Pharmaceutical
Sector Study

May 2021

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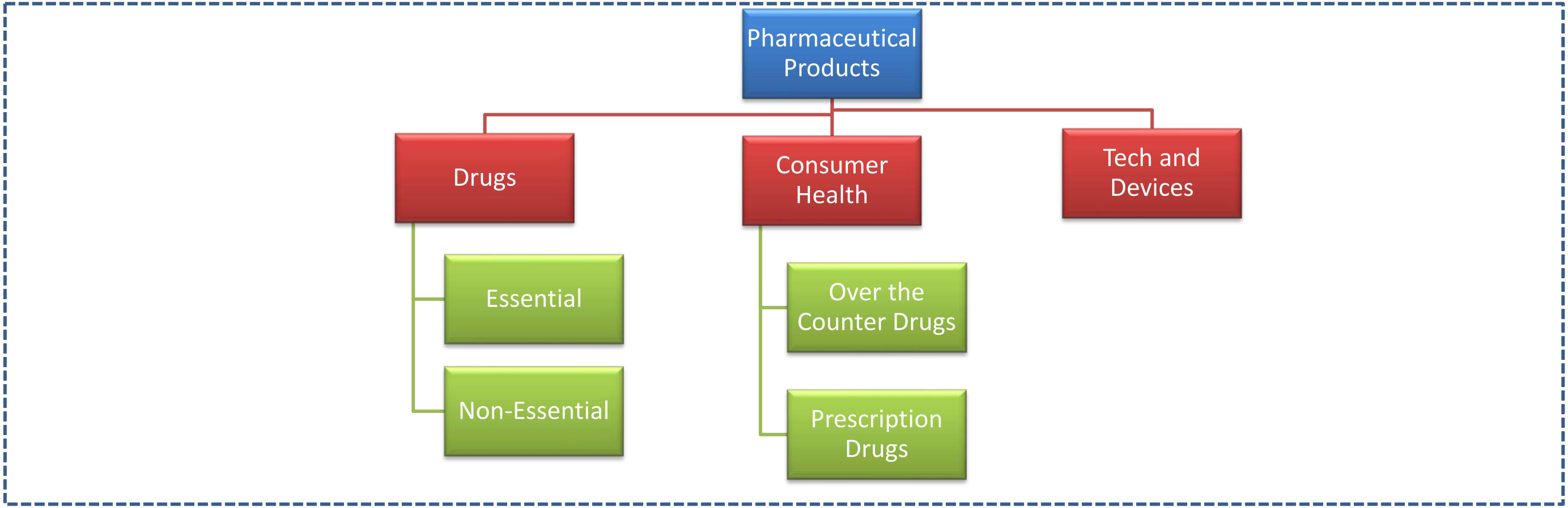
Sector Overview

- 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.



