



Pharmaceutical Industry Sector Study

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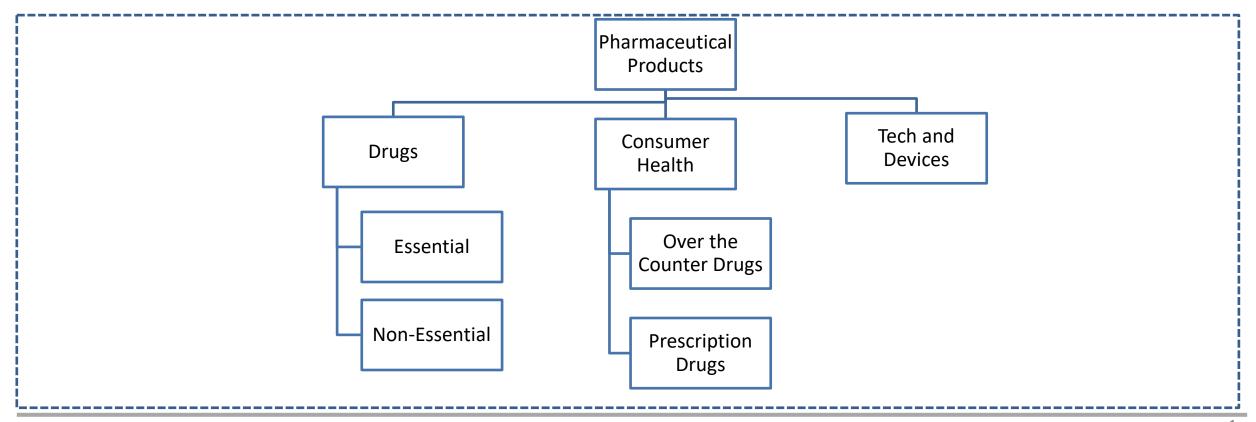
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Sector Overview

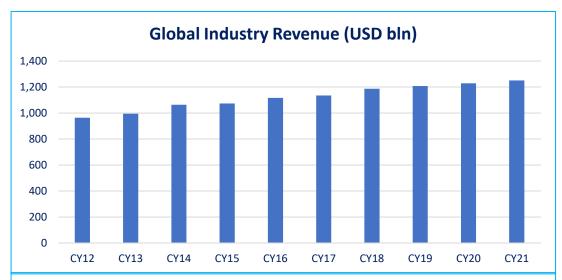
The pharmaceutical sector is responsible for the development, production, and marketing of branded and generic pharmaceuticals. Pharmaceutical companies mainly deal in generic, branded, branded generic and over the counter drugs. Firms may also engage in contract development or manufacturing, where a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

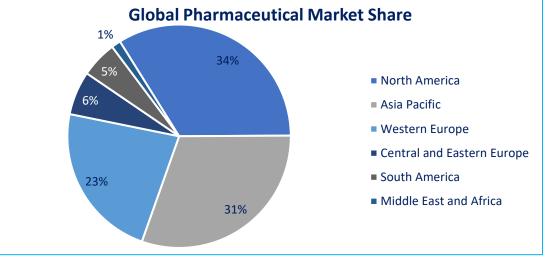


PACRA

Global Overview

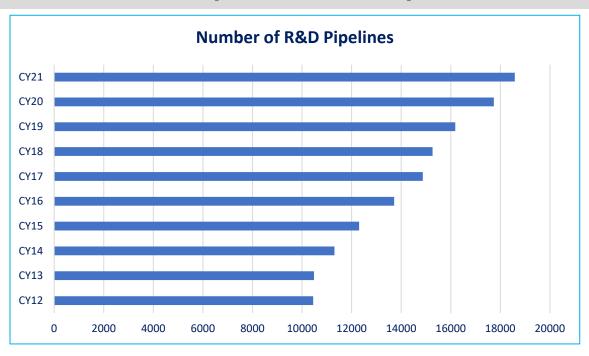
- The Global pharmaceutical industry is estimated to have grown to USD~1,250bln in CY21 (CY20: USD~1,228bln), posting a growth of ~1.8% YoY; the overall industry size is expected to reach to USD~1,700bln by CY25 with a CAGR of ~8%.
- Regionally, in CY22, North America is expected to hold the largest share in global pharmaceutical spending of ~34%, followed by Asia Pacific with a market share of ~31% and Europe with a market share of ~23%.
- 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.

