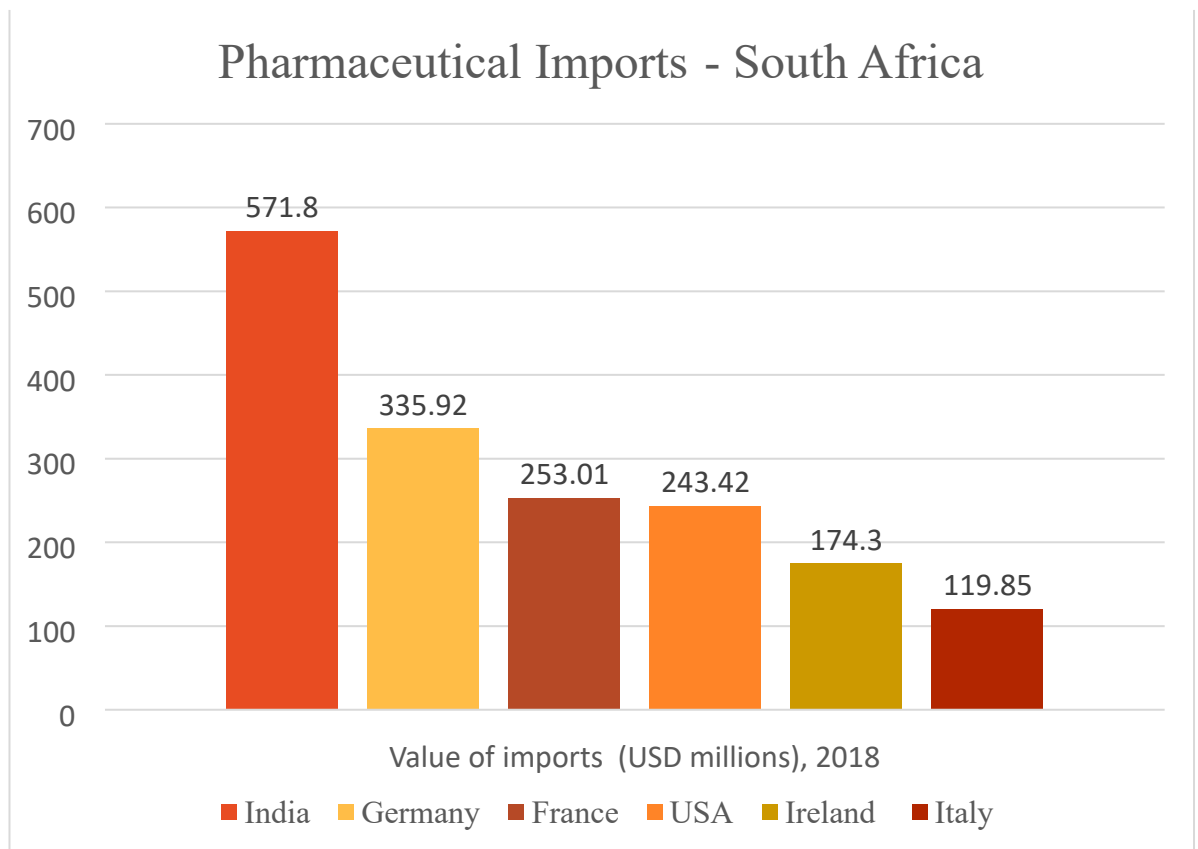


Figure 5: Pharmaceutical Imports to South Africa

- With more emphasis on local production over the last few years by the SA government, India's monopoly in the SA market is expected to diminish.
- The government will try to replace Indian generics by promoting local companies via special schemes included in the tenders.

Import Market Share, 2023

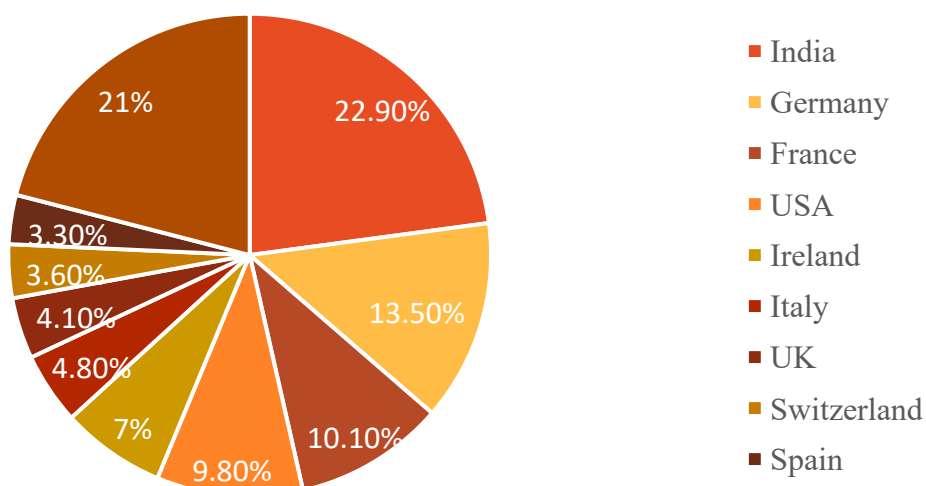


Figure 6: Import Market Share of various countries

- The above chart shows that Indian generics have the highest market share in the country, but the market mainly comprises of innovator molecules from Germany, France, USA etc.

1.5 Private Market Dynamics

Total Sales (USD\$) Split-Channel
Wise: 3.5B\$ (2018)

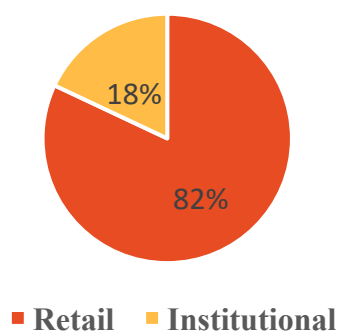


Figure 7: Total sale – Channel Wise

Total Sales (USD\$) Split-
Manufacturer Wise: 3.5B\$ (2018)

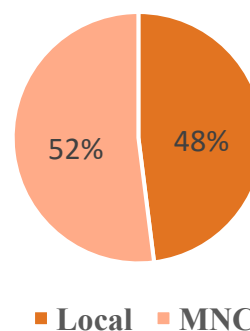


Figure 8: Total Sale – Manufacturer Wise

- Private market products usually sell for anywhere between 3-4x of the price
- quoted at an institutional level.

- The local companies over the past decade have been performing well. But this is not a true representation as most of their products are supplied by Indian companies

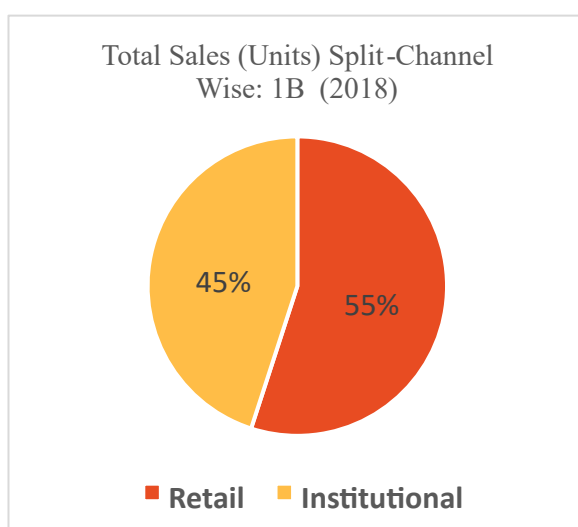


Figure 9: Total Units – Channel Wise

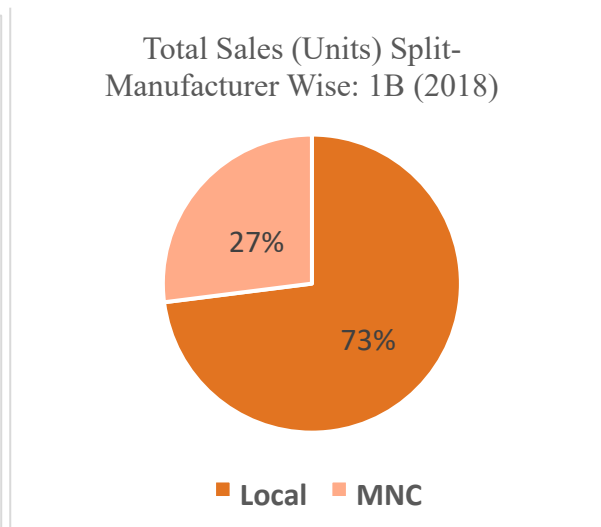


Figure 10: Total Units – Manufacturer Wise

- South Africa as a country floats tenders (HP01-HP16) with high volumes. Hence, making it viable for Indian companies to participate as they have economies of scale.
- Most of the treatment guidelines in SA recommend the usage of innovator/patented products. Whereas local companies usually deal with generics or OTC markets

1.6 Disease Burden in South Africa

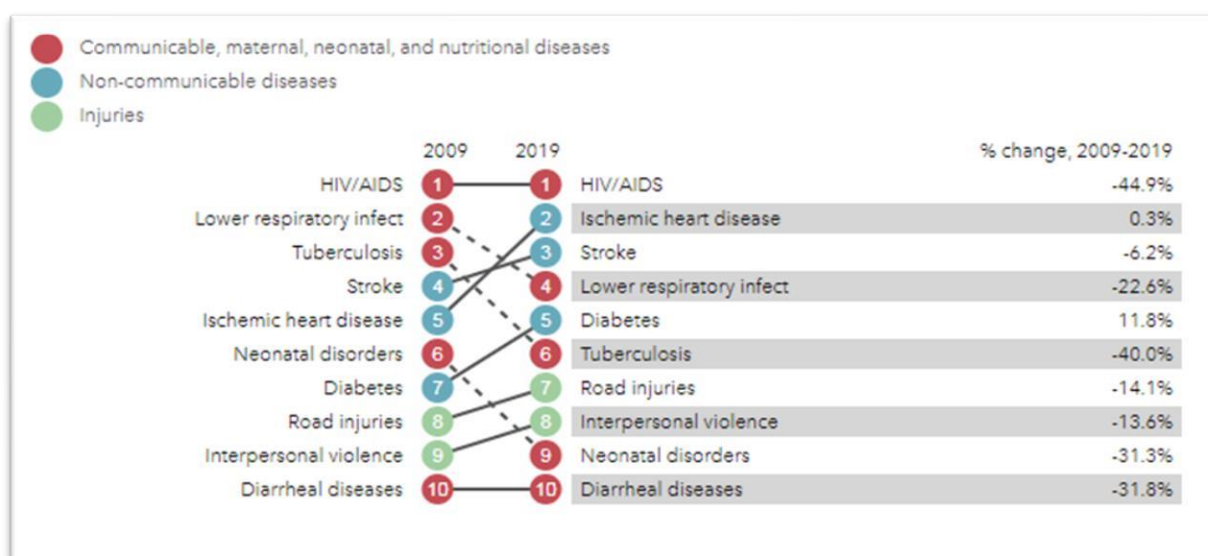


Figure 11: Comparative figure of Disease burden in SA (2009 vs 2019)