Source: DRAP

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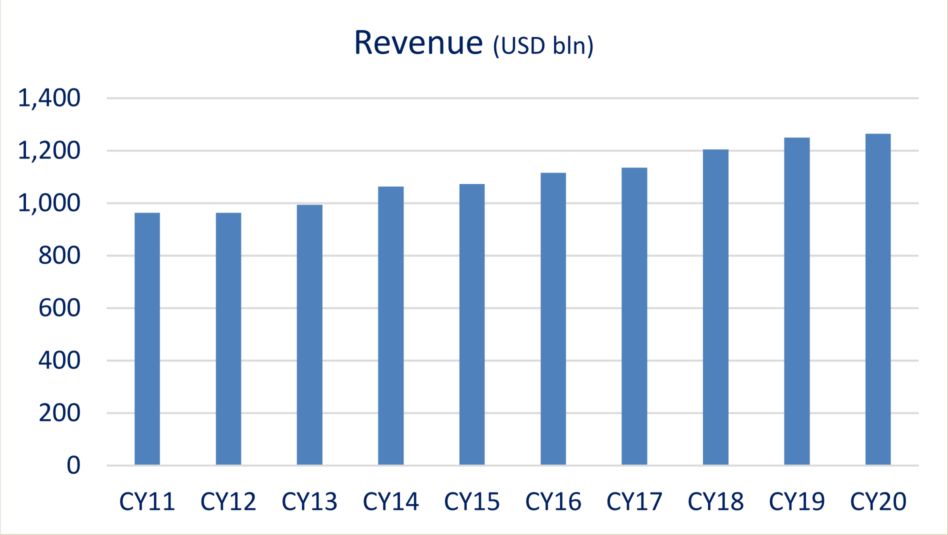
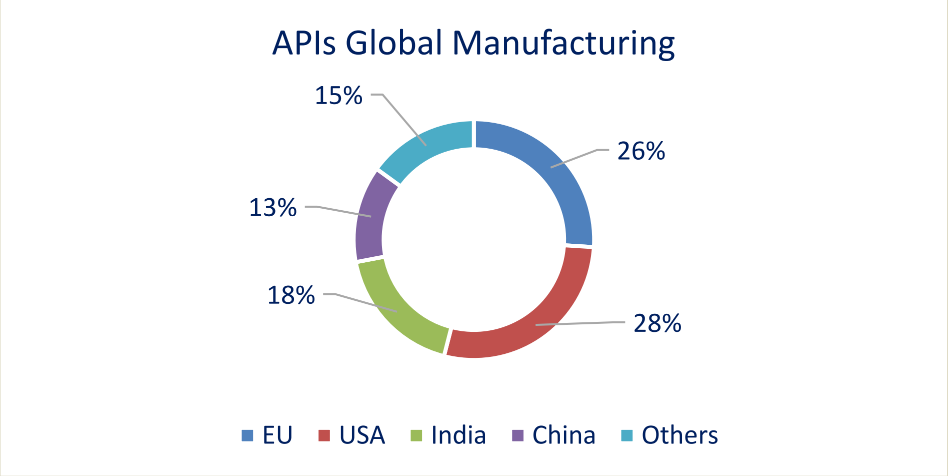
Global Overview

- The global pharmaceutical sector revenue is expected to reach USD~1,570bln in CY23 at CAGR of ~7.5% while standing at USD~1,265bln as at end CY20. During the COVID-19 pandemic, the focus of pharmaceutical sector was diverted towards viral vectors in the virotherapy and vaccine sectors in delivering effective vaccines and pharmaceutical treatments. After the vaccine, the pharmaceutical sector will return back to pre-covid projects. Many of these projects will benefit from lessons learned by the sector during the COVID-19 outbreak, helping to speed up their successful development.

- North America was the largest region in the global pharmaceutical market, accounting for ~46% of the market in CY20. Asia Pacific was the second largest region accounting for ~26% of the global pharmaceutical market. Africa was the smallest region.

- The manufacturing side of the pharmaceuticals 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. The global pharmaceutical manufacturing market is expected to garner growth at a noteworthy CAGR of ~13% from CY21 to CY30.





