Pharmaceuticals

Sector Study

May 2023

Table of Contents

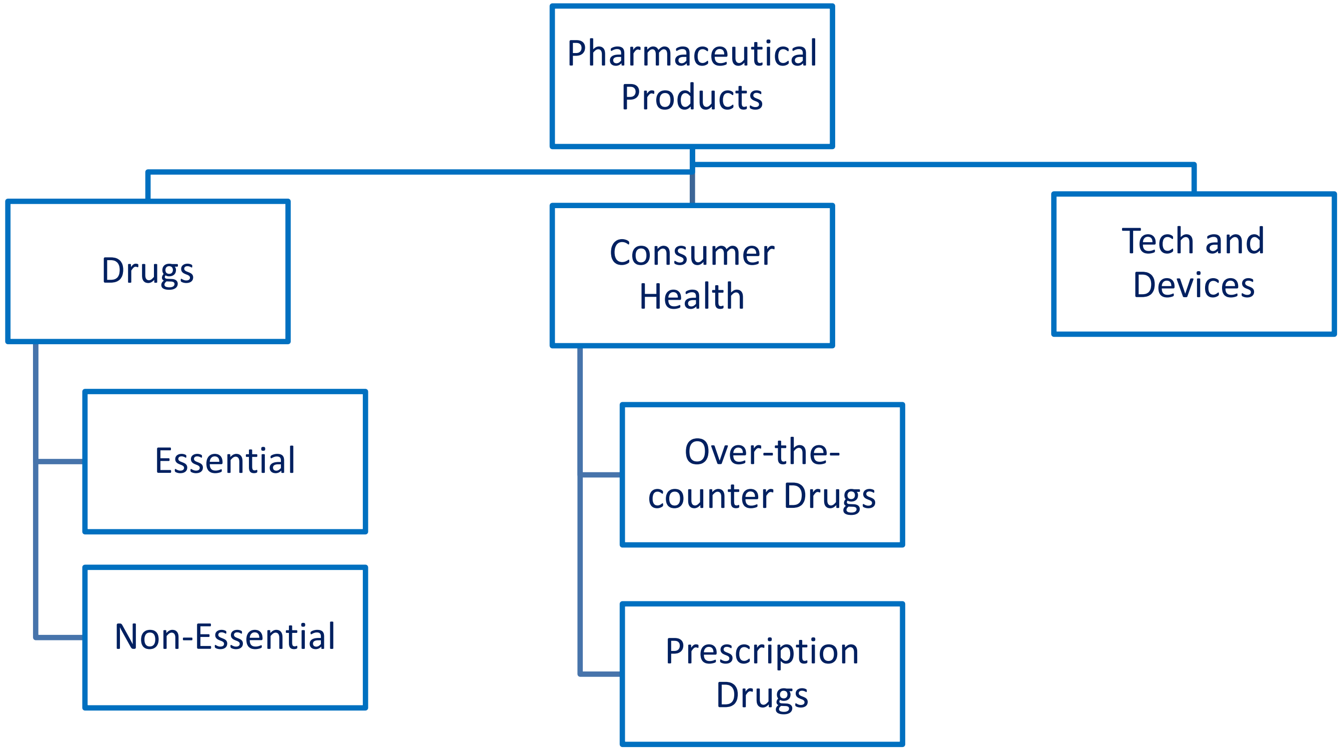
Contents	Page No.
Sector Overview	1
Global Overview	2
Global Overview | Growth Prospects	3
Manufacturing Process	4
Large Scale Manufacturing- Overview	5
Industry Snapshot	6
Supply|Raw Material	7
Demand|Consumption	8
Demand|Price Dynamics	9
Supply|Production	10
Supply|FDI	11
Business Risk	12

Contents	Page No.
Financial Risk | Leverage	13
Financial Risk | Working Capital	14
Financial Risk|Borrowings	15
Rating Curve	16
Duties and Taxes	17
Regulation	18
Porters 5 Forces Model	19
SWOT Analysis	20
Outlook	21
Bibliography	22

Pharmaceuticals

Introduction

- The pharmaceutical sector is responsible for the development, production, and marketing of branded and generic pharmaceuticals.
- Pharmaceutical companies mainly deal in generic, branded, branded generic and over the counter drugs.
- Firms may also engage in contract development or manufacturing, where a company provides comprehensive services from drug development through drug manufacturing to another firm.



Source: DRAP

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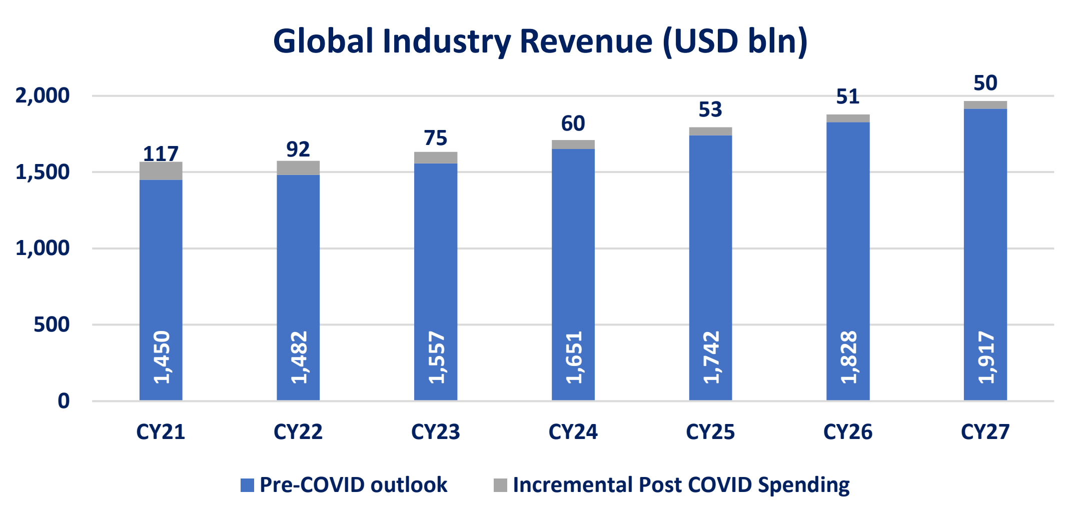
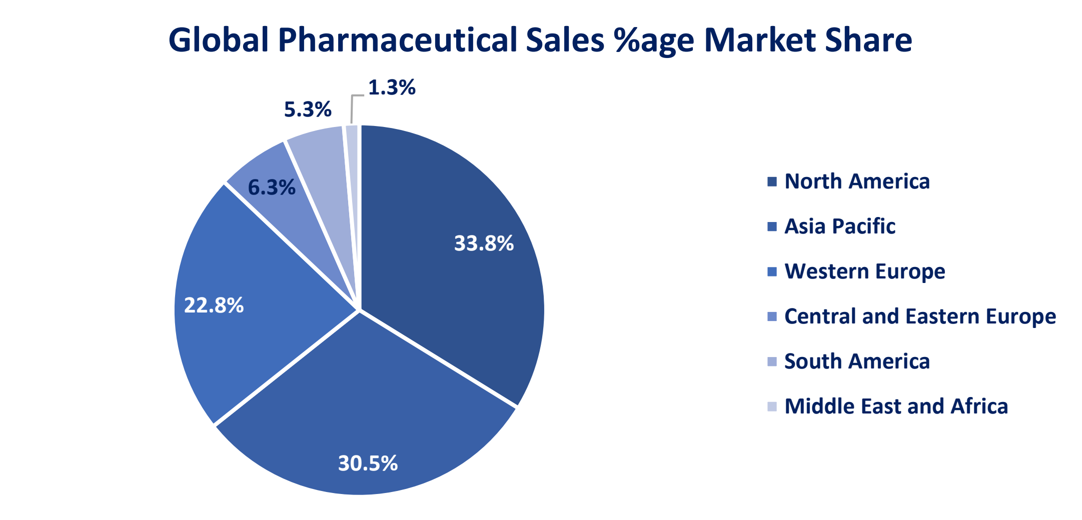
Global Overview

- The global pharmaceutical industry is estimated to have grown to USD~1,574bln in CY22 (CY21: USD~1,567bln), ~6.2% higher than pre-COVID outlook (CY21: ~8.1% higher than pre-COVID outlook). The global pharmaceutical industry is expected to grow at a more sustainable ~5.1% rate (excluding incremental COVID impact) as markets recover and base drivers normalize.

- Regionally, North America is expected to hold the largest share in global pharmaceutical spending of ~33.8%, followed by Asia Pacific with a market share of ~30.5% and Europe with a market share of ~22.8%.