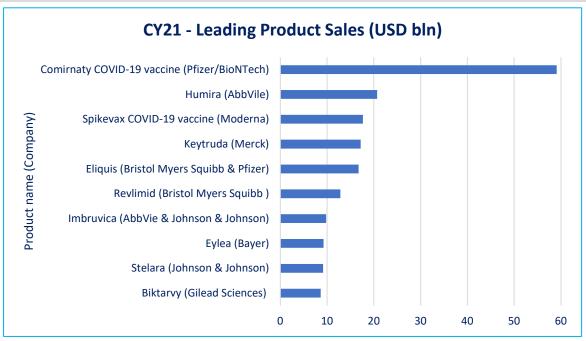






Global Overview | Growth Prospects





- The R&D (Research and Development) pipeline represents the aspirations and goals of the company; they are the sole source of future
 product development and potential innovation.
- The number of R&D pipelines grew to 18,582 (CY20: 17,737) in CY21, of these ~55.0% were at Preclinical stage, ~14.4% in Phase 1 testing, ~14.8% in Phase 2 testing, ~5.5% in Phase 3 testing, ~1.4% in Pre-registration Stage, ~1% in registration stage, ~7.2% in Launch stage; while the remaining have suspended status.
- In CY21, top 10 best performing drugs posted cumulative sales of USD~102bln; of these Pfizer's COVID-19 vaccine was the top performer as it ranked in revenues worth USD~59bln, ~2.9x the sales of the second best performing drug.



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.

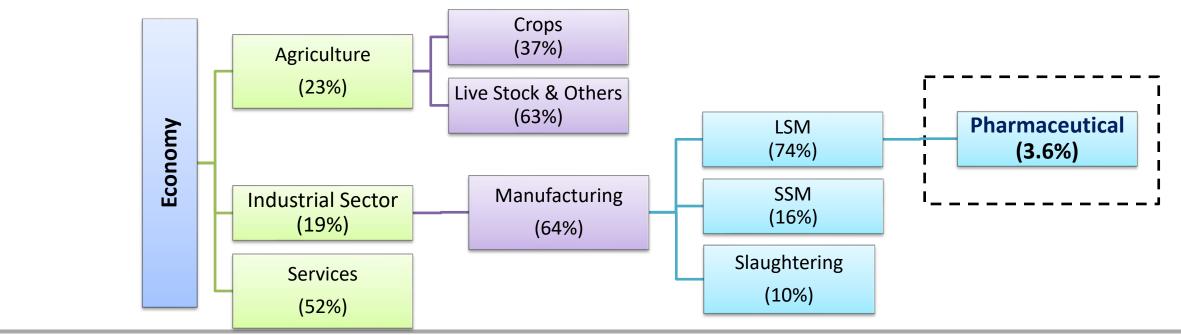
Finished product is mostly in Tablet or serum form and quality control is performed to authenticate drug specifications.

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



Economy - Overview

- In FY21, Pakistan's GDP (nominal) stood at PKR~52tln (FY20: PKR~45tln) while the real GDP stood at PKR~39tln (FY20: PKR~37tln), posting a growth of ~6% YoY with a similar growth rate expected to preset in FY22, as per SBP estimates.
- Industrial activities in FY21 represented ~19% share in the GDP and rebounded to a growth of ~7.8% YoY (FY20: ~-5.8%), while manufacturing activities representing ~64% value in industrial activities rebounding to a growth of ~10.5% in the same period.
- Large Scale Manufacturing (LSM) in Pakistan is essential for economic growth considering its linkages with other sectors. The LSM represented ~74% value of all manufacturing activities in FY21 and recovered to a growth of ~11.4% YoY in FY21 (FY20: ~-11.2%).