- While South Africa's largest killer remains the HIV/AIDS epidemic, nearly 100 South Africans die of heart attacks or strokes each day, although this figure is significantly less than the 1,000 people that are estimated to die of AIDS (Total: 7.7 million as of 2023)

1.7 Healthcare System – Core Challenges

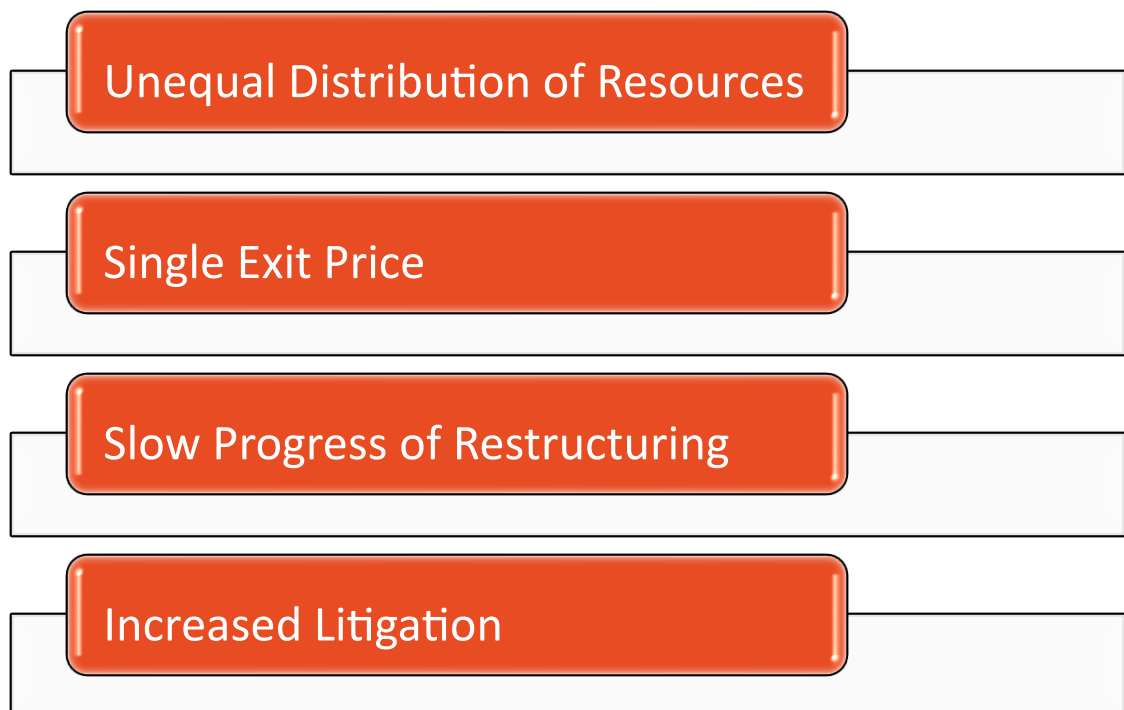


Figure 12: Major challenges faced by the Healthcare system in South Africa

1.7.1 Unequal Distribution of Resources

- Only 16% of South Africans participate in health care programs and are cared for by the private sector. The 16% covered by health care plans consume more than 50% of total health care spending, and the remaining 84% dependent on the under-resourced public sector.
- The MOH also reports that approximately 80% of professionals in South Africa serve 16% of the private sector population.

- Only 72% and 80% of the required medical staff are employed by a very small number of public and private hospitals.

1.7.2 Single Exit Price

- The increase in the single exit price (SEP) level will not adequately cover the cost base of pharmaceutical companies (currency is the main driver).
- For industries that rely heavily on imported materials, SEP prices and annual adjustments do not give manufacturers the flexibility to offset significant exchange rate fluctuations and other cost increases, leading to a steady erosion of margins.

Table 3. Discontinued SKUs classified by the ATC system

ATC classification	n (%)
Anti-infectives for systemic use	848 (22.97)
Nervous system	578 (15.66)
Respiratory system	490 (13.28)
Cardiovascular system	368 (9.97)
Alimentary tract and metabolism	326 (8.83)
Musculoskeletal system	261 (7.07)
Antineoplastic and immunomodulating agents	156 (4.23)
Dermatologicals	138 (3.74)
Genito-urinary system and sex hormones	123 (3.33)
Various	107 (2.90)
Sensory organs	89 (2.41)
Systemic hormonal preparations, excluding sex hormones and insulins	75 (2.03)
Blood and blood-forming organs	67 (1.82)
Antiparasitic products, insecticides and repellents	65 (1.76)
Total	3 691 (100)

SKUs = stock-keeping units; ATC = anatomical therapeutic chemical.

Figure 13: Discontinued SKUs in South Africa

- Close to 3691 SKU's have been discontinued in South Africa since the introduction of SEP.

1.7.3 Slow Progress of Restructuring

- Although equity was high on the agenda of the South African government in a democratic era, little was done to reallocate

resources from the private to the public sector, delaying the implementation of the National Health Insurance 3 (NHI) policy.

- In SA, the government needs to improve infrastructure in the rural areas where some of the primary care centres do not have tap water. Healthcare overburden

1.7.4 Increased Litigation

- Medical malpractice lawsuits against the Ministry of Health have increased, resulting in massive payouts that further squeeze the health budget.
- According to a report showing medical claims paid by the government in each province in South Africa, the total amount paid for legal claims in 2015 was R500 million.
- 4
- The KwaZulu-Natal Ministry of Health leads with total payment claims of R153 million and pending claims to the state of over R5 billion.

1.8 Market Composition

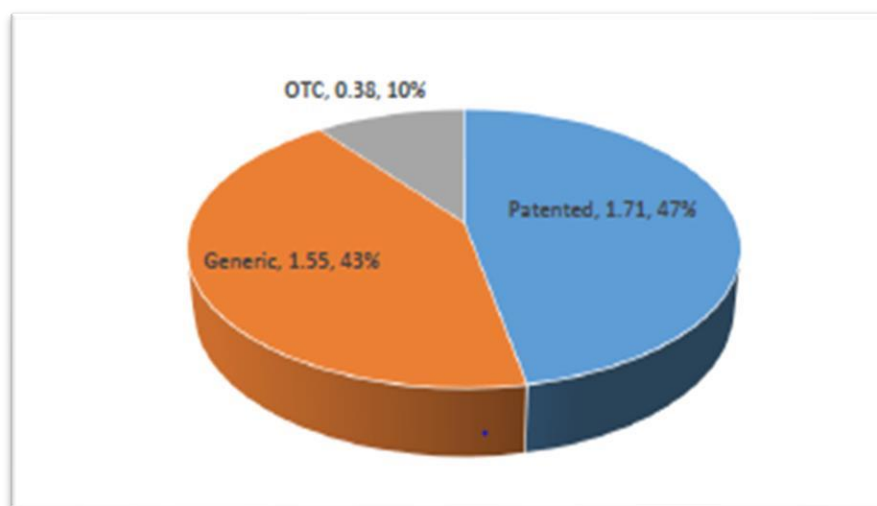


Figure 15: South Africa's market composition in \$Billion

- The market will continue to experience relatively high generic drug penetration rates as in the recent past, and generic drug revenue growth is expected to outpace the branded drug market over our 10-year forecast period.

- The focus on cost containment, along with a growing middle class and a disposable price structure and the government's push for local manufacturing in South Africa is driving demand for generic drugs.

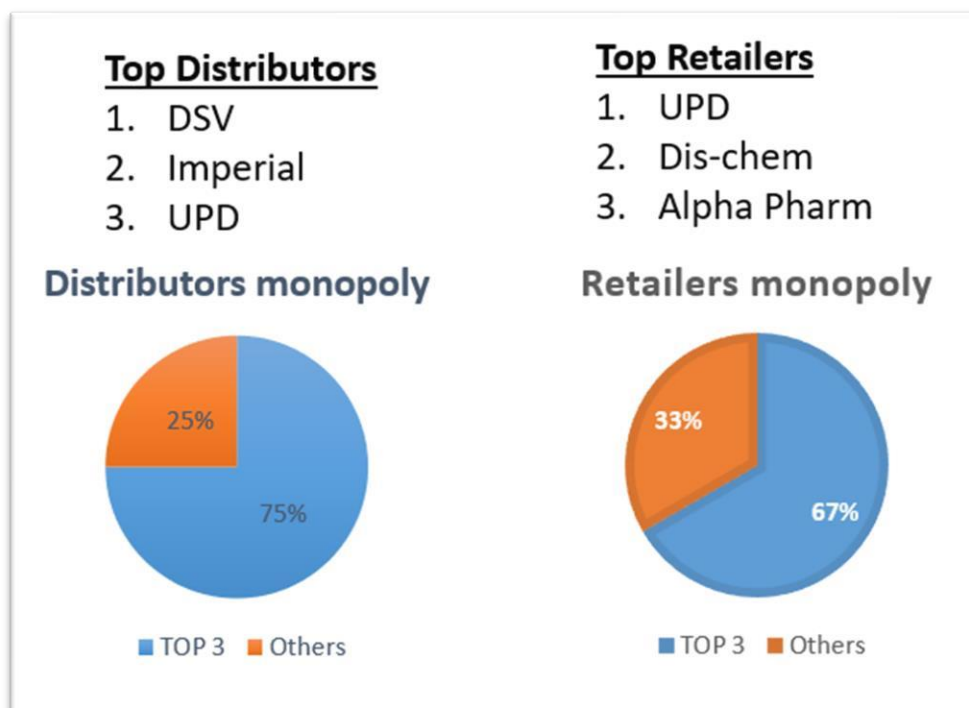


Figure 15: Pie charts demonstrating the Retailer and Distributor monopoly

- The above figure shows that the private market in South Africa has a huge monopoly of selective players, which allows them to put downwards pressure on prices quoted by pharmaceutical companies.