- The manufacturing side of the pharmaceutical industry is expected to receive an even greater boost. Aging population in developing countries, amplified focus on elderly and pediatric patients, high incidence of cardiovascular disorders, growing demand for home-based healthcare and increased cancer and diabetes cases are further propelling the pharmaceutical manufacturing expansion across the globe.





Source: EIU, IQVIA

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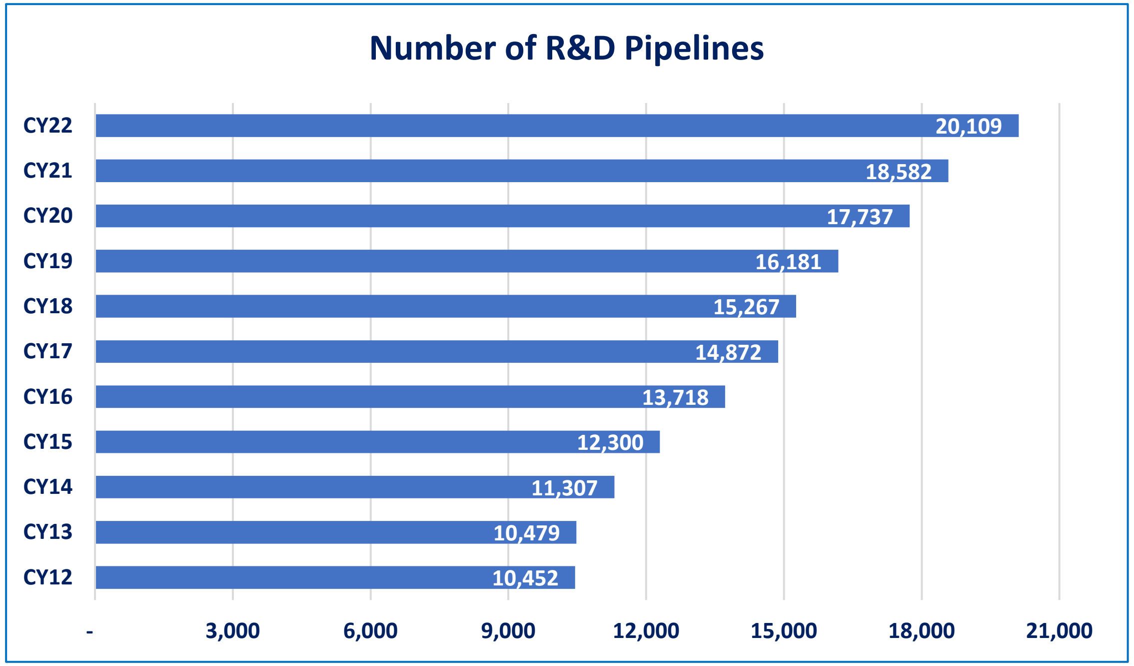
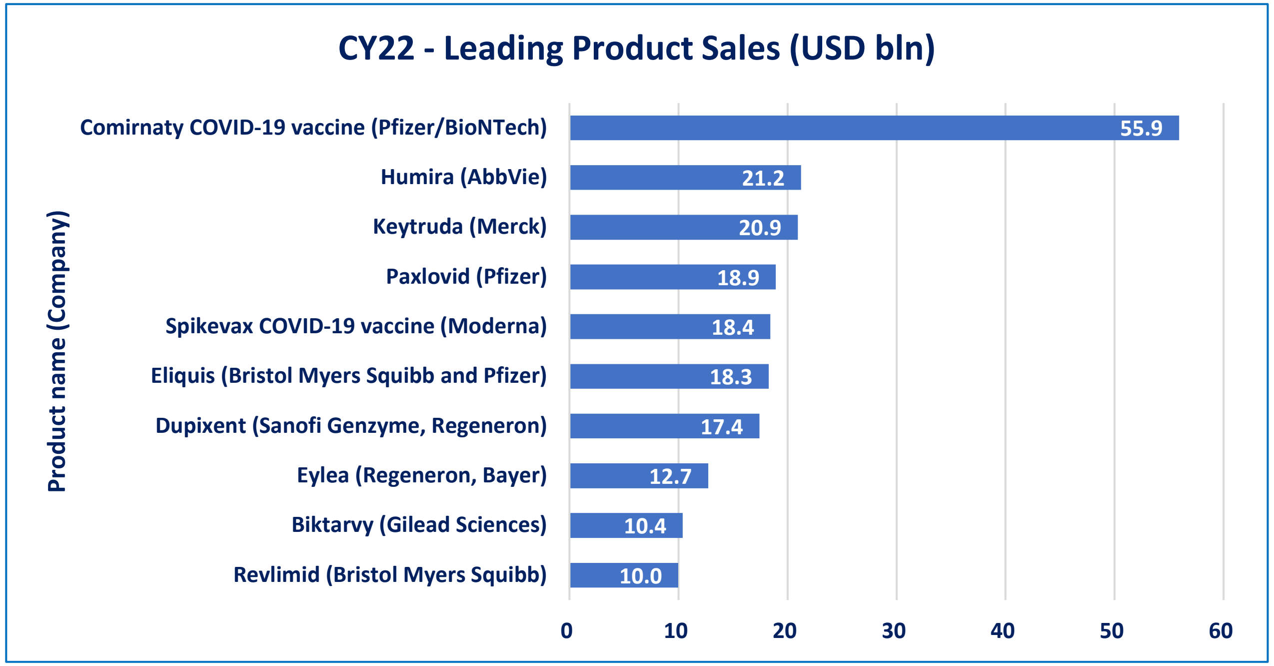
Global Overview | Growth Prospects





- The R&D (Research and Development) pipeline represents the aspirations and goals of a company and are the sole source of future product development and potential innovation.
- The number of R&D pipelines grew to ~20,109 (CY21: ~18,582) in CY22; of these ~56.5% were at Pre-clinical stage, ~14.7% in Phase 1 testing, ~14.5% in Phase 2 testing, ~5.6% in Phase 3 testing, ~1.1% in Pre-registration Stage, ~0.8% in registration stage, ~6.2% in Launch stage; while the remaining have been suspended.
- In CY22, the top 10 best performing drugs posted cumulative sales of USD~204bln; of these Pfizer's COVID-19 vaccine was the top performer as it ranked in revenues worth USD~55.5bln, ~2.6x the sales of the second best performing drug.

Source: Pharma Intelligence, Drug Finder

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Manufacturing Process

Raw Chemicals such as Dicalcium phosphate, Tyrosine, valine etc. are processed and refined for further use.

Active Pharmaceutical Ingredients (APIs) are produced mainly in organic and inorganic synthetic drugs from refined chemicals.

Excipients most commonly produced are Disintegrants, Glidants and Lubricants from APIs.

Finished product is mostly in Tablet or serum form and quality control is performed to authenticate drug specifications.

Packaging is done and properly labeled for usage. Ingredients and side affects are listed. The final product is than shipped for retail.

Source: PPMA

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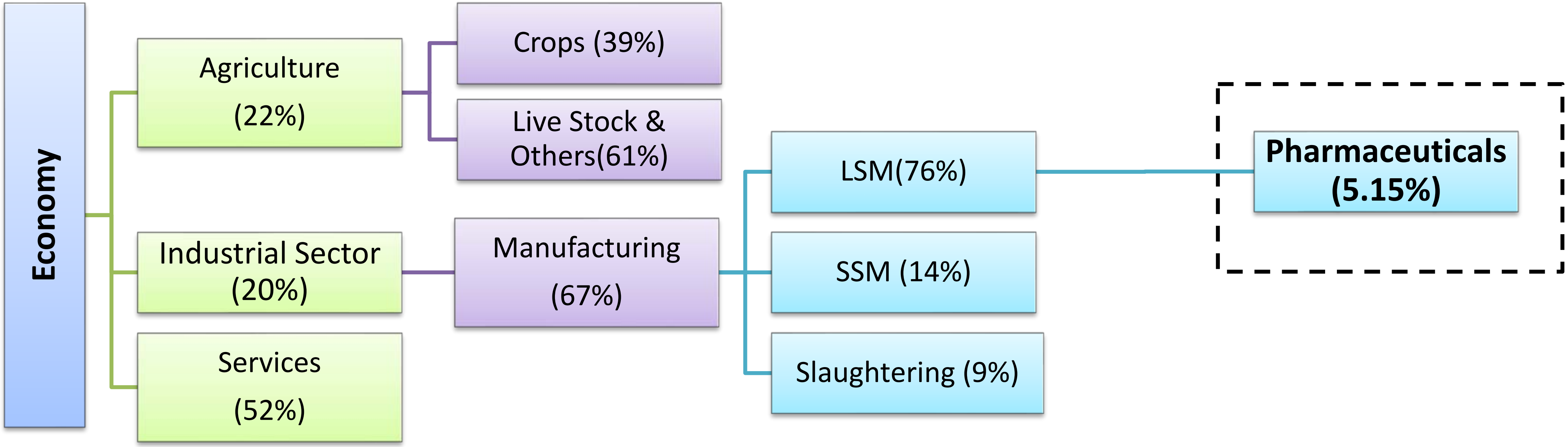
Economy | Overview