Industry Snapshot

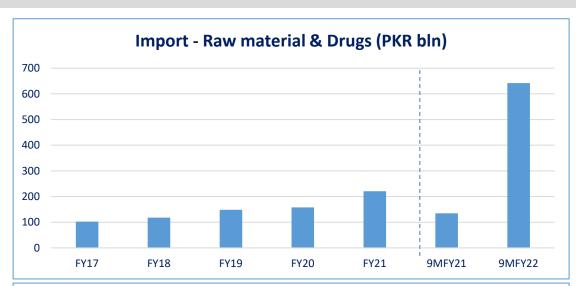
- Pharmaceutical sector recorded a revenue of PKR~508bln during FY21 with a YoY growth of ~12% (FY20: PKR~508bln); while pharmaceutical manufacturing also grew by ~12% YoY in FY21.
- Despite the large number of registered companies, the sector is dominated by the top local and Multinational Companies (MNCs). Top 100 companies hold ~97% of the total market share whereas, remaining more than 500 companies hold only ~3% market share. Moreover, top ~50 companies hold ~80% of market share.
- The sector is highly dependent on imports to meet the demand of basic raw material APIs. As per the 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~1,100/capita while the average health expenditure per capita in Pakistan is significantly lower standing at USD~43/capita.

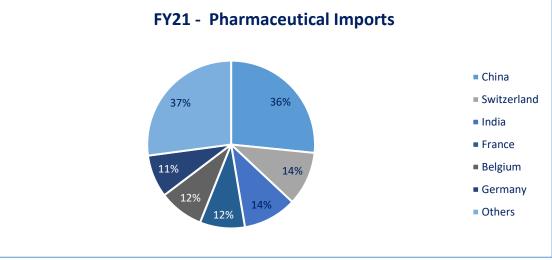
Particulars	FY20	FY21
Gross Revenue (PKR bln)	453	508
Contribution to GDP	1.17%	1.13%
Registered Manufacturers	620	620
Structure	Oligopolistic	
Imports (PKR bln)	158	221
Exports (PKR bln)	33	43
Regulator	Drug Regulatory Authority of Pakistan (DRAP)	
Association	Pakistan Pharmaceutical Manufacturers Association	



Supply | Raw Material

- Pakistan pharmaceutical industry is only able to make up ~5% of its APIs locally whereas the rest of the ingredients are being imported. Low emphasis on Research and Development (R&D) by local companies is the major reason behind significant reliance on imported raw material.
- During FY21, pharmaceutical imports were recorded at PKR~221bln (FY20: PKR~158bln) with a YoY growth of ~40% and imports reached to PKR~642bln during 9MFY22 (9MFY20: PKR~135bln) up ~3.6x YoY due to vaccine imports, international price hikes and PKR devaluation.
- 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.
- by Switzerland, India, France, Belgium and Germany; this significant reliance on imported raw material increases the inherent risk of supply chain disruption; however, non-reliance on any single country for imported APIs provides some comfort against potential disruptions in the supply chain.