Source: Statista, Global news wire

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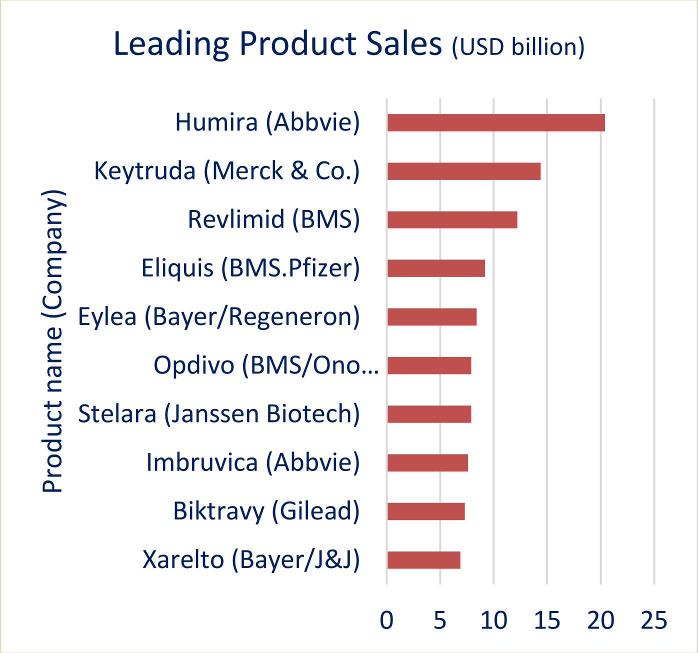
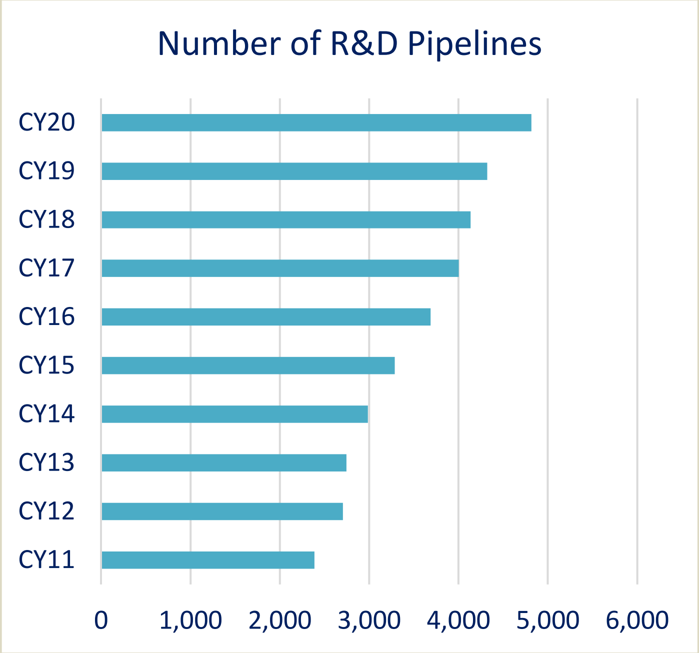
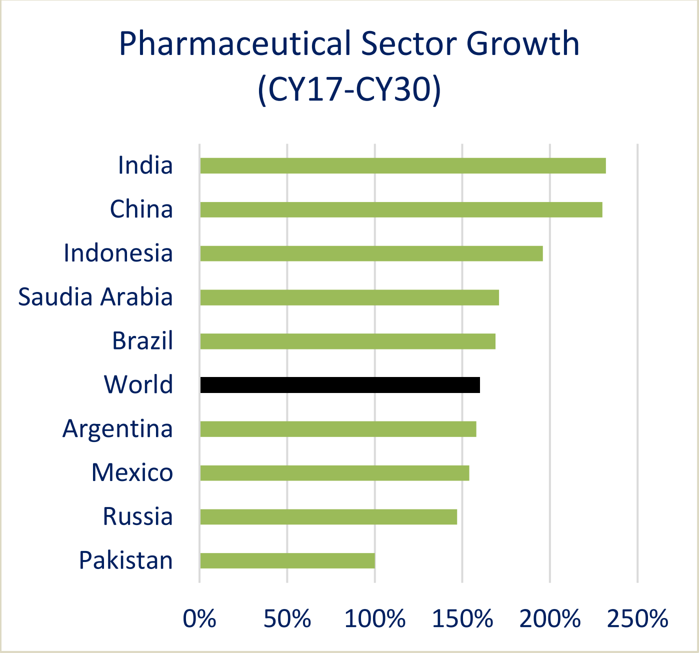
Global Overview|Growth Prospects







- 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 from ~2,387 in CY11 to ~4,816 in CY20. The global pharmaceutical sector is expected to grow ~1.6x from CY17 to CY30. China and India are two most promising in pharmaceutical growth.

- As the largest producers of Active Pharmaceutical Ingredients (APIs), a basic raw material used in manufacturing, in the world were battling against COVID-19 in CY20, the supply chain was disturbed and sales target were not met. This has highlighted the risk of global supply chain concentration and emphasized on further need of global manufacturing diversification.