- In FY22, Pakistan's GDP (nominal) stood at PKR~67tln (FY21: PKR~56tln) and posted real growth of ~6.2% (FY21: ~6.5%). Industrial activities in FY22 represented ~20% share in the GDP and grew at ~7.2% YoY (FY21: ~-7.8%), while manufacturing activities representing ~65% value in industrial activities grew at ~9.8% (FY21: ~10.5%) in the same period.
- Large Scale Manufacturing (LSM) in Pakistan is essential for economic growth considering its linkages with other sectors, as it represented 76% value of all manufacturing activities in FY22 and grew at ~10.5% YoY in FY22 (FY21: ~11.5%).
- FY23, however, inherited multiple macro-economic and socio-political vulnerabilities, both at local and international levels from the last quarter of FY22, including devastating floods of Aug'22.
- Culmination of these have led to Mar'23 inflation levels touching ~35.4% and 9MFY23 LSM manufacturing shrinking by ~8.7%. The Multilateral Agencies now forecast real GDP growth to remain restricted at ~0.4-0.5% in FY23.



Source: PBS, SBP

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Industry Snapshot

- The Pharmaceutical sector recorded a revenue of PKR~705bln during CY22 with a YoY growth of ~14.3% (CY21: PKR~616bln); while pharmaceutical manufacturing also grew by ~22.7% YoY in CY21.

- Despite the large number of registered companies, the sector is dominated by the top local and Multinational Companies (MNCs). Top 100 companies hold ~97.2% of the total market share whereas, remaining more than 500 companies hold less than ~3% market share. Moreover, top ~50 companies hold ~89.1% of market share.

- The sector is highly dependent on imports to meet the demand of basic raw material – APIs. As per estimates, ~95% of the APIs requirements are met through imports while the remaining ~5% is being manufactured domestically. Heavy reliance on the imported raw material significantly increases the inherent risk of supply chain disruption and price fluctuations.

- Pharmaceutical sector is critically important for the health and lifestyle of any country and its population. The average world health expenditure per capita stands at USD~1,177/capita while the average health expenditure per capita in Pakistan is significantly lower standing at USD~38/capita.

Particulars	CY21	CY22
Gross Revenue (PKR bln)	616	705
Contribution to GDP	1.10%	1.05%
Registered Manufacturers	~620	~646
Structure	Oligopolistic	
Imports (PKR bln)	105	96
Exports (PKR bln)	44	44
Regulator	Drug Regulatory Authority of Pakistan (DRAP)	
Association	Pakistan Pharmaceutical Manufacturers Association	

Source: IQVIA, PPMA,PBS,DRAP, PACRA Database, WB

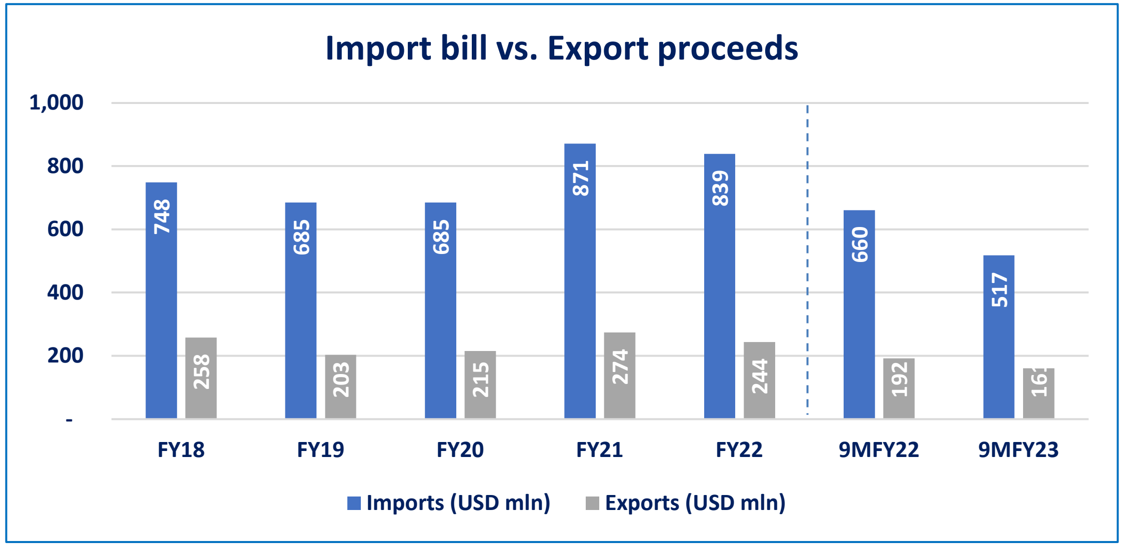
Supply | Raw Material

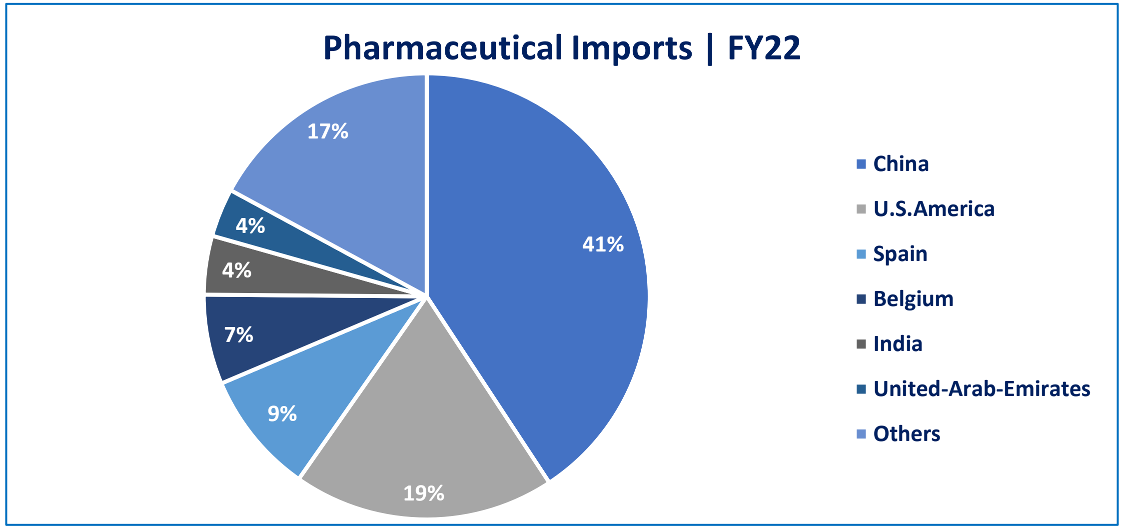
- Pakistan's pharmaceutical sector is only able to make up ~5% of its APIs locally whereas the rest of the ingredients are being imported. Low emphasis on R&D by local companies is the major reason behind significant reliance on imported raw material.

- During FY22, pharmaceutical imports were recorded at PKR~148bln (FY21: PKR~139bln) with a YoY growth of ~6.8% YoY; while during 9MFY23 imports grew by ~7.5% YoY clocking in at PKR~122bln (9MFY22: PKR~113bln); due to massive depreciation in PKR value. As in USD terms imports declined 3.7% YoY in CY22 and ~21.6% YoY in 9MCY23.

- The nature of APIs and medical devices requires sensitive handling, proper storage and transport facilities. Hence, efficient supply chain is of utmost importance for pharmaceutical companies.

- China is the largest exporter of pharmaceutical products to Pakistan followed by USA, Spain, Belgium, India and UAE. Significant reliance on imported raw material increases the inherent risk of supply chain disruptions, however, non-reliance on any single country for imported APIs provides some comfort against potential disruptions in the supply chain.