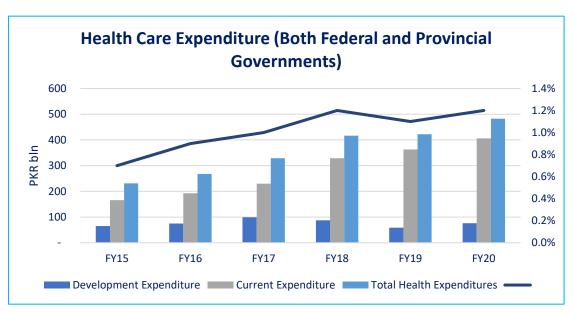


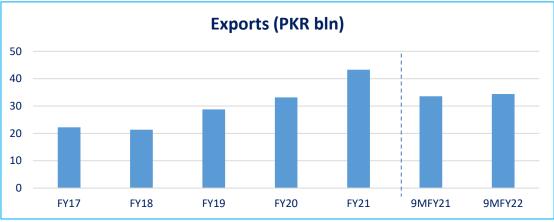




Demand | Consumption

- Pakistan's current population stands at ~222mln. 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 2,000 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 and hence increasing the demand of robust healthcare system.
- With rising population and increasing health issues, especially during the pandemic, the demand for pharmaceutical products remains stable; unaffected by harsh economic conditions, pharmaceutical industry is considered recession resistant.
- Health care expenditure was recorded at PKR~482bln in FY20 with a CAGR of ~9% since FY15; total expenditures showed improved YoY growth of ~14.4% during FY20; although the government is facing fiscal difficulties but health care expenditure growth is reasonably expected to persist owing to continued immunization programs and the "Sehat Card" and "Sehat Sahulat" programs.
- National pharmaceutical exports grew by ~30% YoY in FY21 and declined by ~2.5% YoY in 9MFY22.







Demand | Price Dynamics

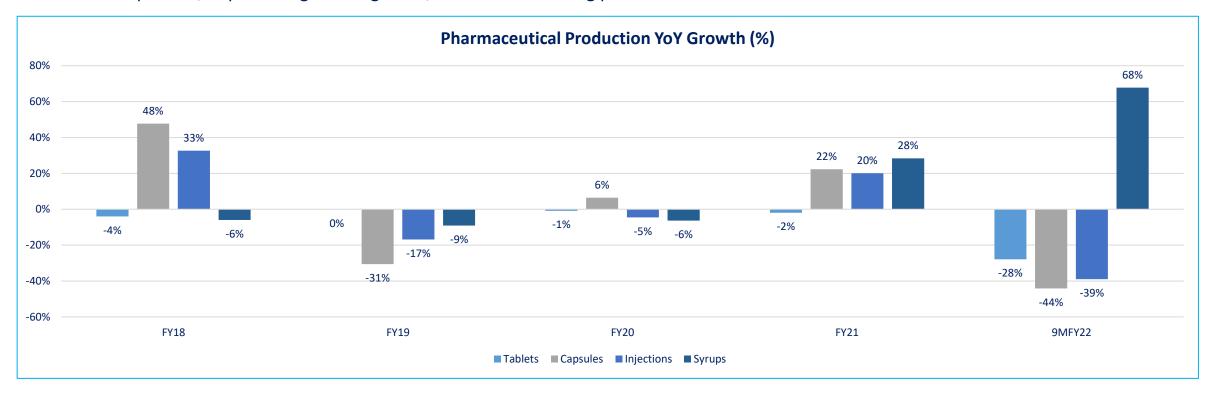
- In Pakistan, prices of Pharmaceutical products are regulated by DRAP and cannot be changed unilaterally by the pharmaceutical companies. Any price determination of new products and increase requires approval from the DRAP. Prices are adjusted with respect to Consumer Price Index (CPI).
- As a positive 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		
	Essential Drugs: MRP Increase by 70% of CPI (Cap of 7%)	
Annual Price Increase		
	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.	
	First Generic: MRP of drugs to be set at 30% less than the cost of the Originator brand, subject to conditions	
New Drugs		
	In other cases MRP fixed at prevailing highest MRP of Generic brand in the market	
	Locally Manufactured Drugs: MRP = Cost x Factor	
Hardship Cases	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	