Source: Statista

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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.

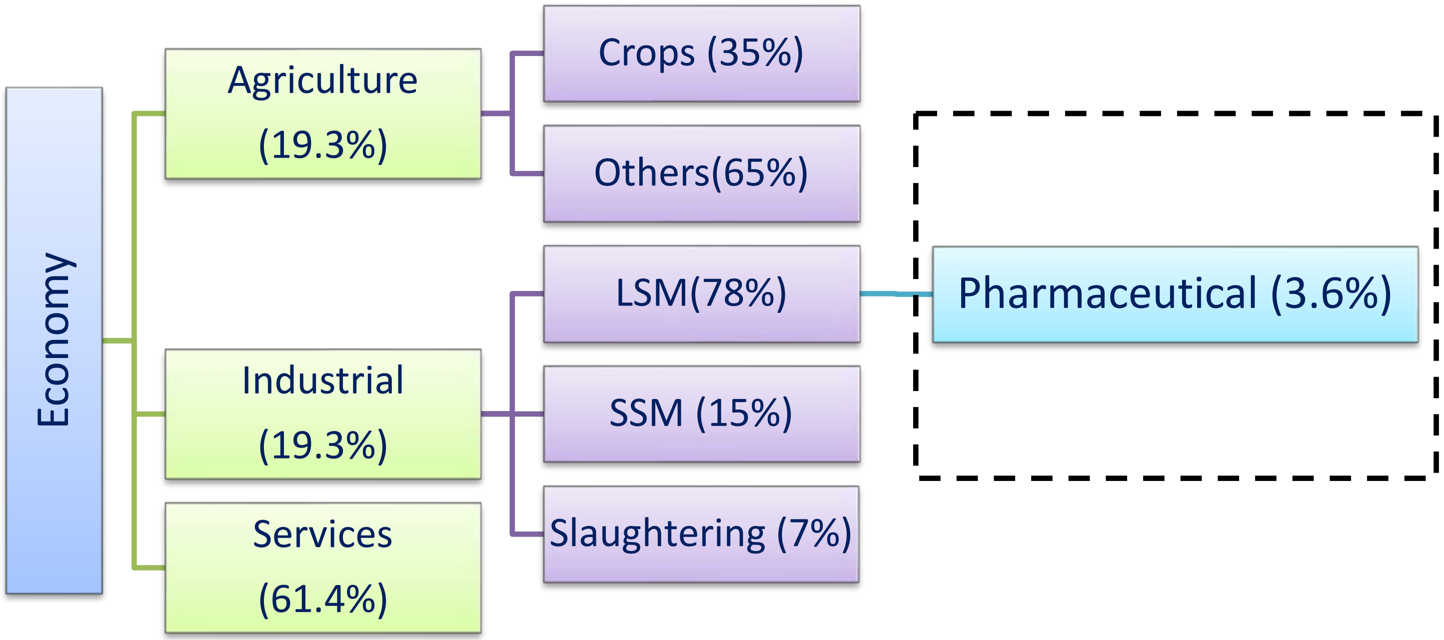
Packaging is done and properly labeled for usage. Ingredients and side affects are listed. The final product is than shipped for retail.

Source: PPMA

Large Scale Manufacturing- Overview

- Large Scale Manufacturing (LSM) is essential for economic growth considering its linkages with other sectors. It contributes ~9.5% to Pakistan's GDP. During FY20, the country's overall GDP contracted by ~0.4% on account of the COVID-19 pandemic spread (FY19: Growth ~1.2%). COVID-19 lockdown and overall economic slowdown had severe implication for LSM as it registered negative growth of ~10.17% during FY20 (FY19: ~-3.4%).

- The government of Pakistan and SBP announced a series of incentives during 4QFY20 to support businesses and to stimulate business activity. The stimulus measures started to yield positive results for the economy as the LSM posted a growth of ~9% during 3QFY21 (3QFY20: ~-5.4%).