Source: PPMA,SBP

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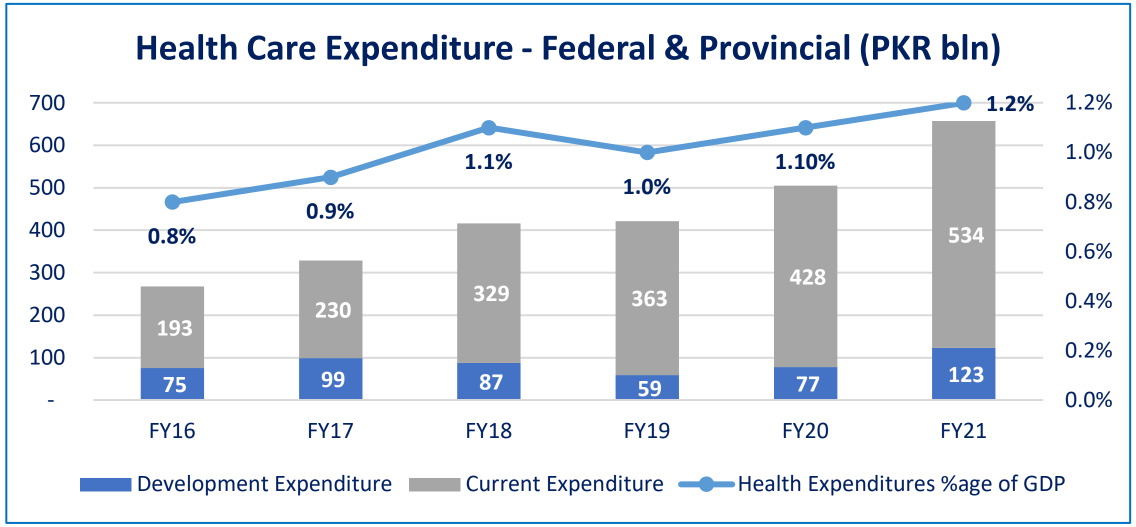
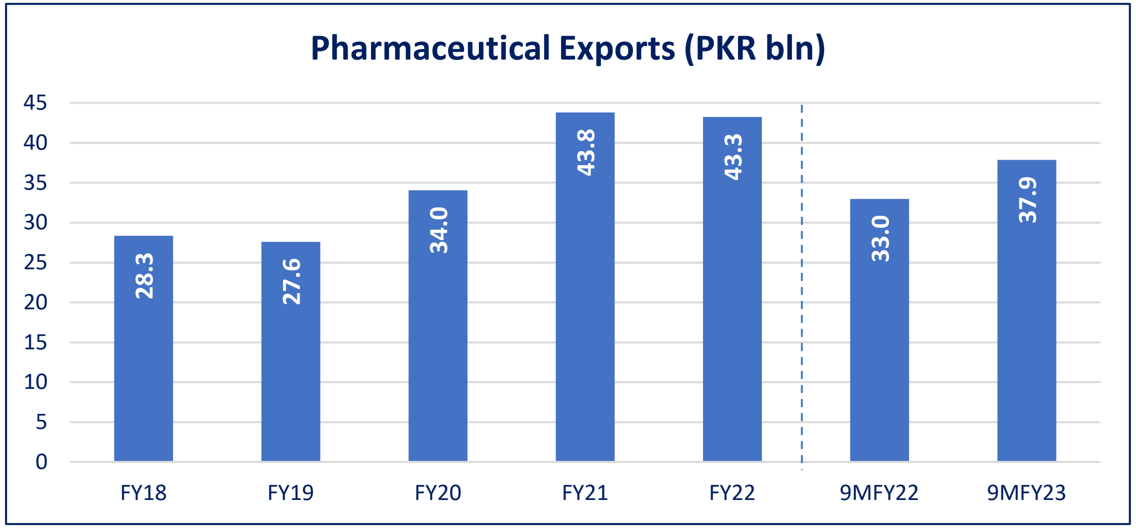
Demand | Consumption

- Pakistan's population in FY22 stood at ~227mln. The population growth rate of the country is ~2%, almost double of the global growth rate of ~1%.
- Decrease in mortality rate from 84.3/1,000 births in 2000 to 55.6/1,000 births in 2019 and increasing average age from ~62 in 1990 to ~70 by 2020 has resulted in more people reaching older age, hence increasing the demand of robust healthcare system.
- Given the current economic slowdown amidst high inflation and interest rate environment, a base line demand can reasonably be expected to persist since pharmaceutical products are often considered essential goods.
- Health care expenditure was recorded at PKR~657bln in FY21 with a CAGR of ~9% since FY16; total expenditures showed improved YoY growth of ~20% during FY21.
- National pharmaceutical exports declined by ~1.2% YoY in FY22 and grew by ~14.7% YoY in 9MFY23 in PKR terms. While in USD terms exports fell ~10.9% YoY in FY22 and ~16.4 YoY in 9MFY23.





Source: SBP, MoF

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Demand | Price Dynamics

- In Pakistan, prices of Pharmaceutical products are regulated by DRAP and cannot be changed unilaterally by the pharmaceutical companies. Any price determination of new products and increase requires approval from the DRAP. Prices are adjusted with respect to Consumer Price Index (CPI).

- As a positive development for manufacturers, after the amendments in Drug Pricing Policy 2018, DRAP is mandated to respond to companies request for price revision within 30 days of submission otherwise the price increase as submitted by the companies is made effective.

Pricing and Costing Under Drug Pricing Policy 2018	
Annual Price Increase	**Essential Drugs**: MRP Increase by 70% of CPI (Cap of 7%) **Non-Essential Drugs:** MRP Increase by 100% of CPI (Cap of 10%)
Low-Priced Drugs	Low-priced drugs are such that their MRPs are lower than the threshold prescribed by DRAP. MRPs of such drugs are to be increased equivalent to CPI every year, subject to conditions.
New Drugs	**First Generic:** MRP of drugs to be set at 30% less than the cost of the Originator brand, subject to conditions In other cases MRP fixed at prevailing highest MRP of Generic brand in the market
Hardship Cases	**Locally Manufactured Drugs:** MRP = Cost x Factor **Imported Drugs:** Trade Price= Landed Cost + mark up 45% (40% markup for anti-cancer, biological etc.) **Partially Imported Drugs**: Trade Price = Landed Cost + packaging cost + markup

Source: TSL Research, PBS,DRAP

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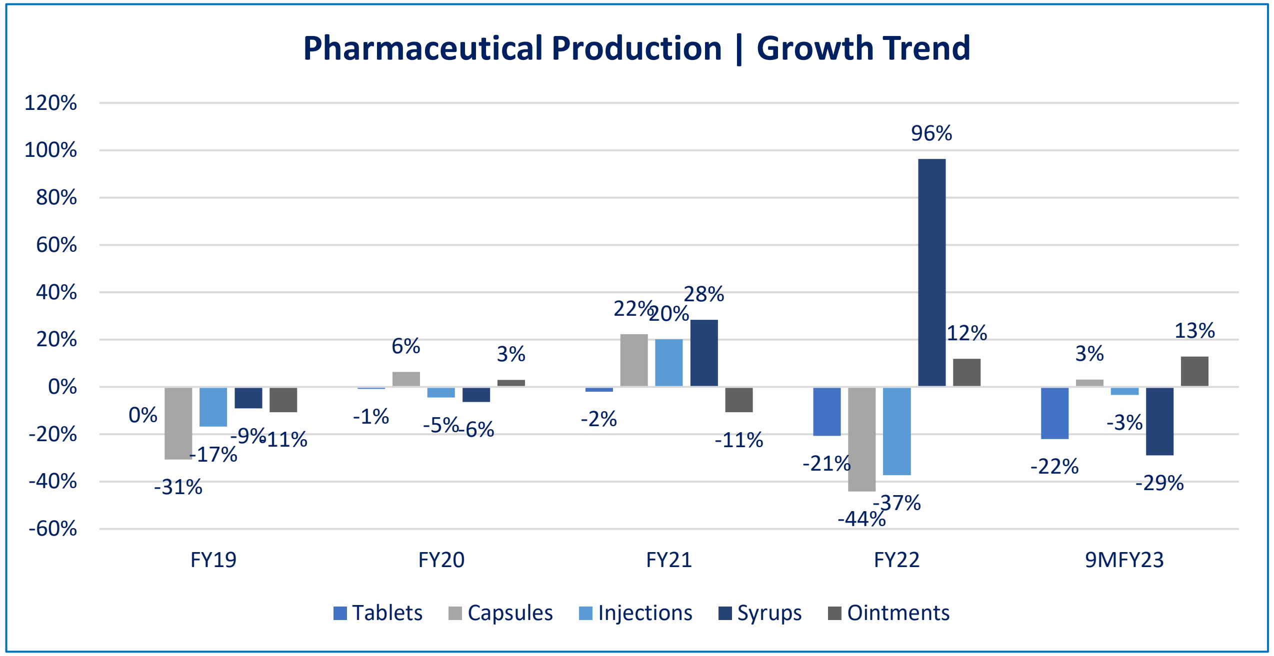
Supply | Production

- Despite the large number of registered manufacturers, the sector is dominated by a few top players. Top ~100 companies hold ~97.3% of the total market share while remaining more than ~500 companies have less than ~3% market share. Moreover, top ~50 companies hold ~80% of market share.
- Overall production of the sector posted a negative growth of ~23.2% YoY during 9MFY23. The sector consists of both local players and MNCs and while the number of total companies increased, the market share of MNCs decreased. MNCs are reducing operations in local market due to inconsistent policies, depreciating exchange rate, and controlled drug prices.