Goals:

- To understand the South Africa market from a broad perspective before I start with portfolio specific work.
- To get brief idea about the disease burden, healthcare infrastructure and the local market.
- To understand the core challenges faced by Indian companies from a market entry and regulatory perspective.

2. In-depth Analysis of Market (Location: Johannesburg)

Aim: To work with the Brand Managers based out of Vivimed SA office which is in

Johannesburg and understand specifics with regards to the value chain, regulatory pathways, granular level analysis, regional dynamics in South Africa.

Methodology:



Figure 16: Value Chain of South Africa Private Market

2.1 Medical Aids

- The medical aids in SA covers 8.87 million beneficiaries, approx. 14% of the total population.
- In total the country has 80 medical aids, top 15 accounts for 84% of all members.
- 21 are open schemes, means anyone can join these medical aids.
- 59 are closed schemes, mostly either company/industry specific or group specific.
- Most schemes cover hospitalization cost and in-clinic cost including medicines.
- Maintain PMBs (Prescribed Minimum Benefits)
- Top Medical Aids based on their schemes are listed below in the table:

Medical Aids	Schemes	No. of Beneficiaries	Beneficiaries
Discovery Health	Open Scheme	2.80 million	Open for all
Bonitas	Open Scheme	0.82 million	Open for all
Momentum	Open Scheme	0.30 million	Open for all
GEMS	Closed Scheme	1.81 million	Govt. Employees
Polmed	Closed Scheme	0.52 million	Police Dept
BankMed	Closed Scheme	0.22 million	Bank Employees

Table 3: Medical aids and their details

2.2 Fund Administrators

The Fund Administrators support Medical Aids with the followings:

- Collecting contributions from the members of the scheme
- Paying the claims of beneficiaries on behalf of the scheme
- Dealing with members and their queries regarding the scheme
- Liaising with health service providers who service beneficiaries of the scheme
- Negotiating rates with such providers on behalf on the medical scheme
- Maintaining information system and databases

Main Fund Administrators in SA:

Fund Administrator	Medical Aids	Keys Focus	Key Service Providers
Discovery	Discovery Health	PMBs, Very Low Prices	Mostly Retail Chains
MMAF (Medikredit)	Mostly all open schemes	Lower Prices	Retail chains, Independent Pharmacies
MPL (Medscheme)	Mostly Closed schemes like GEMS, Bonitas and PolMed.	Availability is Key, hence prices higher than MMAF	Mostly courier pharmacies

Table 4: Fund Administrators and their key services

2.3 Courier Pharmacies (CPs)

- The CPs mainly focus on chronic therapeutic areas.
- Fund Administrators share the Rx's and contact details of the scheme's beneficiaries with CPs.
- CPs dispatch the monthly packs directly to the patient's given address.
- The CPs claim the cost from the Fund Administrators.
- Manufacturers provide a marketing fee (discounts) to the CPs which is purely competition driven.
- However, Rx's with the manufacturer brand name is key to negotiate for a smaller discount.
- After many years of operations and consolidation, there are 3 main CPs in the country.

Courier Pharmacies	Fund Admins	Remarks
MED Express	Discovery	Only Discover
Medi Post	MMAP, MPL	Mostly MPL, prefer higher prices
Pharmacy Direct	MMAP, MPL	Mostly MPL, prefer higher prices
Dis-Chem Direct	Discovery	Owned by Dis-chem
Direct Medicine	Discovery	Owned by Clicks, small in size

Table 5: Courier Pharmacies and their dynamics

2.4 Retail Chains:

- Dis-chem and Clicks are the 2 biggest Retail Chains in SA. Combined they control almost 55% of the retail market.
- Others are part of the Departmental Stores present across the country e.g., PnP Pharmacies, Medirite with Checkers and Spar Pharmacies.
- The number of independents is either shrinking or getting acquired by the Retail Chains.
- The front shop business (FMCG, Lifestyle, Personal Utility items) is key.
- In Rx business, they focus mainly on Cash Patients (patients without medical aid), OTCs and Patients on Chronic medication.
- They all have their own wholesalers or designated wholesalers to procure the stock.

- The manufacturers compete for the shelf space and thus provide marketing fees (discounts).
- First to Market, OTC and a Basket of Products is key to get a shelf space followed by discounts offered.
- Non-availability of stock is detrimental, may result in de-listing.
- With Discovery they also operate their in-house CPs at a lower price due to the discounts from the manufacturers.
- They also have their in-house brands usually offered by the manufacturers to get a shelf space.

2.5 Independent Pharmacies

- The number of independent pharmacies has gone down significantly in the last 5 years.
- With minimal/zero discounts from the MFGs they struggle to keep the complete range of stock resulting in lower foot falls impacting both Front Shop as well as Rx business.
- Many of the independent pharmacies have been acquired by the retail chains.
- Others, mostly created independent pharmacy groups along with Wholesalers to survive.
- Examples of the groups and their geographical presence in the country: Alpha Pharm (Nationally), Arrie Nel (GP). TLC (GP), Sparkport (KZN) and Essential Health (WC).

2.6 Private Hospital Pharmacies

- Three large corporate chain of hospitals in SA:
 1. Medi-Clinic
 2. Life Healthcare
 3. Netcare
- Each of these hospitals have their in-house pharmacy mostly catering to in-hospital patients.
- All purchases happen through central procurement office (CPO)
- Every year the CPO enlists selected companies and their products with a commitment to make certain volumes available at all time.
- The usage of ARVs is purely for HIV patients undergoing treatment.

2.7 Mining Companies

- The big mining companies provide Medical Aid support to their workers like:

1. Anglo American
 2. Exxaro
 3. BHP Billiton
 4. Kumba Iron Ore Ltd.
- These mining companies prefer low-cost products usually with MMAP approved reimbursement price. Some of them maintain their own formulary.
 - Tenofovir-Lamivudine-Emtricitabine (TLE) has been moving well within the mining companies as it was positioned at a lower cost compared to TenofovirEfavirenz-Emtricitabine (TEE).
 - However, with the TEE prices already below the TLE prices, the advantage will be lost soon.
 - Apart from the price, regular meetings with the procurement manager/ in-house doctors are key.

Goals:

- In-depth understanding about the value chain in SA market (Retail and Courier sales – pathway)
- Understanding the healthcare system with emphasis on Medical Aids in SA, and how they undertake the complete process of reviewing a medical prescription.
- Working with ARV and Oncology brand managers to understand the market trends and prescription trends of doctors in different regions.

3. South African DoH – Tender Analysis

Aim: To analyse various tenders that are floated by the Department of Health – South Africa, and suggest the team various high potential molecules which Vivimed needs to have in product basket for the next tender cycle.

Methodology:

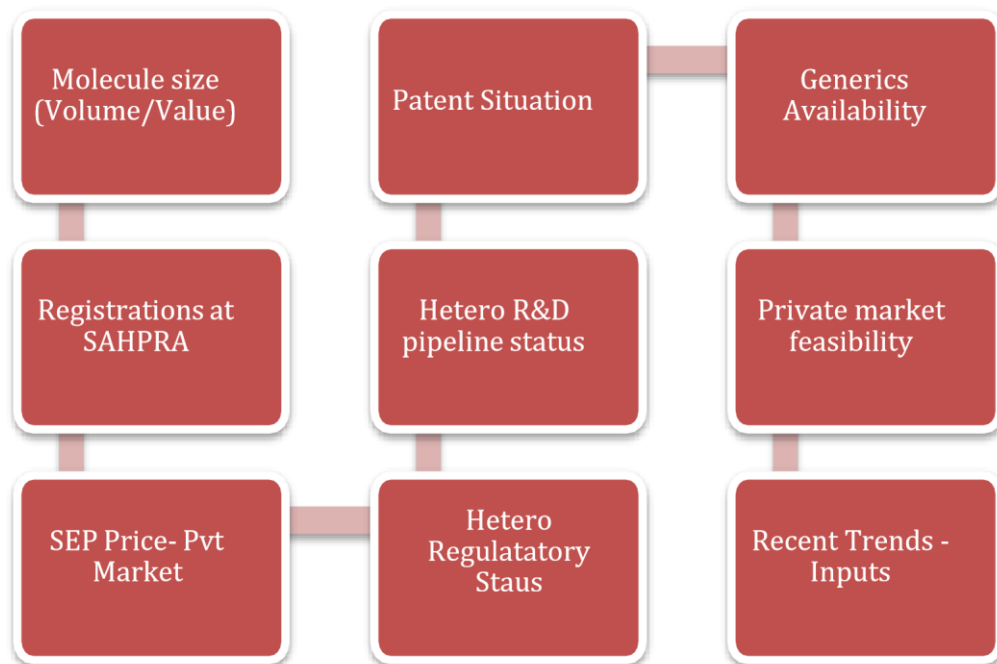


Figure 17: Process of Tender Analysis.