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Industry Snapshot

- Pharmaceutical sector recorded a revenue of PKR~453bln during FY20 with YoY growth of ~9% (FY19: PKR~416bln). The revenue was impacted by the closure of Outpatient Departments (OPDs) as the sector registered a growth of only ~4% in 4QFY20.
- Despite the large number of registered companies (620), the sector is dominated by 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	FY19	FY20
Gross Revenue	PKR 416bln	PKR 453bln
Contribution to GDP	1.16%	1.17%
Registered Manufacturers	620	620
Structure	Regulated & Oligopolistic	
Imports (PKR)	PKR 148bln	PKR 158bln
Exports (PKR)	PKR 29bln	PKR 33bln
Regulator	Drug Regulatory Authority of Pakistan	
Association	Pakistan Pharmaceutical Manufacturers Association	

Source: IQVIA, PPMA,PBS,DRAP

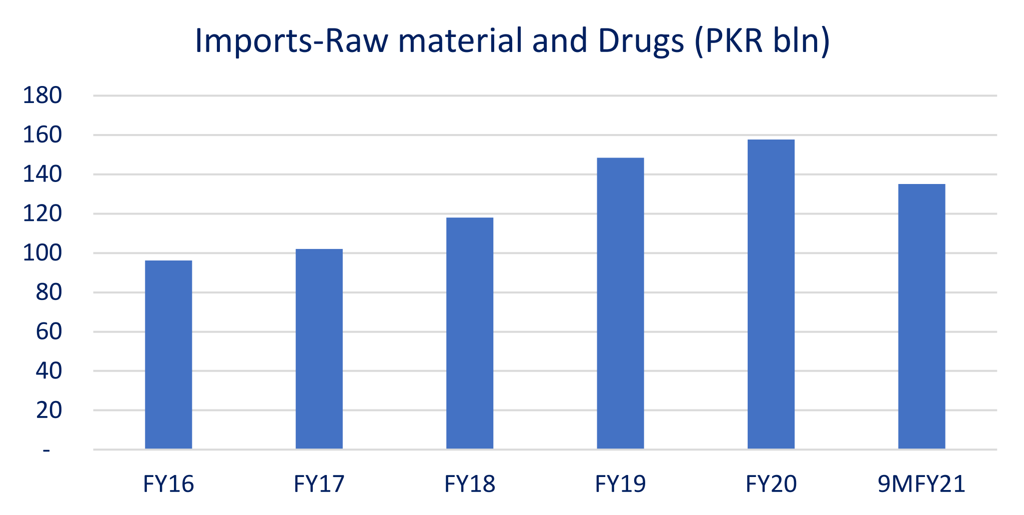
Supply|Raw Material

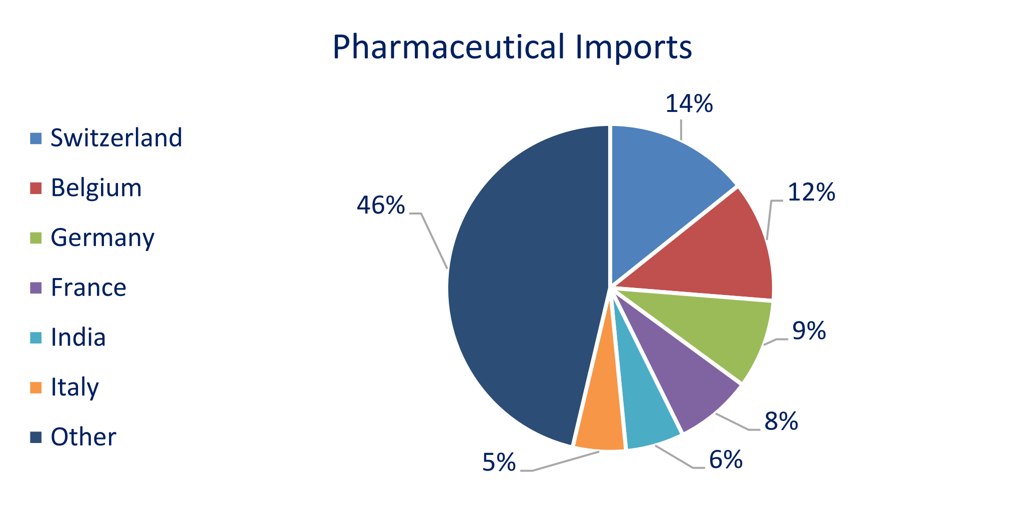
- Pakistan pharmaceutical industry is only able to make up ~5% of its APIs locally whereas, the rest of the ingredients are being imported. Low emphasis on research and development by local companies is the major reason behind significant reliance on imported raw material.