Category	Unit	FY19	FY20	FY21	FY22	9MFY22	9MFY23
Tablets	000' Nos	27,802,433	27,557,865	27,016,282	21,442,852	14,690,798	11,379,437
Capsules	000' Nos	3,585,562	3,814,808	4,665,966	2,606,086	1,997,494	2,079,235
Injections	000' Nos	1,337,891	1,277,320	1,533,866	960,819	723,379	702,454
Syrups	000' Liters	100,136	93,775	120,369	236,358	144,574	101,595
Ointments	000' Kg	3,253	3,349	2,990	3,344	2,441	2,646
Galenical	000' Liters	39	74	69	51	41	27

Source: PPMA,PBS

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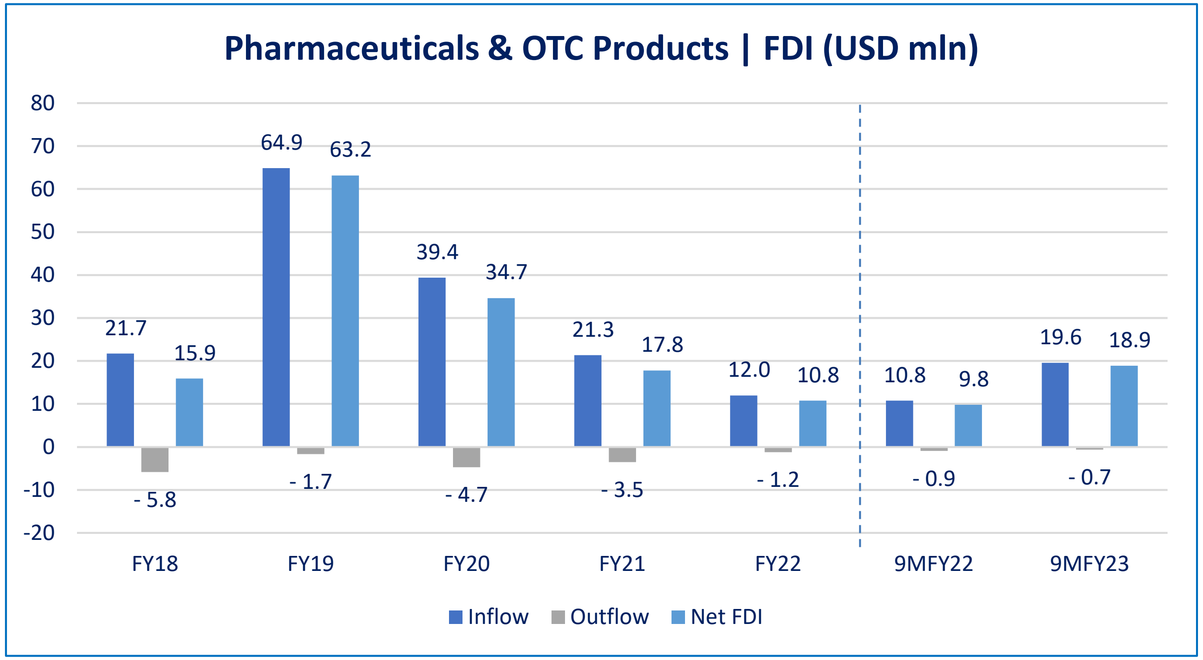
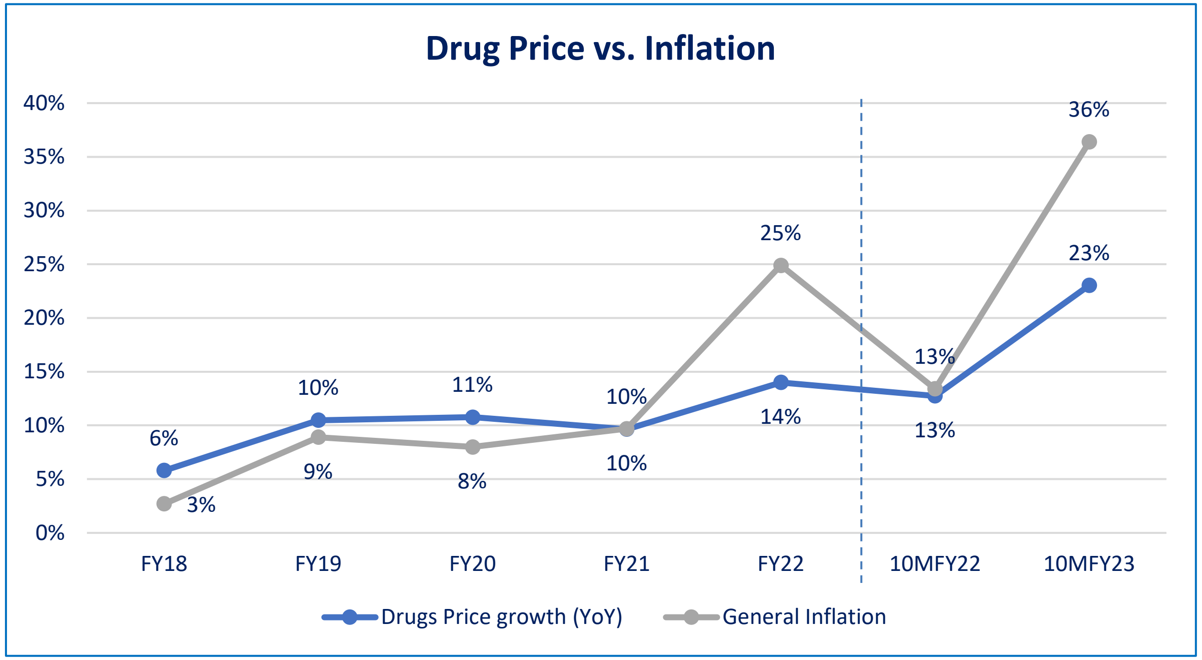
Supply | FDI

- In the early 2000s, ~36 multinational pharmaceutical companies used to operate in Pakistan. That number, as of 2022, stood at ~24, Massive FDI outflows of USD~59bln were observed in FY15 and USD~47bln in FY17.
- With DRAP linking the price hike with CPI, it is becoming increasingly difficult for R&D cost to be transferred to consumers. For this reason, market share of MNCs has decreased and it is expected they may continue to exit Pakistan's market.
- While FDIs picked up momentum during the COVID period, it too lost momentum as net FDI for FY22 were recorded at USD~11mln, while a delta of ~13.4% between inflation and drug price growth was observed in April'23, further highlighting the challenge.





Source: PPMA,PBS

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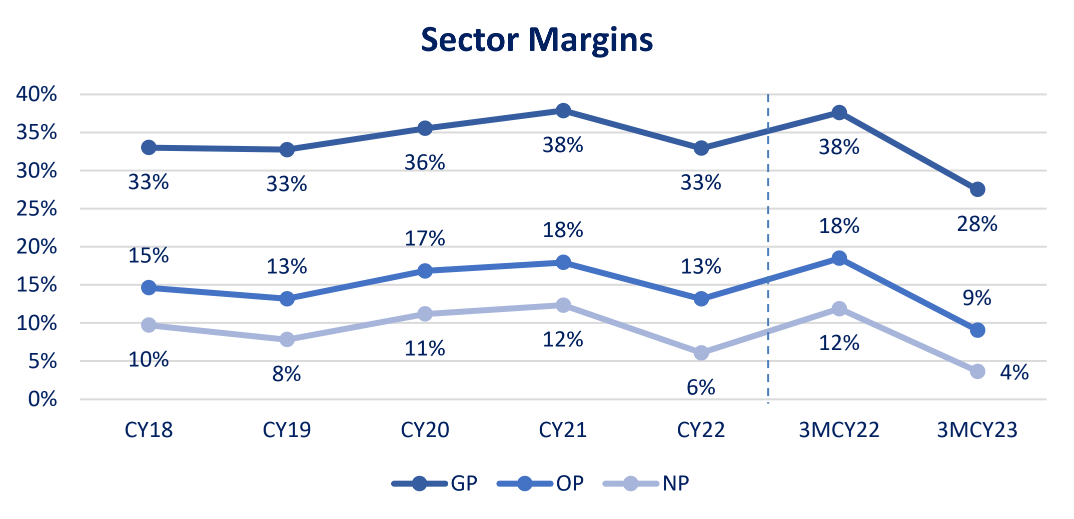
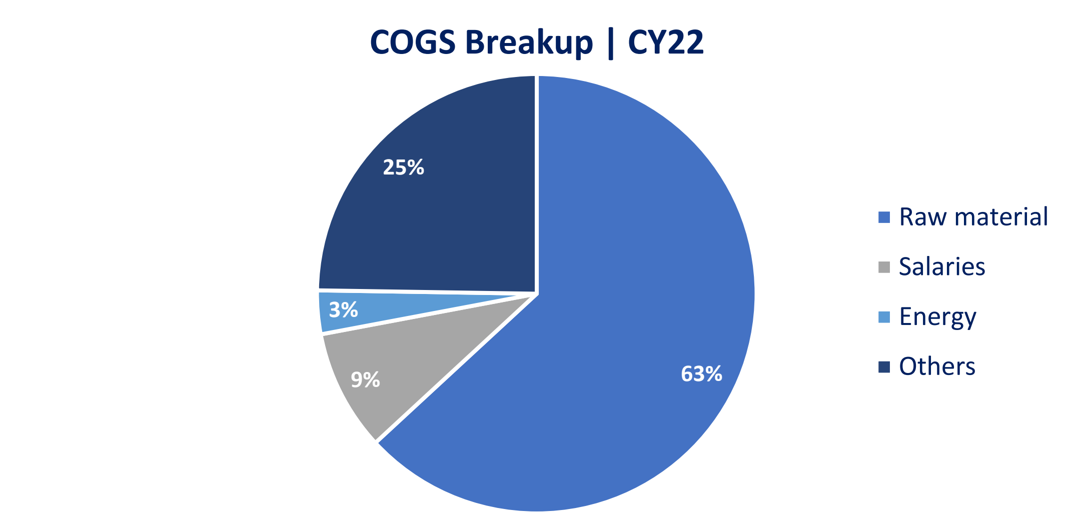
Business Risk | Margins