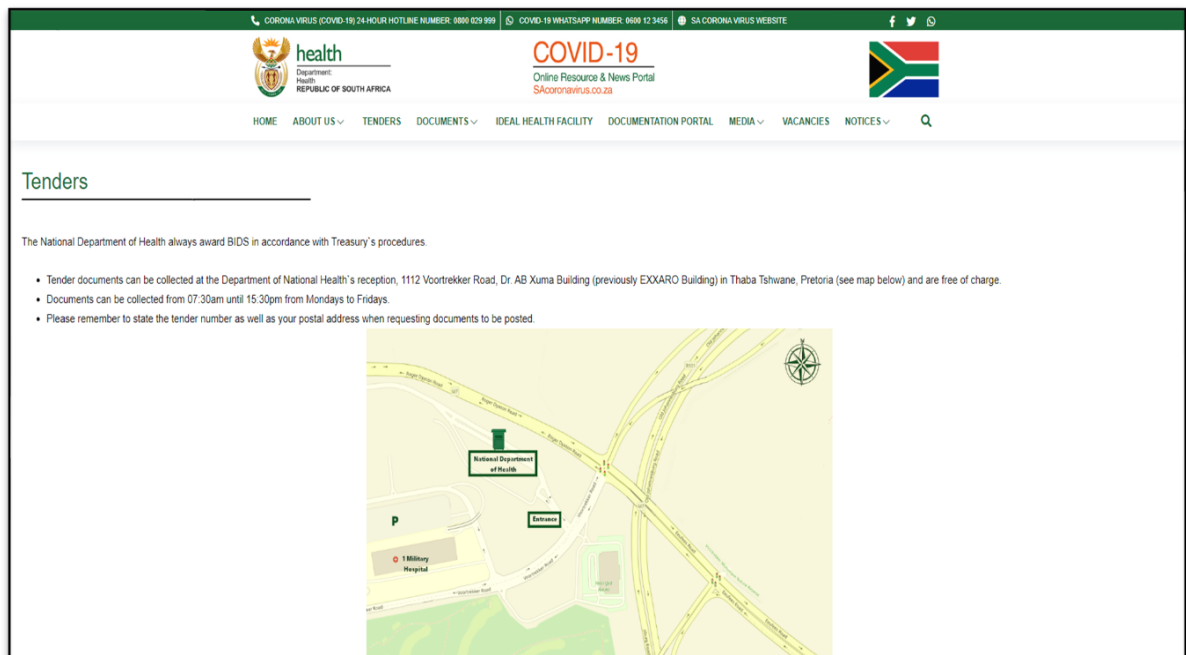


Figure 18: South Africa DoH Website _ Tenders Page

TENDER NO	DESCRIPTION	BULLETIN DATE	CLOSING DATE
HP03-2023CHM	Supply and Delivery of contraceptives and hormone modulating agents for the period 1 October 2023 to 30 September 2026. 1. Invitation to bid – 16 September 2022 2. Final Bid Pack – 16 September 2022 3. Annexure A – 16 September 2022 4. PBD9 Directors Categorisation – 16 September 2022 5. Final BidResp – 16 September 2022	16 September 2022	14 November 2022 @ 11.00am
HP02-2023AI	Supply and Delivery of Anti-Infective Medicines (Antibiotics, Antifungal, Antiprotozoal and Antiviral Agents) for the period 1 October 2023 to 30 September 2025 1. Invitation to bid – 16 September 2022 2. Final Bid Pack – 16 September 2022 3. Annexure A – 16 September 2022 4. PBD9 Directors Categorisation – 16 September 2022 5. Final BidResp – 16 September 2022	16 September 2022	14 November 2022 @ 11.00am

Figure 19: Latest tenders released on the DoH website

Contract	Medicine Pack short Description	Supplier Name	Price	Quantity Awarded	Split %
HP01-2021TB	Ethionamide; 250mg; Tablet; 28 Tablets	Macleods Pharmaceuticals SA (Pty) Ltd	69.35	3775	100
HP01-2021TB	Rifampicin, Pyrazinamide, Ethambutol, Isoniazid; 150mg, 400mg, 275mg, 75mg; Tablet; 84 Tablets	Macleods Pharmaceuticals SA (Pty) Ltd	153.65	333200	50
HP01-2021TB	Clofazimine; 100mg; Tablet; 100 Tablets	Novartis South Africa (Pty) Ltd	948.75	70940	100
HP01-2021TB	Rifampicin, Isoniazid; 300mg, 150mg; Tablet; 56 Tablets	Macleods Pharmaceuticals SA (Pty) Ltd	85.93	293985	30
		Macleods			

Figure 20: Glimpse of the Master sheet for Tender Analysis

Goals:

- Identify high potential molecules for each tender category and suggest portfolio strategy for next tender cycle.
- Identify First to File opportunities for the next 5 years.
- Suggest molecules which are needed in the product portfolio from both, private and institutional viability perspective.
- Segregate various molecules based on their viability for only tender, only private and both the markets.

4. Algerian Market Overview

4.1 Details:

Understanding the Algerian Pharma Market in-depth by conducting secondary research. This was the second project assigned to me which was aimed to gauge my understanding about the dynamics of a military run market such as Algeria. I used various research articles, blogs, and various other online sources to make a presentation on the same.

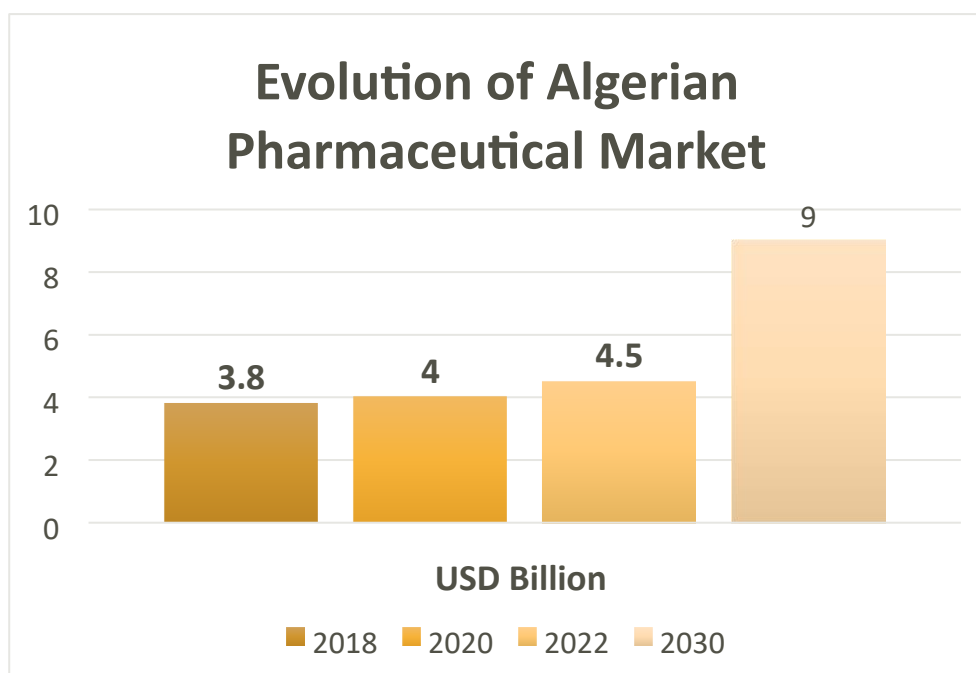


Figure 21: Market Evolution – Algeria

- The growth of local production increased from 25% in 2008 to 65% in 2023.
- Algeria consumes about 80% of innovative medicines, so about 85% of the market is supplied by imported medicines.

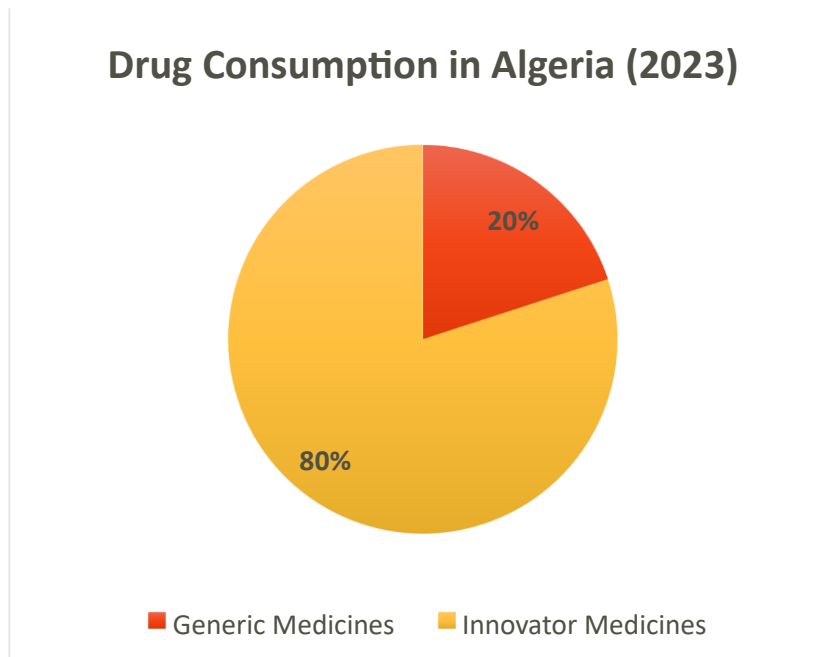


Figure 22: Drug Consumption in Algeria – Pie Chart

4.2 Disease Burden

- There has been a rise of non-communicable diseases in Algeria, which presents an opportunity for global players like us to enter the market with robust solutions while the health care policy makers are facing difficulty to tackle the same.

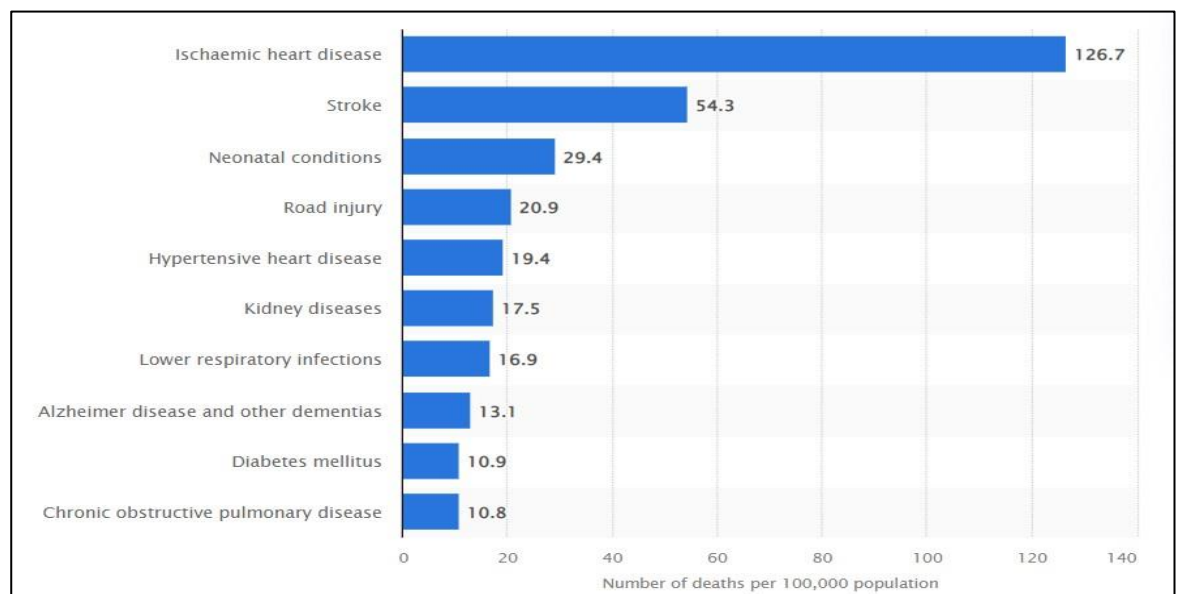


Figure 23: Leading Causes of Death in Algeria, 2023

4.3 Economic Context

- Algeria's economy has always been a rentier economy with an increasing dependence¹ on hydrocarbons.
- Since 2014, Algeria's economy has suffered from two limitations. Declining hydrocarbon prices in global markets resulted in lower oil and gas production and sales.¹
- A new health law was promulgated in July 2018. The law aims to restructure the health system, aims to increase the role of the private sector by strengthening it a, replenishing public sector resources and meeting the growing demands of the population.