Supply | Production

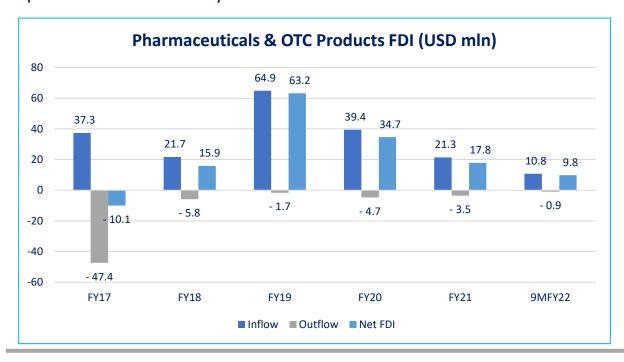
- Despite the large number of registered manufacturers, the industry is dominated by top players. Top ~100 companies hold ~97% of the total market share while remaining more than ~500 companies have only ~3% market share. Moreover, top ~50 companies hold ~80% of market share.
- Overall production of the sector posted a negative growth of ~0.4% YoY in 9MFY22; the industry consists of both local players and MNCs. Although the number of total companies increased, the market share of MNCs has decreased; MNCs are reducing operations in local market due to inconsistent policies, depreciating exchange rate, and controlled drug prices.

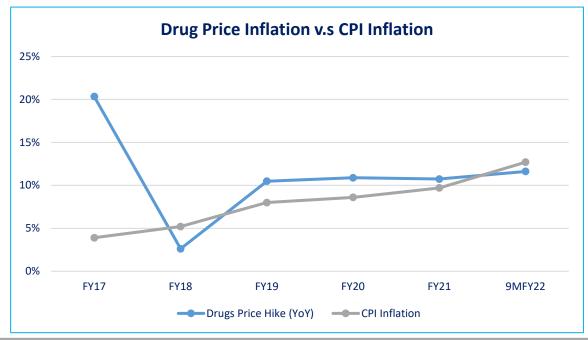




Supply | FDI

- Net outflow of investment from the pharmaceutical sector can be observed between FY06 to FY20. Massive outflow of investment by MNCs can be seen in FY15 after companies struggled to maintain profit margins. Following this, DRAP allowed the prices increase four times in FY16 which resulted in higher FDI in the sector.
- 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. In the last 10 years, a total of 16 MNCs like
 Johnson & Johnson, Bristol-Myers Squibb, Merck Sharp & Dohme Limited (MSD), Organon and others have taken exit from Pakistan's
 pharmaceutical industry.

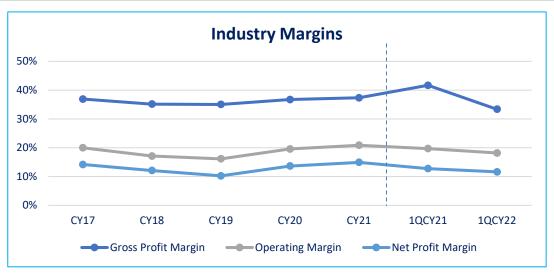


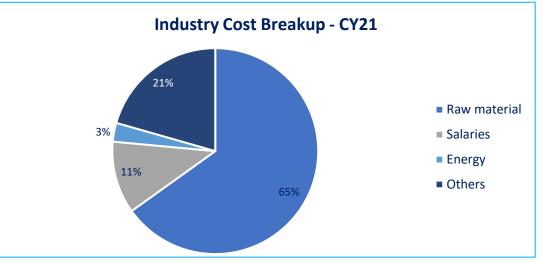




Business Risk

- The pharmaceutical business relies heavily on raw material as it makes up ~65% of its cost of sales while energy cost being the lowest component accounts for ~3%; salaries and other expenses account for ~32% of the Industry's average cost of sales.
- 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 certain risks for the Industry.
- 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.
- In the beginning of CY22, 17% sales tax was levied on the purchase stage of raw material therefore, sector margins have come under greater pressure.
- As the tax is only refundable on the supply of finished pharmaceutical products; therefor working capital requirements have increased, because it takes 1-2 years for full consumption of raw materials on the manufacturer's end.