- The pharmaceutical business relies heavily on raw material as it makes up ~63% of its cost of sales while energy cost, being the lowest contributor, accounts for ~3%.
- With DRAP regulating the prices of drugs, the profits margins are sensitive to exchange rate fluctuation and changes in cost of raw material. ~95% of raw material (APIs) is imported and therefore, exposes the sector to these risks.
- Companies with larger concentration of non-essential and low-priced drugs bear a larger impact on revenue from price changes every year, all else equal.
- During the 3MCY23 period, PKR depreciated by ~47.0% YoY against the USD, which resulted in ~27.4% YoY higher landed cost per MT in PKR terms, while it decreased ~14.3% YoY in USD term. Contemporaneously, manufacturing dipped by ~20.2% YoY.
- In 3MCY23, Net Revenues grew by ~25.2% YoY given improved pricing, while COGS grew ~43.8% YoY pushing gross profits down by ~8.4% YoY. While ~13.2% YoY higher operating and other expenses led to ~38.6% YoY lower operating profits. Similarly, ~2.7x YoY higher finance costs and ~56 lower tax expense led to ~62% decrease net profits in the same period.





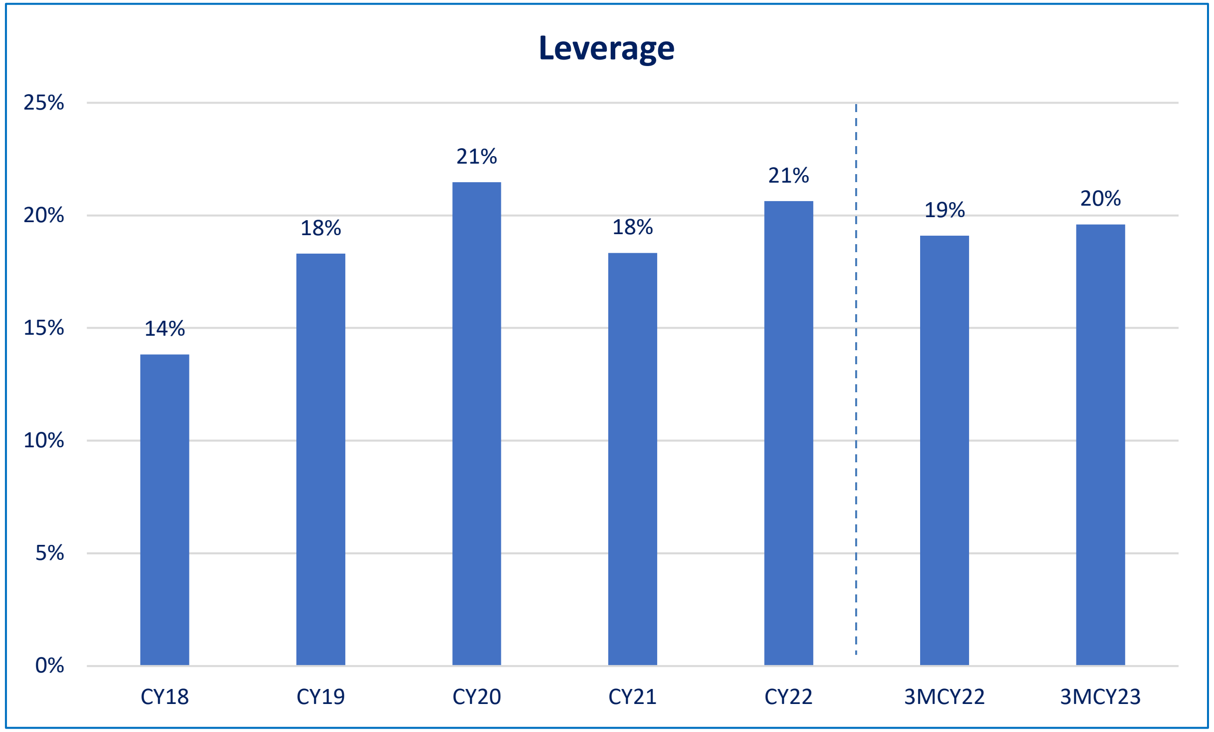
Note: Calculations based on PACRA-rated and selected PSX listed companies; prorations and adjustments made where needed.

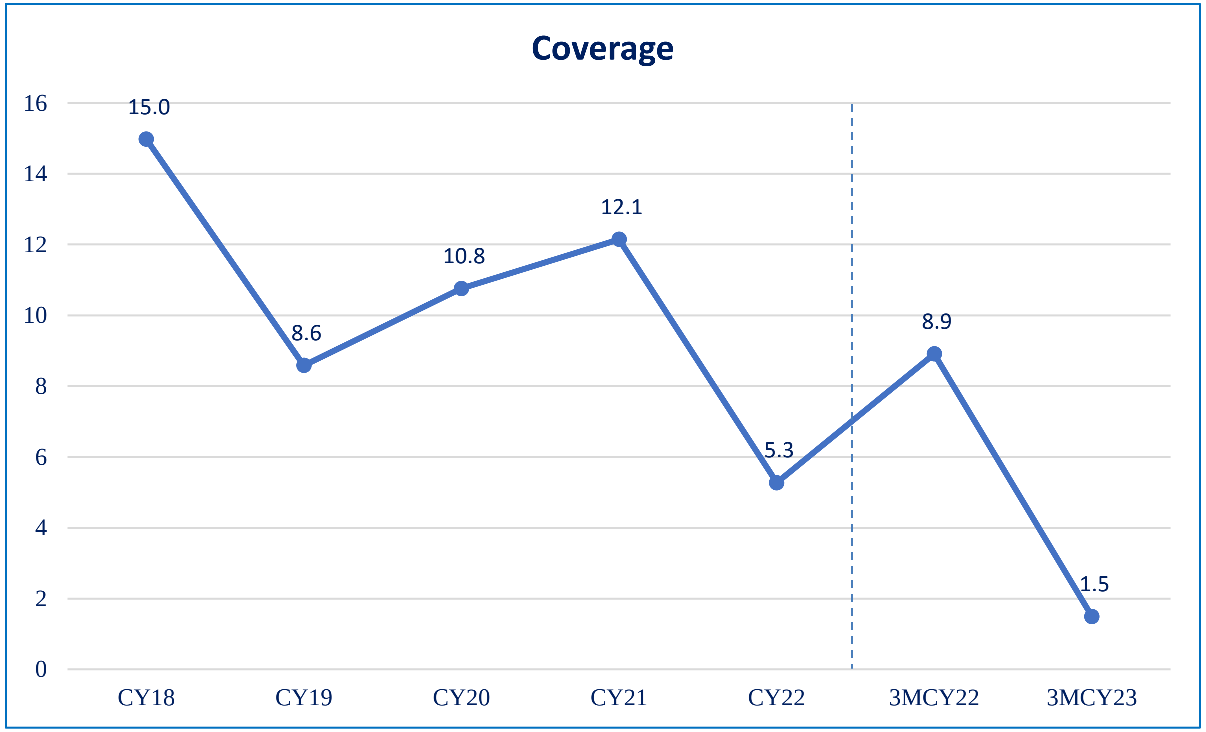
Source: PACRA Internal Database, Financial Statements, PBS

Pharmaceuticals

Financial Risk | Leverage

- As of End-3MCY23, the sector leverage stood at a low ~20%, indicating a sufficient equity cushion.
- The sector coverage however dipped to ~1.5x in 3MCY23 compared to ~8.9x in the same period last year, as the current economic environment and lack of inherent localization have placed a significant strain on the sector margins.
- SBP in perusing its hawkish stance hiked the policy rate to average ~18.5% in 3MCY23 compared to ~9.75% in the same period last year. This, combined with massive PKR depreciation, led to ~2.7x higher finance cost.