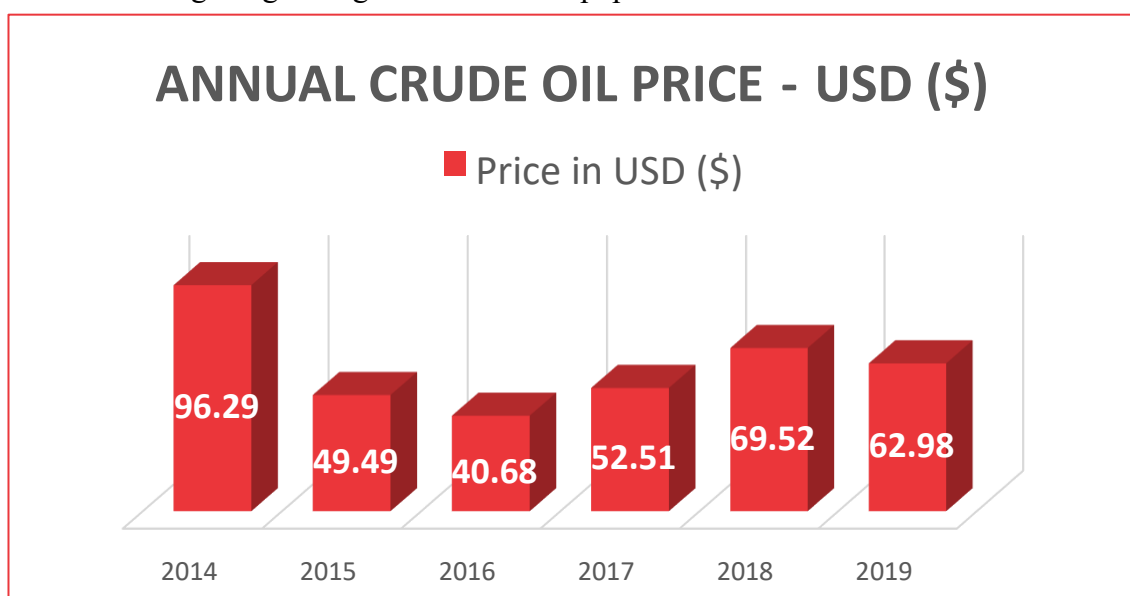


Figure 24: Fluctuation of Oil Price in the Global Markets

Note:

- From 2014, the inflation rate has continued to soar from year to year. According to the IMF in its April 2018 report, inflation would be 7.4% in 2018 and 7.6% in 2019.

4.4 Why Algerian Market?

- Its rapid population growth (1.8%, Morocco: 1.2%) and dynamic transition make it a good choice compared to other Maghreb countries.
- Algerian market is growing at a fast pace, which is not in countries like Morocco and Tunisia.
- Algeria is one of the few countries in the Northwest African cluster that participates in public-private partnerships focused on patient and physician education, a testament to Algeria's vision.

- The Algerian market is large and combined with the maturity of its healthcare system makes it a strategically and commercially viable market.
- Algeria today accounts for 45% of sales in the France-Africa market and is an undisputed huge market for its strategic importance as an interface between north and south.

4.5 Recent Trends – Rise of Local Companies

- The national authorities provided 70% of the national demand for drugs and proposed the development of local production of all types of drugs.
- The pharmaceutical industry raised by 27% in recent years, a rate unmatched by any other sector in Algeria (2008: \$473 million to 2017: \$2 billion).
- Import costs fell from \$5 billion in 2008 to \$2 billion in 2018 (Kerr, 2018).
- Half of the top 15 companies operating in Algeria are local Algerian brands. Other major players: Pharmalliance, LDM Maghreb Diagnostic Laboratories, HUP Pharma, and others.

- Top Algerian local pharmaceutical players include:



Figure 25: Logo's of top local pharmaceutical companies in Algeria

4.6 Major Players in Algeria



Figure 26: Top 20 Pharma companies in Algeria

- Out of the top 20 companies which are active in Algeria, 1/3rd of the companies are Local Algerian labels.
- Most of the MNC's have strategic alliance in the form JV or in-licensing agreement with the local players. Few of the strategic alliances include:
 1. Hikma and Dar Al Dawa
 2. Jamjoom and HUP pharma
 3. Eli-Lilly and Sidal
 4. Cipla and Biopharm (Respiratory portfolio)
 5. Alembic and Adwiya Mami

4.7 Strategies being adopted by Local Companies

- Smart positioning in the value chain

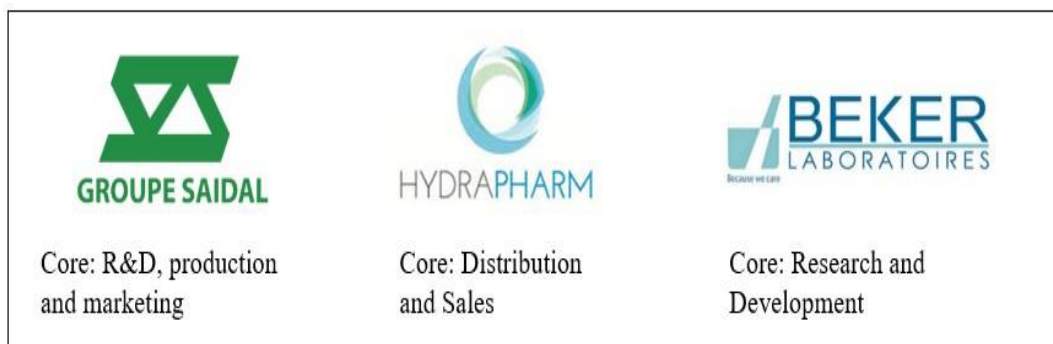


Figure 27 Local Companies and their Core Competency

- Optimize business models by working with global pharmaceutical companies (individual or synergistic)
- Intelligent selection of activities to be kept in-house (core and non-core) from those to be outsourced
- We understand the importance and value proposition as a local player in this market through various initiatives and incentives for Algerian brands.

4.8 New Regulations in Algeria

Since the adoption of the Action Plan by the Ministerial Meeting on 12 July 2020, a review of the regulatory framework has begun and the Ministry of Pharmacy has published more than 40 regulatory documents. Importantly, the distribution and registration of pharmaceutical products.

- It will save around 800 million euros in revenue in 2021. Manufacturer status is now available for companies that outsource manufacturing.
- If a company in the issuing country has a registration permit, it must designate an “operator. Promotion of exports through various incentives, such as exemption from the 49/51% rule.



Figure 28: Main changes in Regulations for Pharmaceutical Industry

- Import of Medicines:
 - a. A new set of technical conditions for import services was announced on February 14, 2021.
 - b. One of the most important measures is to limit the import of pharmaceutical products to factories that have a factory license.
 - c. One of the purposes of the new standard is to limit imports to essential products that are not locally or locally produced.
- Manufacturing Activity:
 - a. The new policy in the pharmaceutical industry aims to meet 70% of the country's pharmaceutical demand by boosting local production and reducing import costs.
 - b. The new rules allow not only establishments with manufacturing facilities to obtain producer status, but also establishments that outsource one or more manufacturing operations to other manufacturers.
 - c. However, it remains to be seen whether these institutions that do not have a place of production being recognized as a manufacturer and outsourcing products can have the same rights as a manufacturer that owns a site.
- Registrations of Products:
 - a. From a regulatory point of view, a holder of a registration certificate in Algeria can now only be a pharmaceutical manufacturing facility or an organization that has been authorized to sell in the country of manufacture.

- b. If the registration certificate is held by a company in the issuing country, it is mandatory to submit the registration certificate form to the local representative.
 - c. This local agent must be an Algerian commercial company recognized as a Ministry of Pharmaceutical Industry operator.
 - d. The holder of the foreign registration card and the operator are jointly responsible for the marketing of the product.
 - e. As per the trend, Ministry of Pharmaceutical Industry has announced its intention to prioritize the registration of generic drugs and similar biotherapeutics to combat the monopoly situation.
- Liaison Offices:
 - a. Minister of Commerce does not allow foreign or local pharmaceutical companies to establish liaison offices, whether new or existing.
 - b. Market research activities in Algeria must be conducted within an MBI approved medical promotion company.
- Export Promotion:
 - a. Algeria wants to increase drug exports, especially to Africa. On 25 April

2021, the country ratified an agreement on the establishment of the African Medicines Agency (AMA) to enable greater trade in medicines between African countries.

4.9 Reimbursement System in Algeria

- It will save around 800 million euros in revenue in 2021. Manufacturer status is now available for companies that outsource manufacturing.
- The number of Chifa cards is now 14 million and since their introduction in 2007 they provide social security for over 39 million Algerians (90% of the population).
- Published in the Official Gazette, the decision authorizes employees to enrol in the third-party payment system of the NSIF. This paved the way for 100% reimbursement of medical expenses and medical expenses instead of 80%.

- The share of insurance sales for all types- 60.1% of the Algerian market, share of prescription sales- 78.2%. Surprising signs of self-healing; Especially after the development of online "stethoscopes" and the prevalence of "virtual doctors". Disclosure of information on the Internet could have a greater impact on the pharmaceutical market of the future.



Figure 29: El Chifa card – Algeria

4.10 Plan Ahead - Vivimed

For unique/innovative molecules

- This is for the private marker. We can get our products registered under the import program. And also for the (X-a/X-b) international tender list.
- Viability is key here. But this is a short lived option, because if local player enters with same molecule, they will get more priority (Pricing and allocation)

Find new molecules in the X-b list

- X-b list consists of molecules which are not yet registered in the Algerian market.
- So find molecules which are in the X-b list which are/can be a part of our product portfolio and shift that given molecule from X-b to X-a list (Fast registration and preference)

For molecules not made by Local players

- According to the new regulatory texts of the Algerian authorities, a company can be called a manufacturer if they can conduct 1 step of the manufacturing process.
- We can target products which are not made by local players, get re-packaging registration approval – Register ourselves in the Local player tenders and export the product from Algeria.