- During FY20 pharmaceutical imports were recorded at PKR~158bln (FY19: PKR~148bln) with YOY growth of ~7%. Imports reached PKR~135bln during 9MFY21 (9MFY20: PKR~118bln) up ~14% YOY.

- 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.

- Switzerland is the largest exporter of pharmaceutical products to Pakistan followed by Belgium, Germany, France, India and Italy. 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.





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Demand|Consumption

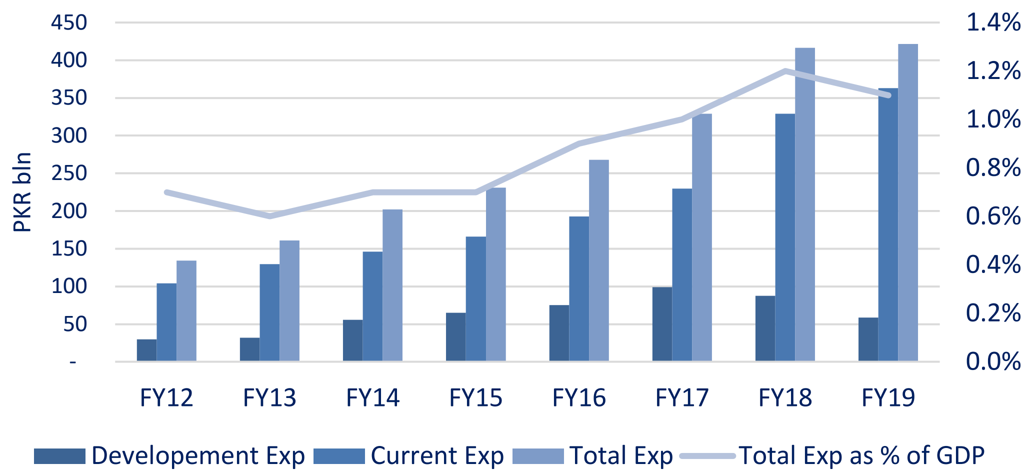
- With current population of more than ~220mln, the population growth rate of Pakistan is ~2% significantly higher than global growth rate of ~1%. Decrease in mortality rate from 84.3/1,000 births in 2000 to 55.6/1,000 births in 2019 and increasing average age from ~62 in 1990 to ~70 by 2020 has resulted in more people reaching older age and hence increasing the demand of robust healthcare system.

- Due to 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.

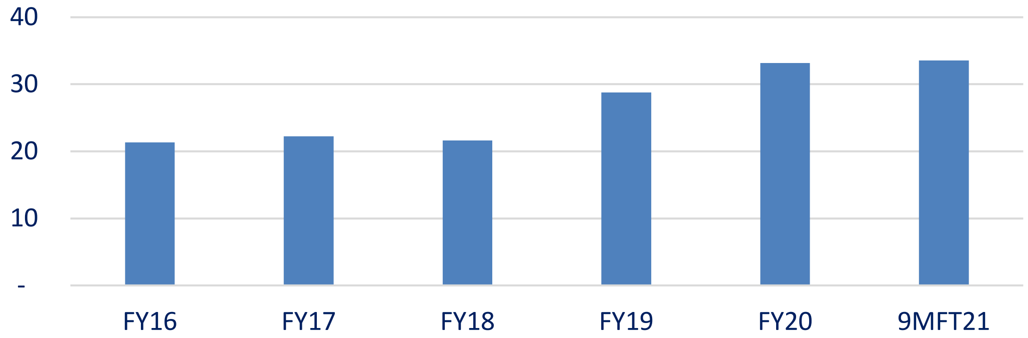
- Health care expenditure was recorded at PKR~422bln in FY19 with CAGR of ~18% since FY12. Total expenditures showed subdued growth of ~1.28% during FY19 due to rising fiscal deficit. Going forward spending is expected to increase owing to COVID-19 outbreak and substantial increase in number of families enrollment under Sehat Sahulat Program.