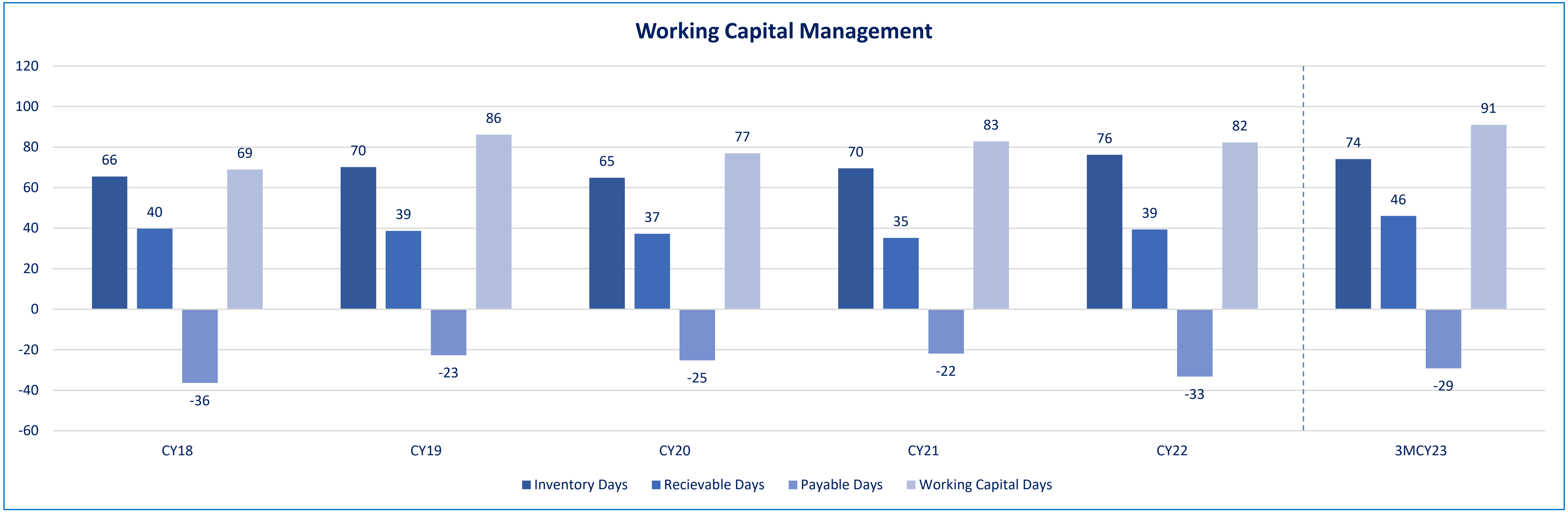
Note: Calculations based on PACRA-rated and selected PSX listed companies; prorations and adjustments made where needed.

Source: PACRA Internal Database, Financial Statements, SBP

Financial Risk | Working Capital

- The sector's working capital structure is characterized by high inventory days. In 3MCY23, the average working capital days of the sector increased to ~91 days (3MCY22: ~80 days).

- A breakdown of the working capital cycle reveals that average inventory days increased to ~74 days (3MCY22: ~65 days) and average receivable days increased to ~46 days (3MCY22: ~40 days), while average payable days increased to ~29 days (3MCY22: ~25 days).



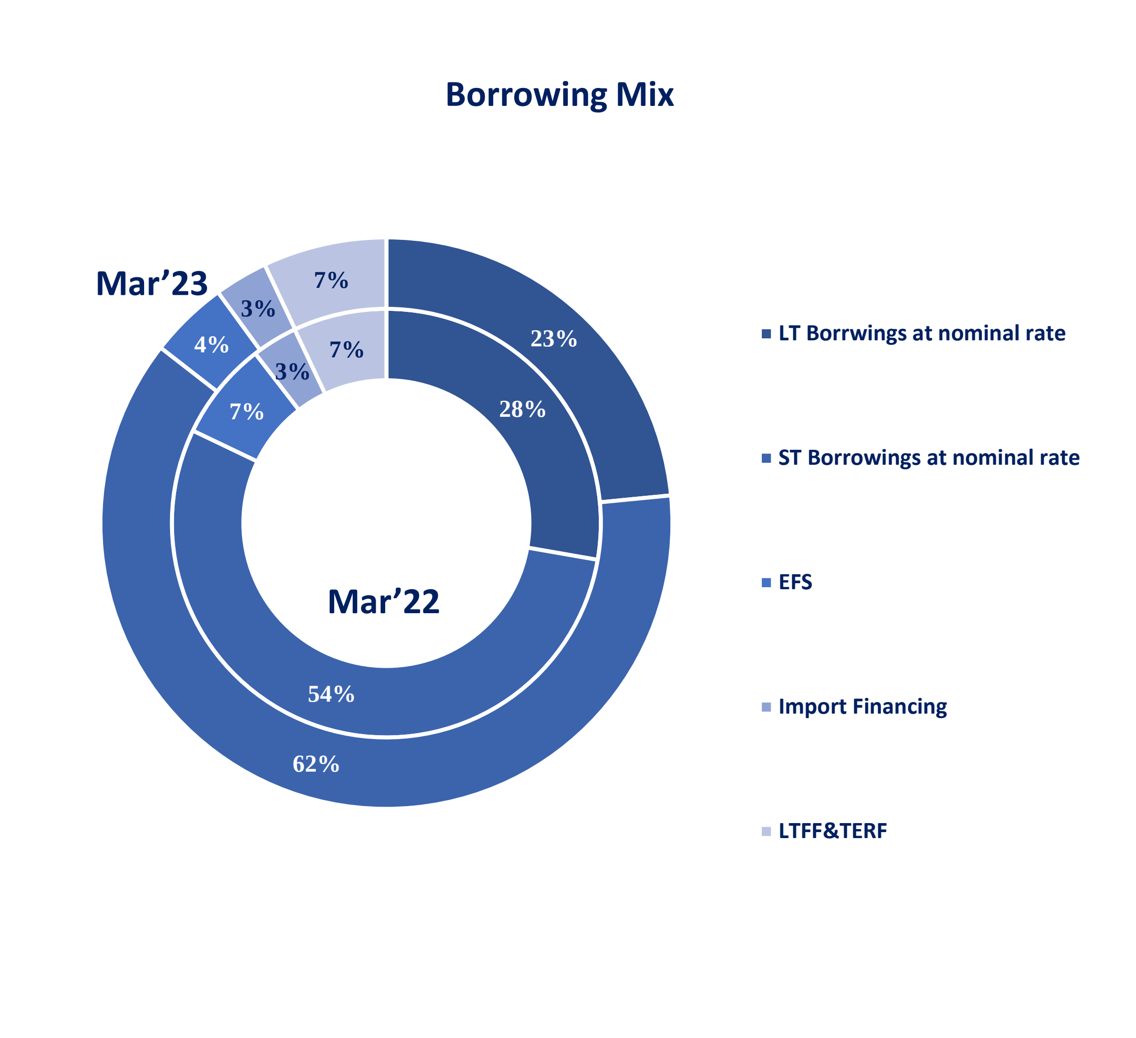
Note: Calculations based on PACRA-rated and selected PSX listed companies; prorations and adjustments made where needed.

Source: PACRA Internal Database, Financial Statements, SBP

Together. Creating Value.

Financial Risk | Borrowings

- As of March'23, sector borrowings stood at PKR~102,571mln (March'22: PKR~89,230mln) posting a growth of ~15.0 YoY.
- Seeing as the sector is heavily reliant on imported inventory, short-term loans held the largest portion of ~62.1% in the borrowing mix and stood at PKR~63,669mln (March'22: PKR~48,508mln), recording a growth of ~31.3% YoY.
- Long-term financing held the second largest portion of ~23.5% in the borrowing mix and stood at PKR~24,054mln (March'22: PKR~24,752), after decreasing by ~2.8% YoY.
- Discounted borrowings in terms of LTFF & TERF held a ~7.0% share in the borrowing mix; standing at PKR~7,177mln (March'22: PKR~6,277) grew by ~14.3% YoY.
- While EFS held a ~4.5% share in the total borrowings mix, standing at PKR~4,569mln (March'22: PKR~6,631) declined massively by ~31.1% YoY.
- Import financing, which stood at PKR~3,102mln (March'22: PKR~3,062mln), grew by 1.3% YoY and held a share of ~3.0% in the total borrowing mix.