For new portfolios – Local player benefits (Algeria and Export)

- Find budding pharma companies/contract manufacturing companies which are looking to build their portfolio in a specific therapeutic segment.
- Help the company in their establishment of manufacturing unit (economical or technical), and get your complete portfolio manufactured by them. Can avoid JV in this scenario, and also be a part of the new export relations being built by across Africa

Regulatory pathway based strategy:

- The new registration approval timelines (Response to initial request (1 month) + Appointment dates (1 month) + Dossier Evaluation (4-5 months).
- Register several products which are specifically for International companies, and compete in this space with a bigger product basket. Emphasis on products that cannot be made by local players. Risk of competing with other Indian companies

Strategic Alliance for a specialized portfolio :

- Enter into a Joint Venture with a local player for a specific therapy area which has viability on a national tender level and also possible export opportunities that might be given.
- 27% price markups can be availed, and can be better placed than most of the global players without any strategic alliance in Algeria

4.11 Portfolio Analysis

International Company Portfolio

A strategy which will completely focus on molecules which are not manufactured by local manufacturers and has limited competition from external MNC's (Xa and Xb List specific)
Resources Needed: Tender documents, IQVIA-IMS data, registration data of overall market, Regulatory and market guidance and EXIM data.

Local Company Portfolio

Will try to shortlist high potential molecules considering the possibility considered as a local player via repackaging/JV/Contract Manufacturing.

Mapping with current product portfolio and R&D pipeline by considering the usage of all the local player benefits and price markups.

Conclusion:

Over the course of last 3 months, I have learnt a lot about the intricacies of South African and Algerian pharmaceutical market. Building a portfolio strategy for two countries that are so dynamic and different was one of my biggest takeaways. This project allowed me to understand how the regulatory pathways in each country differ and how important it is to be ahead of others in terms of entering the market at the right time. Overall, this project has been very insightful and will help me in my future endeavours.

References:

- Vivimed Official Website: <https://Vivimed.com/>
- <https://www.globaldata.com/store/report/south-africa-healthcare-regulatory-andreimbursement-analysis/>
- <https://www.fitchsolutions.com/pharma-healthcare/multinational-drugmakers-willcontinue-use-south-africa-hub-access-ssa-26-01-2022>
- Pharmaceuticals Export Promotion Council of India Report, 202112
 - https://link.springer.com/chapter/10.1007/978-1-349-08434-0_4
- IQVIA Report on MEA Region Overview, 2022.
- Akullian A et al. Large age shifts in HIV-1 incidence patterns in KwaZulu-Natal, South Africa. Proceedings of the National Academy of Sciences 118: e2013164118, 13 July 2021
- Evaluating the impact of single exit pricing (SEP) on medicine product withdrawal from the private healthcare market in South Africa, 2014
- Africa Health Report: Healthcare Market Insights for South Africa

5. OVERALL PHARMA LANDSCAPE – LATIN AMERICA (COLUMBIA)

The pharmaceutical industry in Latin America is experiencing robust growth, marked by a significant market size of US\$136.5 billion in 2024, with an anticipated Compound Annual Growth Rate (CAGR) of 9.7% until 2026. This growth is outpacing other global regions and is attributed to rising healthcare service demands, an expanding middle class, and the development of innovative products like gene therapies and biologics.[1]

a) Pharmaceutical Contract Manufacturing and Research Services Market:

The Latin American pharmaceutical contract manufacturing and research services market, valued at USD 22.50 billion in 2022, is expected to grow to USD 40.3 billion by 2030, with a CAGR of 7.46% from 2023 to 2030. Brazil, the market leader with 69.44% share in 2021, benefits from its biotechnology hub, GMP-certified plants, and low manufacturing costs. Key growth drivers include drug shortages, increased competition, budget constraints, resource limitations, and patent expirations. Leading companies in this market are Catalent, Pfizer, Jubilant Lifesciences, and Boehringer Ingelheim.

b) Key LATAM Markets:

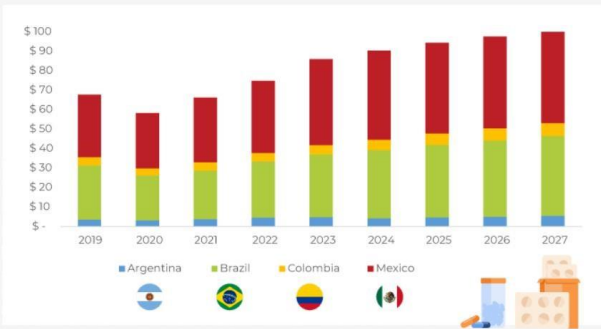
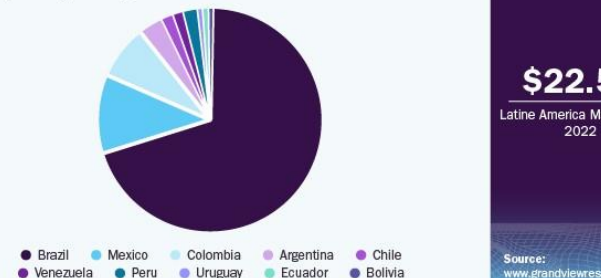
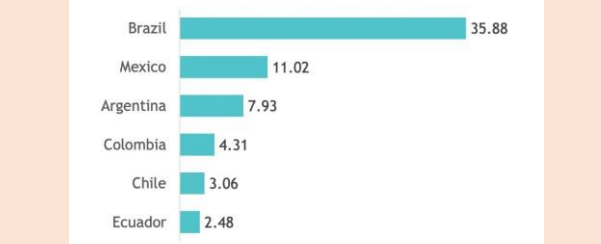
The four key pharmaceutical markets in LATAM are Mexico, Brazil, Argentina, and Colombia. Combined, these markets are projected to reach US\$90 billion in 2024, with an annual growth rate of 3.7% (in dollar terms) expected until 2027, reaching a total value of US\$101 billion.[1]

c) Factors Driving Market Growth:

Innovation is a key driver that contributes to the economic landscape of Latin America. It is marked by the diffusion of knowledge, cost reduction, and high-quality standards, is boosting the economy. This is evident as technologies and medicines have not only improved patient diagnosis but also fostered economic growth.

STATS

REFERENCES

	2019-2027: Pharmaceutical sales (US\$bn) for select LATAM economies  Source: EIU		[1]
	Latin America Pharmaceutical Contract Manufacturing & Research Services Market Share, by Country, 2022 (%)  Source: www.grandviewresearch.com	\$22.5B Latine America Market Size, 2022	[2]
	Sales Volume of Pharmaceutical Industry, In Billion Units, In Selected Latin America Countries, 2019 		[3]

Economic Impact of the Pharmaceutical Industry: For every U.S. dollar from the pharmaceutical industry, an additional 70 cents are generated in other sectors of Latin America's economy.

Job creation in the pharmaceutical industry results in the generation of 1.7 additional jobs elsewhere. **Quality of Life and Consumption:** Despite a relatively small share in gross value added and employment, the pharmaceutical industry significantly raises salaries (5x in clothing, 1.6x in beverages, 1.2x in telecommunications).

This boost in salaries enhances the quality of life and consumption levels in the broader economy **Demand for Healthcare Services:** The increasing demand for healthcare services is a primary driver of pharmaceutical industry growth in LATAM.

Middle-Class Expansion: The expanding middle class contributes to greater affordability and accessibility to pharmaceutical products

REGIONAL OVERVIEW: The Colombian **Pharma Market**

Aspect	Information
Market Size and Employment	Colombia's pharmaceutical industry constitutes around 1.5% of the country's GDP. - The industry employs over 47,000 people.
Manufacturing and Import Dynamics	Local drugs account for 80% of all units sold. - However, they contribute only 33% to the total revenues. - Colombia heavily relies on imports for pharmaceuticals.
INVIMA's Report (June 2023)	INVIMA reported 36 out of 214 medicines were out of stock. - Causes include increased demand, contracting restrictions, delivery issues, bureaucratic factors, production problems, and lack of timely information, exacerbated by the COVID19 pandemic.
Growth Prospects and Productivity	Despite recent shortages, the industry has become 35% more productive. - Four state-of-the-art production plants are under construction, including a vaccine production plant in Bogota, BogotaBio, operated by China's Sinovac.
Transportation Spending Estimate	AMI estimates transportation spending at US\$240 million in 2023, with an expected annual growth of 8% through 2027.

[1]

According to an IQVIA report from 2018 following are the challenges and strategies being employed in Colombia to achieve Healthcare Sustainability:

Universal Health Coverage (UHC) in Colombia: Established UHC in 1993 with Law 100 and reinforced health as a fundamental right through a statutory law in 2015.

Healthcare Challenges in Colombia: Colombia faces challenges related to constrained or reduced healthcare budgets despite increasing demand for healthcare services and technologies. The country is dealing with a challenge concerning health expenditure growth. Currently, health expenditure as a percentage of GDP is 6.2%, below the OECD average of 9.1%.

Strategies for Sustainable Healthcare in Colombia: Sustainable healthcare systems in Colombia involve strategies aimed at growing GDP and improving allocative efficiency.

GDP Growth Approaches in Colombia: In Colombia, GDP growth strategies such as technology transfers and local partnerships within the private sector are seen as highly impactful and feasible to replicate.

Allocative Efficiency Approach: An allocative efficiency approach, particularly the integrated healthcare model, is considered relevant for addressing challenges in Colombia.

Public-Private Cooperation in Colombia: Public-private cooperation, involving partnerships and innovative contracting and reimbursement models, is crucial for sustainable healthcare. However, the troubled past relationship between the pharmaceutical industry and governments needs to be overcome.

Feasibility and Replicability: The feasibility/replicability of GDP growth approaches, especially technology transfers and local partnerships, is assessed as high for Colombia.