- The COVID-19 pandemic and global supply chain disruptions gave rise to pharmaceutical exports. Exports during 9MFY21 were recorded at PKR~34bln (9MFY20: PKR~26bln) with YOY growth of ~31%.

Health Care Expenditure (Both Federal and Provincial Governments)



Exports (PKR bln)



Source: PBS

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 will be 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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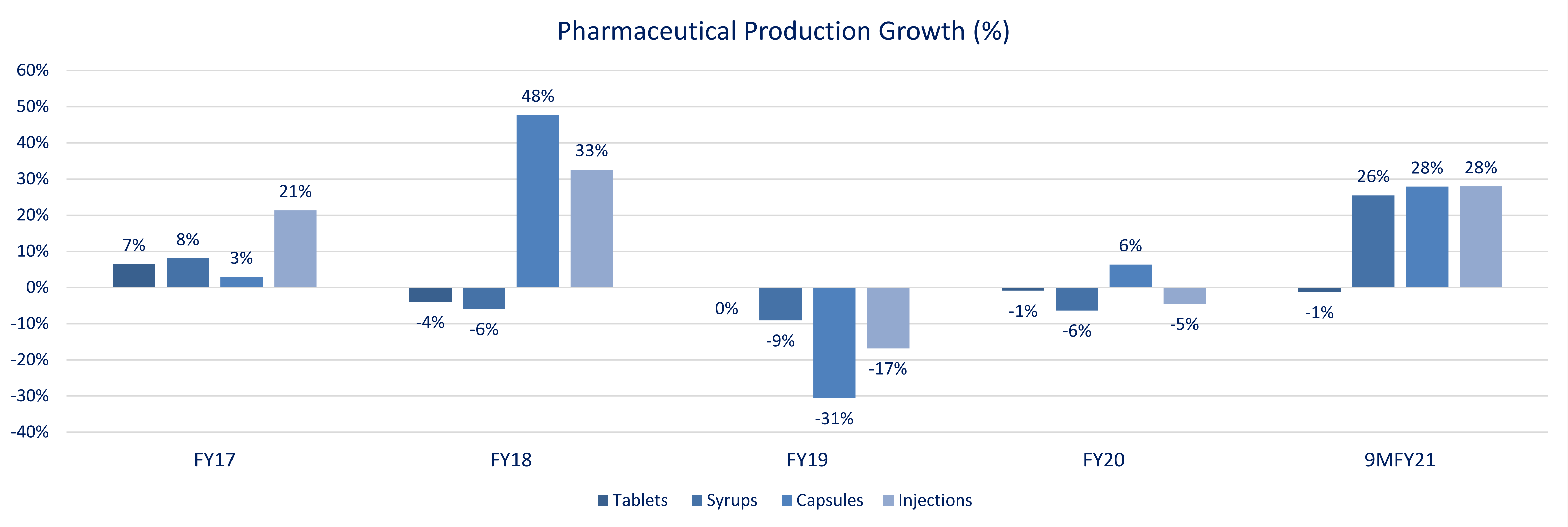
Supply|Production

- Overall production of the sector showed positive growth during 9MFY21. 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.