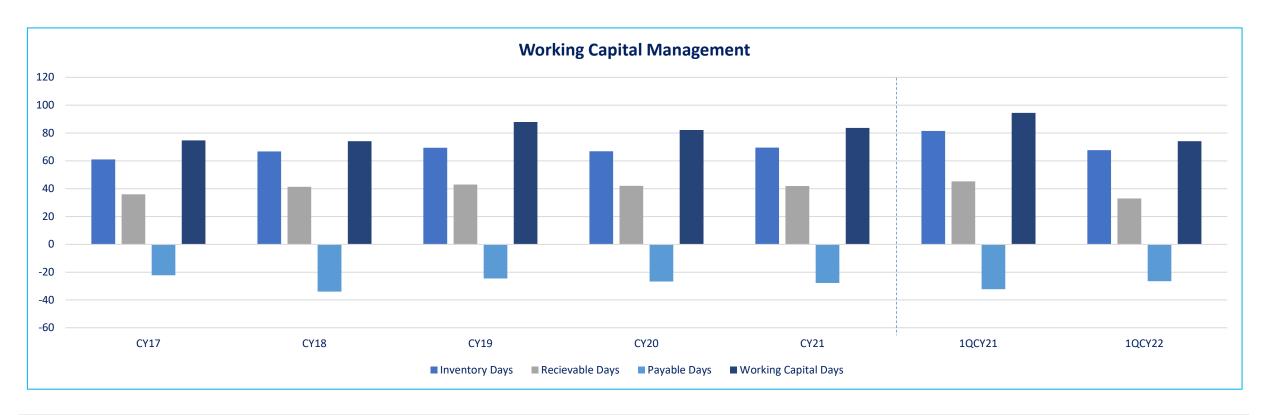






Financial Risk-Working Capital

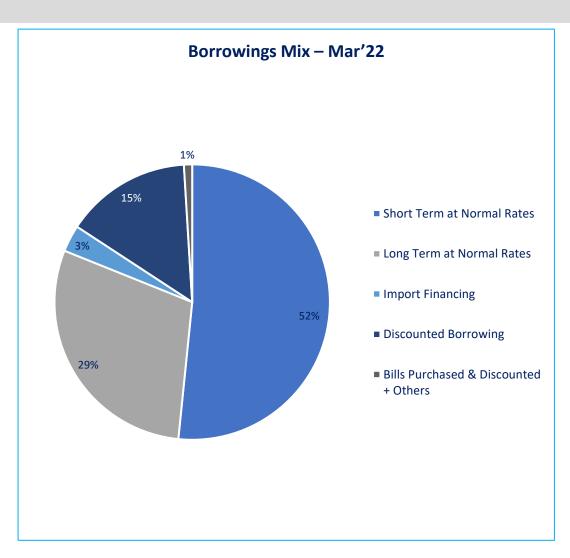
- The sector's working capital structure is characterized by high inventory days. However, in 1QCY22 the working capital days of the industry reduced to ~74 days (1QCY21: ~95 days).
- Average cash conversion cycle of the sector is ~83 days. Working capital cycle reduced during 1QCY22, mainly due to higher revenue and inventory offtake.