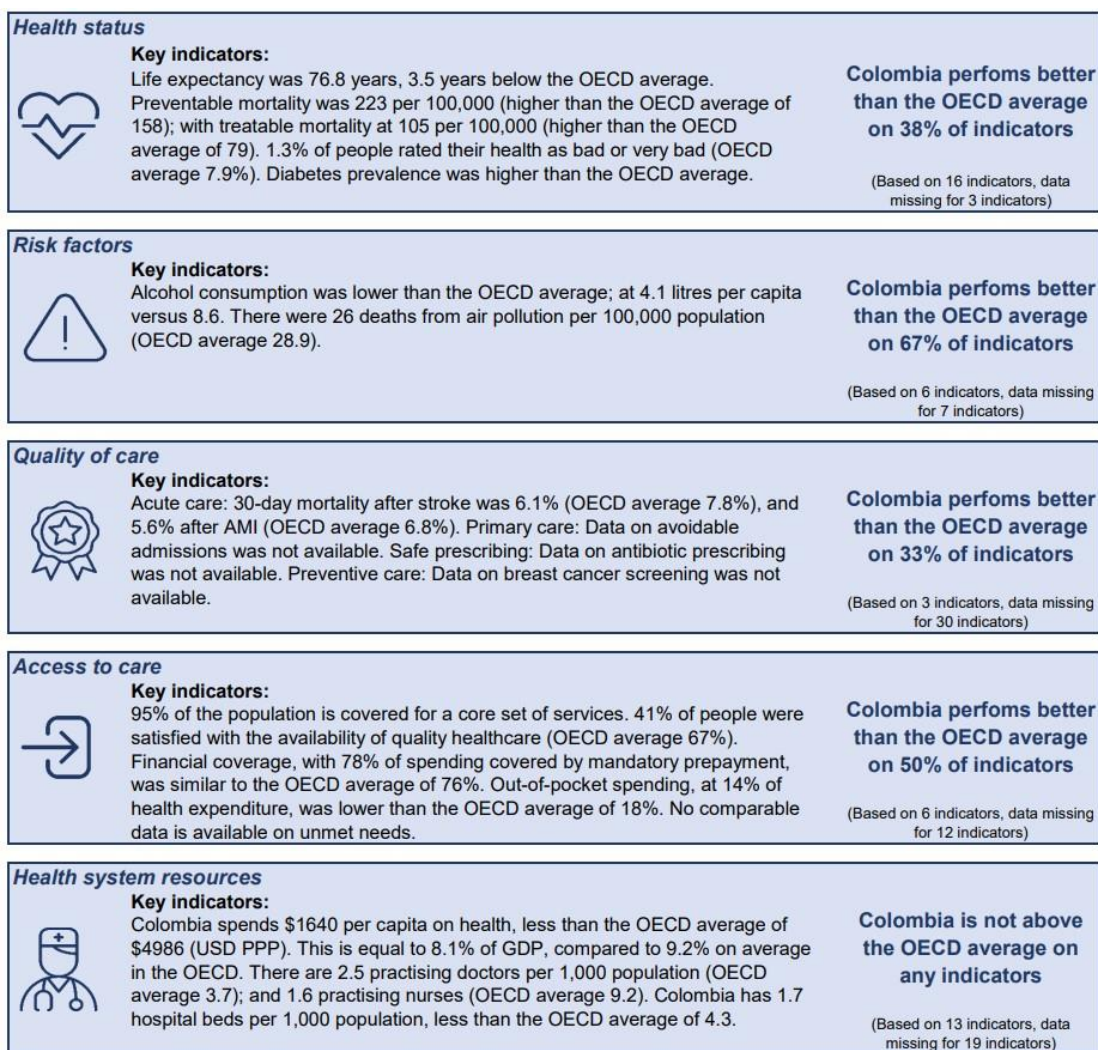
Key players:



HEALTHCARE STATISTICS

Colombia has a stable and attractive health system. With a population of 50 million, it is the third most populous country in Latin America (after Mexico and Brazil), and 95% of the population is insured under the General Social Security Health Care System (SGSSS, Spanish acronym). Colombia ranks third in public spending on health care in the region, with 63% of total spending being paid for by public funds and the remaining 36% being paid for by the private sector. Total health spending in 2019 was \$21.6 billion. By 2028, health spending will increase from 6% in 2018 to 7.3% of GDP, and per capita spending will increase from \$417 in 2018 to \$757 in 2026.

In the OECD Health at a Glance 2023 Country Note, it was seen how Colombia compares to other OECD countries across indicators in the report.



[7]

[For additional info, refer to supplementary material (1)]

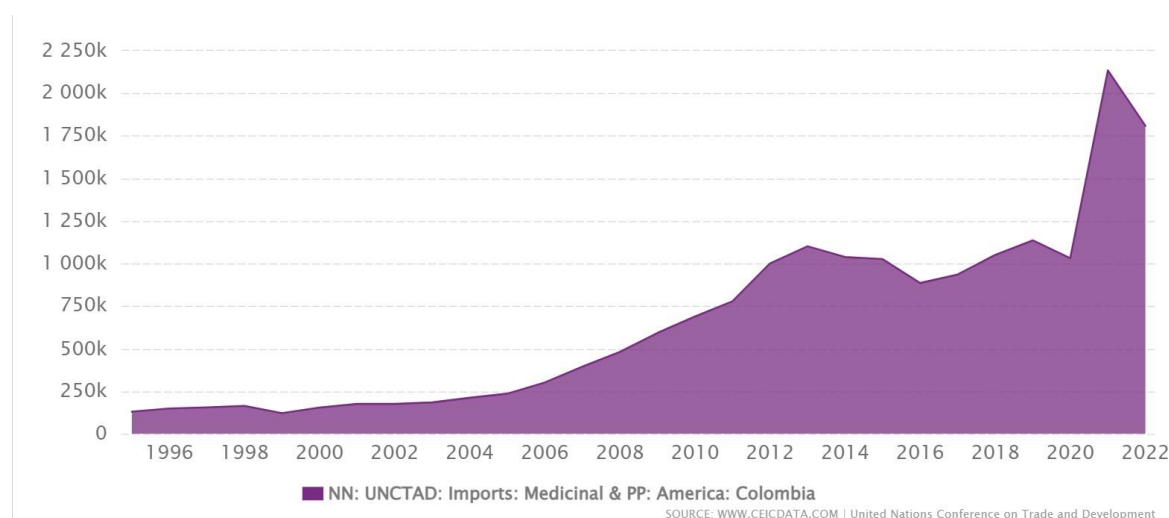


PHARMA IMPORT DYNAMICS

Under President Juan Manuel Santos, Colombia has prioritized strengthening its commercial sector. Since 2011, free trade agreements with 14 countries, including the United States, have boosted foreign direct investment to a record COP 29 trillion (USD 16 billion) in 2012. Despite the positive impact on the pharmaceutical industry, debates continue on improving healthcare in Colombia. The country's pharmaceutical market depends significantly on imported raw materials and finished products, causing a trade imbalance with higher imports than exports.

The sector lacks advantageous resources and capabilities, making Colombia dependent on countries with such assets. Colombian pharmaceutical companies compete with foreign counterparts by cutting costs through importing raw materials and supplies. The industry's international dynamics are shaped by a combination of exports and imports, with the supply chain relying heavily on imports. Import dynamics play a crucial role in determining the industry's export levels, emphasizing the significance of supply costs and logistics in Colombia's pharmaceutical sector.

In December 2022, Colombia's imports of medicinal and pharmaceutical products were 1,809,154.50 USD, down from 2,134,787.28 USD in December 2021. The annual data, averaging 537,108.20 USD from 1995 to 2022, peaked at 2,134,787.28 USD in 2021 and hit a low of 121,655.22 USD in 1999.



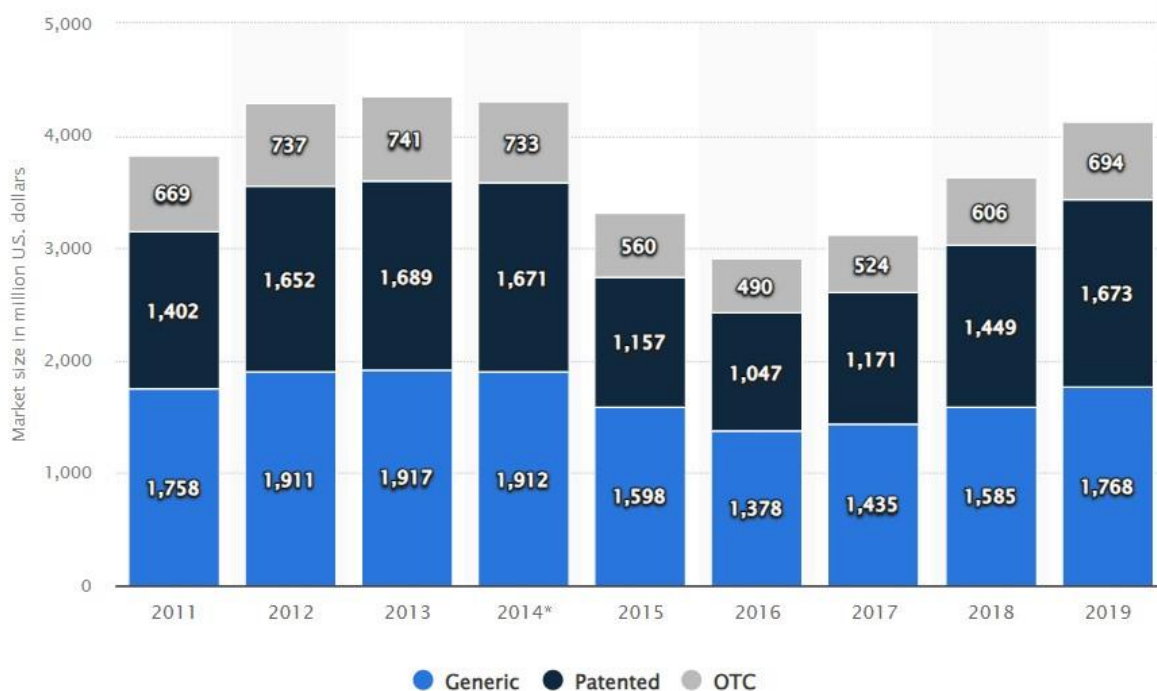
PRIVATE MARKET DYNAMICS

The Law Entidades Promotoras de Salud (EPS) consist of both public and private health insurance providers, or while this system brought about near-universal health coverage, some argue that the EPS has evolved over the last twenty years into a business, rather than being a basic right guaranteed to all Colombians. Many accuse the EPS of corruption and mishandling finances. Colombia's health system operates under two schemes, contributory and subsidized. Forty percent of the Colombian population holds formal employment and receives health insurance through the contributory scheme that is paid for by both employees and employers, granting access to private hospitals. The remaining 60 percent of the population, who do not hold formal employment, are subsidized by the public health system, which is generally of lesser quality. Proposed changes aim to replace EPS with a single-payer "Fondo Unico," integrating both schemes for better resource control.