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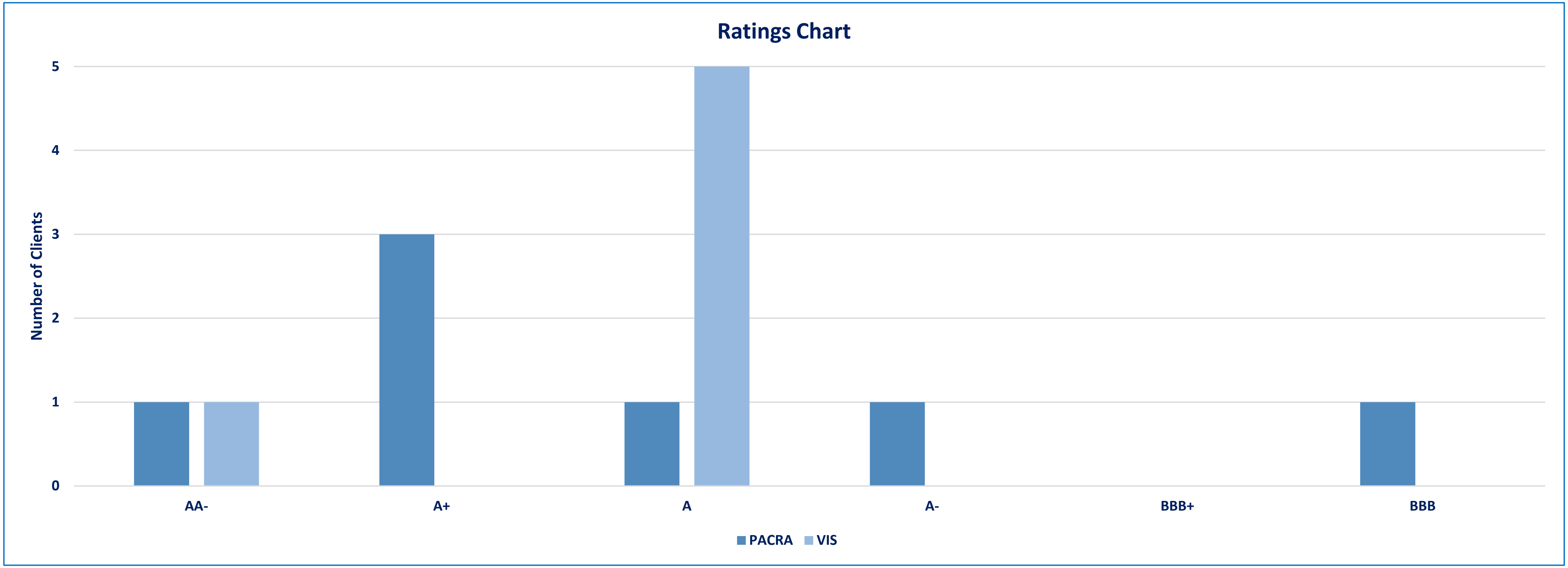
Ratings Chart

PACRA rates 7 clients of the Pharmaceutical sector. Rating bandwidth of the sector is AA- to BBB.



Duties and Taxes

Pakistan's SRO 567 (1) 2006 abolishes the import duty on all medicines for cancer, kidney dialysis, hepatitis and cardio vascular diseases.

	Year	Custom duty	Sales tax	Income tax	Additional Custom duty
API	FY22	0%-20%	17%	2%	0%
	FY23	0%	18%	11%	2%
		Custom duty	Sales tax	Income tax	Additional Custom duty
Excipients	FY22	5%	0%	2%	0%
	FY23	5%	18%	11%	2%-7%
		Custom duty	Sales tax	Income tax	Additional Custom duty
Drugs	FY22	0%-10%	0%-17%	0%-2%	0
	FY23	0%-10%	18%	11%	2%-6%

Source: FBR

Regulatory Framework

- In Pakistan, medicine licensing, manufacturing, registration, pricing, imports, and exports are dealt by the federal government, whereas distribution and sales are regulated by the respective provincial governments.
- DRAP was formed in November 2012 with enforcement of the DRAP act. DRAP functions as an autonomous body under the Ministry of National Health Services. The new organizational structure of DRAP consists of eight technical and five supportive divisions. The department of quality assurance has five field offices supported by federal drug inspectors, assistant drug controllers, and an appellate board.
- All pharmaceutical products have to be approved by DRAP and a strict quality check is kept by the regulatory department on the manufacturing process and ingredients to be used.
- Pakistan has undergone many reforms and policy changes in the past few years for ensuring the delivery of safe and efficacious medicines to the people. In Nov'18, the country acquired a full membership status to the World Health Organization's (WHO) Programme for International Drug Monitoring (WHO-PIDM). This concept was established in 1968; the main purposes include developing a pharmacovigilance system in member countries and coordination at national and international level for timely intimating on any medicine safety alerts. With full membership status, Pakistan has access to the respective WHO databases "VigiBase" and "VigiLyze" for performing signal detection and signal strengthening and for being able to access global data for evaluating national reports.

Source: DRAP

Pharmaceuticals

Porters 5 Forces Model

POTENTIAL NEW ENTRY

- Low threat to Entry
- High Capital cost of Drug development
- Extensive regulatory requirement to approve new drugs.
- Lack of research in the pharmaceutical sector

BUYERS

- Medium to low
- Bargaining power vary depending upon the nature of medicine where incase of essential and live saving medicine bargaining power is low.

SUBSTITUTES

- Low threat of substitutes
- Essential drugs are mostly imported

SUPPLIERS

- High power
- Only ~5% of supplies needs are met locally
- Heavy reliance on imported Active Pharmaceutical Ingredients comes with its own set of challenges

COMPETITIVE RIVALRY

- Medium to low
- Competitive structure is Oligopolistic in nature.

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SWOT Analysis

Strengths

- Steadily increasing demand
- High reliance of customer on the product
- High profit margins in non essential drugs

Weaknesses

- Reliance on imported raw material
- Exposure to exchange rate volatility
- Extensive regulatory requirements
- Shortage of locally available materials
- Inability to pass on increased cost of production to end consumers for drugs regulated by DRAP.
- Highly research extensive sector

Threats

- High level of competition
- Increasing cost of energy
- Rising Interest rates
- Rising costs

Opportunities

- Low per capita consumption
- High profit margin opportunities in non essential drugs and products
- Room of research and drug development.

Pharmaceuticals

Outlook: Stable

- Pharmaceuticals sector represented ~1.0% (FY21: 1.0%) of the GDP in FY22 and is one of the most highly regulated sectors of the economy. The companies operating in the sector require approvals from importing of products to determining/revising prices of end-product. While extensive regulations are essential considering the importance of the sector in the healthcare system; however in the current macroeconomic environment these regulations are restricting the sector's performance.
- As Pakistan's inflation in Apr'23 clocked in at hyper ~36.4%; PKR depreciated by ~54.4% compared to same period last year with import restrictions in place; the MPR stood at a prohibitive 21%, and the World Bank now estimates Pakistan's FY23 GDP growth to clock in at ~0.4%. The QIM of the LSM dipped by ~42.5% YoY in Mar'23 with all but 4 industrial sectors in red. While the critically needed IMF bailout remains stalled.
- In Mar'23 Pakistan's pharmaceutical goods manufacturing dipped ~28.1% YoY; while in 3MCY23 the sector's topline grew by ~25.2% YoY due to improved pricing. However ~43.8% growth in COGS at the same time, reduced the Gross Margins to ~27.5% (3MCY22: ~37.6%), while high operating and finance cost reduced the net margins to ~3.6%.
- The Sector's working capital needs are driven by high inventory days. Most of the borrowed funds of the sector are utilized to finance day-to-day operations rather than for research and development activities, therefore growth and advancement in the sector remains laggard.
- Given the recent performance, inherent weaknesses of the sector and the persistence of macroeconomic vulnerabilities, it can be reasonably expected for the sector margins to remain under pressure. While the rising needs for short term/working capital borrowings under a hawkish monetary regime may keep sector's capacity to meet payments and foreseeably overall perforce subdued.
- However as pharmaceutical products termed as essential commodities; a base level demand is also expected to persist in the local market. While PKR devaluation is also expected to keep, otherwise declining (in USD terms) export numbers stabilized.
- Going forward, further deterioration in the economy's fundamental would adversely impact the sector's stability, PACRA Research is closely monitoring the developing situation and the outlook of the sector in this regard.

Source: PACRA Internal Database

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