Financial Risk-Borrowings

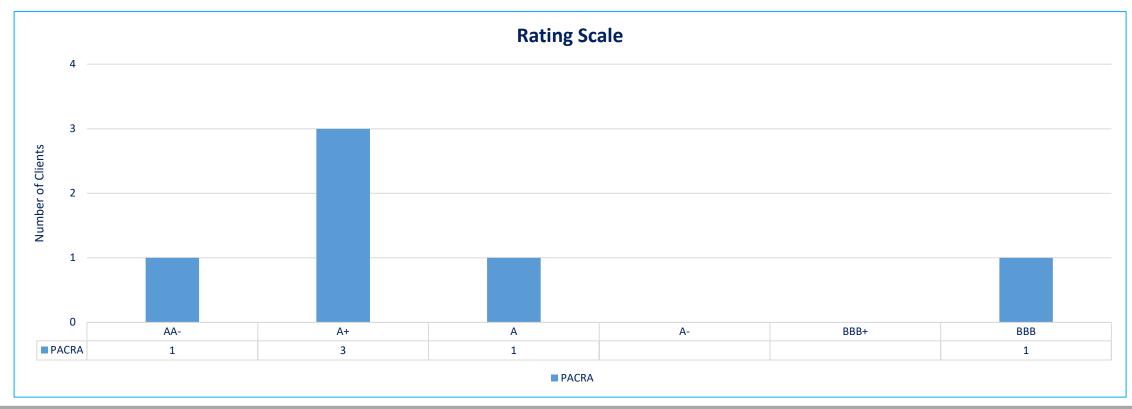
- As of March'22 sector borrowings stood at PKR~83,193mln (March'21: PKR~80,741mln) posting a growth of ~3% YoY.
- As the industry is highly reliant on imported inventory; short term loans held the largest portion of ~52% in the borrowing mix and stood at PKR~42,935mln recording a growth of ~9% YoY.
- Long term financing held the second largest portion of ~29% in the borrowing mix and stood at PKR~24,521mln after decreasing by ~14% YoY.
- Discounted borrowings in terms of LTFF, TERF and EFS held a ~15% share in the borrowing mix and stood at PKR~12,322mln after posting the highest growth among all debt components of ~49% YoY.
- Import financing, which stood at PKR~2,612mln, grew by 4% YoY, and held a share of ~3% in the total borrowing mix.
- Bills Purchased and discounted stood at PKR~803mln after declining by ~63%
 YoY and held less than ~1% share in the total borrowings.
- As of 1QCY22, the sector's average interest cover stood at ~11x (1QCY21: ~12x); while sector gearing ratio stood at ~20% (1QCY21: ~23%), both indicating sound financial strength.





Rating Curve

- PACRA rates 6 clients of the Pharmaceutical industry.
- 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.
- In 2022 GoP through S.R.O. 383 (1)/2022 introduced 17% sales tax on purchase of raw material.

		Custom duty	Sales tax	Income tax	Additional Custom duty
API	FY21	11%-20%	17%	11%	2%-7%
	FY22	0%-20%	17%	2%	0%
		Custom duty	Sales tax	Income tax	Additional Custom duty
Excipients	FY21	3%-90%	17%	11%	2%-7%
	FY22	5%	0%	2%	0%
		Custom duty	Sales tax	Income tax	Additional Custom duty
Drugs	FY21	0%-20%	0%-17%	0%-11%	0%-7%
	FY22	0%-10%	0%-17%	0%-2%	0



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.



Porters 5 Forces Model



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

- 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





- 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.



SWOT Analysis

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



- 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 industry

- High level of competition
- Increasing cost of energy
- Third wave of covid-19 lockdown and possible lock down will disrupt the supply chain
- Rising Interest rates

Threats Opportunities

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



Outlook: Stable

- Pharmaceutical Industry 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; extensive regulations are essential considering the importance of the sector in the healthcare system; moreover forward looking regulations are required to promote research and development in the country.
- The revenue of the sector has shown a robust growth in the recent period. It is further expected to grow considering the population growth rate, currently low per capita healthcare spending and increasing awareness amongst the rising middle class of the country.
- Due to strong fundamentals, the sector has managed to retain healthy margins despite unfavorable factors such as currency devaluation and rising freight costs. An almost ~24% YoY currency devaluation was witnessed in May'22 along with a ~25% increase in ocean freight rates. This could result in exerting cost push pressures on the sector margins.
- 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 operation rather than for research and development activities, therefore growth and advancement in the sector remains laggard.
- SBP has also revised it's policy rate upwards to 13.75%; it is expected to increase the industry's finance cost by PKR~6.2bln compared to the previous year.
- During the current fiscal year, a slight decline in exports was witnessed, but since a major chunk of sector revenue is driven from the local market, demand can reasonably be expected to remain stable.



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