Another proposal suggests replacing POS with "Mi Plan" to exclude non-essential items. Acknowledging the unsustainability of private sector delegation, there's a push to shift state responsibilities for a more robust healthcare system.

The first mechanism was the Maximum Recovery Value scheme (VMR in Spanish, Valor M'aximo de Recobro), which applied only to medicines that were not covered by the social health insurance system's benefits plan, but which were available and usually free of out-of-pocket expenses through a commonly used lawsuit mechanism. The second price cap instrument was the Maximum Price for Sale to the Public (Precio M'aximo de Venta al P'ublico or PMVP), which sets a maximum price for specific medicines that are covered by the benefits plan. Both regulations aimed at limiting laboratories' market power by decreasing their price fixing leeway.

Drug pricing underfocus of the current government, at focusing on correcting the poor enforcement of drug pricing controls that previously existed, by taking direct control of a more centralized pricing strategy, Decision Resource analysts note. Government cost-containment efforts have helped to create a thriving generic sector in the country, according to Decision Resources. The Colombian pharmaceutical market was valued at 8.126 trillion Colombia peso (U.S. \$4.35 billion) in 2013 and is expected to increase at a CAGR of 7.3% to reach COP 10.032 trillion (U.S. \$5.37 billion) by 2016.

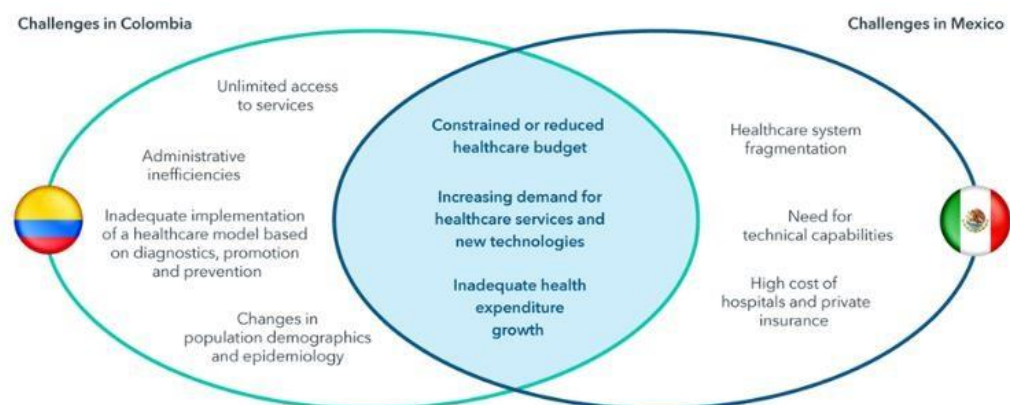


Colombia's pharmaceutical market by drug category from 2011 to 2019[14]

TENDER MARKET DYNAMICS

- While not a lot of data is available on the tender dynamics in Columbia, it seems to be a dual edged swords from the data that is available:
- **Equal Opportunities:** Colombia's pharmaceutical sector doesn't favour domestic manufacturers in tenders, in contrast to protectionist policies in countries like Brazil. The tendering process is unbiased, offering equal opportunities to all players, regardless of their origin.
- **Impact on Pricing and Austerity:** The absence of favouritism has intensified market competition, affected drug pricing and led to austerity measures. Price reductions in government tenders, driven by cost control needs, have raised concerns within the industry.
- **Adverse Effects on Companies:** Industry commentators, including Claudio Ferrari from Scandinavia Pharma, highlight the adverse impacts of severe price reductions in tenders. Such actions may make the distribution of certain products unprofitable, potentially leading to their disappearance from the market.
- **Risk of Product Disappearance:** There is a significant concern about certain products disappearing due to financial unsustainability in distributing drugs at reduced prices. This poses challenges to patient access and choice in the pharmaceutical market.
- **Call for Prioritizing Clinical Advantages:** Amid a race to lower prices, industry voices, exemplified by Claudio Ferrari, emphasize prioritizing high-tech products with clinical advantages. The call is to balance cost considerations while preserving critical medical advancements in the reimbursement agenda.
- **Competitive Market Signals:** The intensely competitive market, driven by impartial tenders, inadvertently triggers a race to lower prices. While cost control is crucial, the competitive landscape may impact market sustainability and the availability of essential pharmaceutical products[15]

CORE CHALLENGES OF THE PHARMA INDUSTRY



Source: IQVIA, Feb 2018

Report: Unlocking the Economic Potential of the Health Sector in Latin America, IQVIA Institute for Human Data Science, Apr 2018

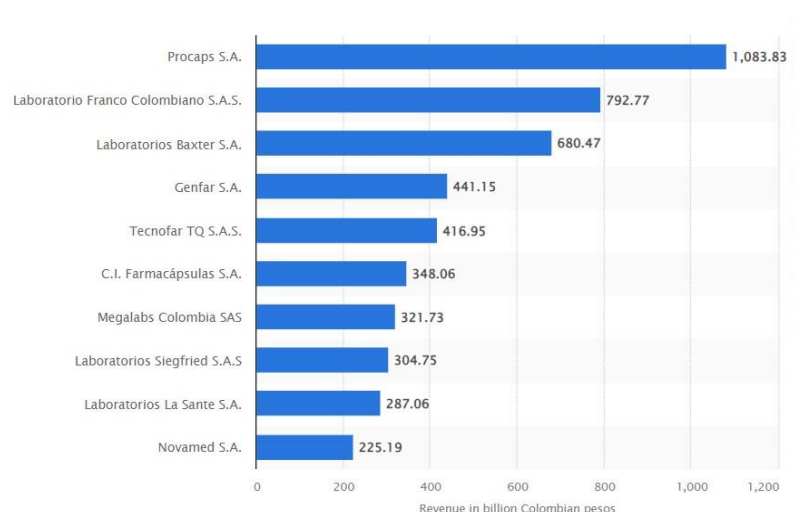
[16]

Colombia's pharmaceutical industry faces a drastic business environment marked by constant changes in customer needs, increased price competition, and the entry of new players. The sector's dynamics have become unpredictable, necessitating companies to acquire new skills and enhance resource management to adapt to evolving conditions. Challenges highlighted in the JSI Opinions include:

- **Intense Market Competition:** High levels of competition pose a significant challenge for businesses in the pharmaceutical sector.
- **Low Demand and Economic Uncertainty:** The industry grapples with low demand, influenced by economic uncertainties, affecting production and sales.
- **Exchange Rate and Raw Material Costs:** Fluctuations in exchange rate and cost and supply of raw materials add complexities to the operational landscape.
- **Smuggling and Unfair Competition:** Issues such as smuggling and unfair competition pose threats to the stability of the pharmaceutical market.
- **Infrastructure and Logistics Costs:** Challenges related to infrastructure and logistics contribute to the overall operational difficulties faced by industry players.
- **Concerns Regarding Tax Reform:** Ongoing discussions about tax reforms, particularly higher income taxes, present a substantial burden on companies with limited tax capacity.
- **Labor Initiatives Impacting Growth:** Proposed labor initiatives raise concerns about slower growth, reduced investment, increased informality, and fewer employment opportunities. Despite these challenges, the industry also demonstrates positive aspects such as stable inventories, favorable business conditions, and positive production and sales levels. However, concerns regarding tax reforms and labor initiatives are critical factors that potential entrants into the pharmaceutical industry in Colombia need to consider when assessing the market landscape and planning their entry strategies.[17]

SUPPLEMENTARY MATERIAL

(1)



Leading pharmaceuticals producing companies in Colombia in 2021, by revenue(in billion Colombian pesos). In 2021, Procaps S.A. was the leading pharmaceutical producing company in Colombia, with a revenue of 1,083.83 billion Colombian pesos. Laboratorio Franco Colombiano S.A. ranked second, with sales amounting to 792.77 billion Colombian pesos. The market value of the pharmaceutical industry in Colombia reached over 1.5 billion U.S. dollars in 2020. In Colombia, public spending on health has been fluctuating in recent years. In 2020, public health care expenditure amounted to approximately 16.76 billion euros in the South American country, a decrease of almost eight percent compared to the previous year when public spending on health care peaked at about 18.14 billion euros.

Colombia: ● Better ● Worse ● Higher ● Lower ● OECD average ● Other OECD countries

Health status



Risk factors



Quality of care



Access to care



Health system resources



REFERENCES

- [1] 1. <https://www.grandviewresearch.com/industry-analysis/latin-america-pharmaceutical-contract-manufacturingservices-market>.
- [2] 2. <https://www.grandviewresearch.com/industry-analysis/latin-america-pharmaceutical-contract-manufacturingservices-market>.
- [3] 5. <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/valuing-the-research-basedpharmaceutical-industry-in-latin-america>.
- [4] 3. <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/valuing-the-research-basedpharmaceutical-industry-in-latin-america>.
- [5] 4. <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/unlocking-the-economicpotential-of-the-health-sector-in-latin-america>.
- [6] Z. He, cOLUMBIA PHARMA MARKET LINKEDIN.
<https://www.linkedin.com/pulse/colombia-pharma-market-zhengchunharry-he/>.
- [7] 6. <https://www.oecd.org/colombia/health-at-a-glance-Colombia-EN.pdf>.
- [8] 9. https://unctad.org/system/files/official-document/diaepcb2011d7_en.pdf.
- [9] 25. <https://www.pharmexec.com/view/country-report-colombia>.
- [10] 10. <https://www.ceicdata.com/en/indicator/colombia/imports-medicinal-and-pharmaceutical-product>.
- [11] 8. <https://www.pharmexec.com/view/country-report-colombia>.
- [12]
- [13] 11. <https://www.pharmavoice.com/news/colombia/613303/>.
- [14] 7. <https://www.statista.com/statistics/872735/colombia-pharma-market-breakdown-by-drug-category/>.
- [15] nn. <https://www.pharmexec.com/view/country-report-colombia-0>.
- [16] 21. <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/unlocking-the-economicpotential-of-the-health-sector-in-latin-america>.
- [17] 20. <https://www.econstor.eu/bitstream/10419/190514/1/1019397918.pdf>.