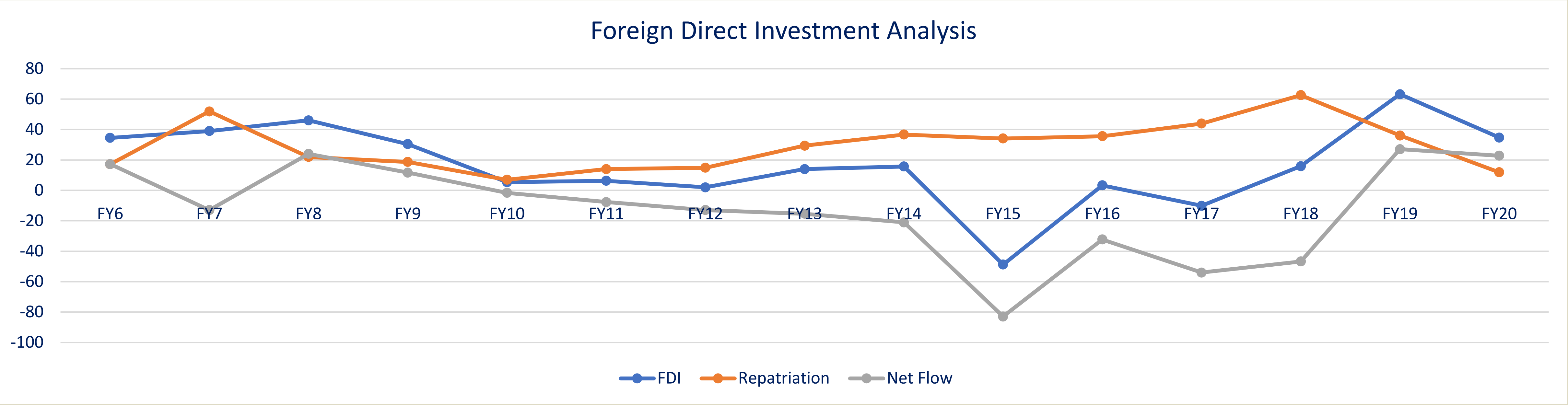


Source: PPMA,PBS

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 exited Pakistan's pharmaceutical industry.



Source: PPMA,PBS

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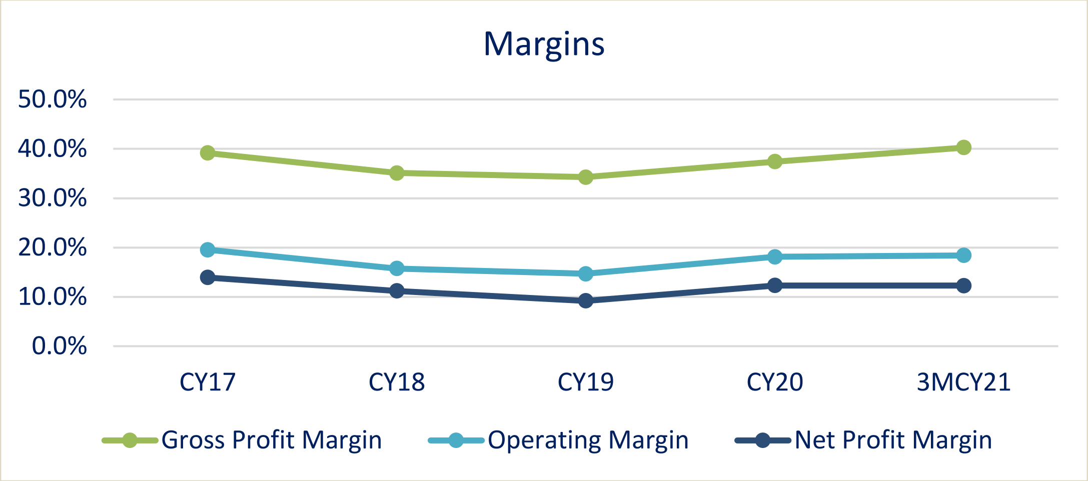
Business Risk

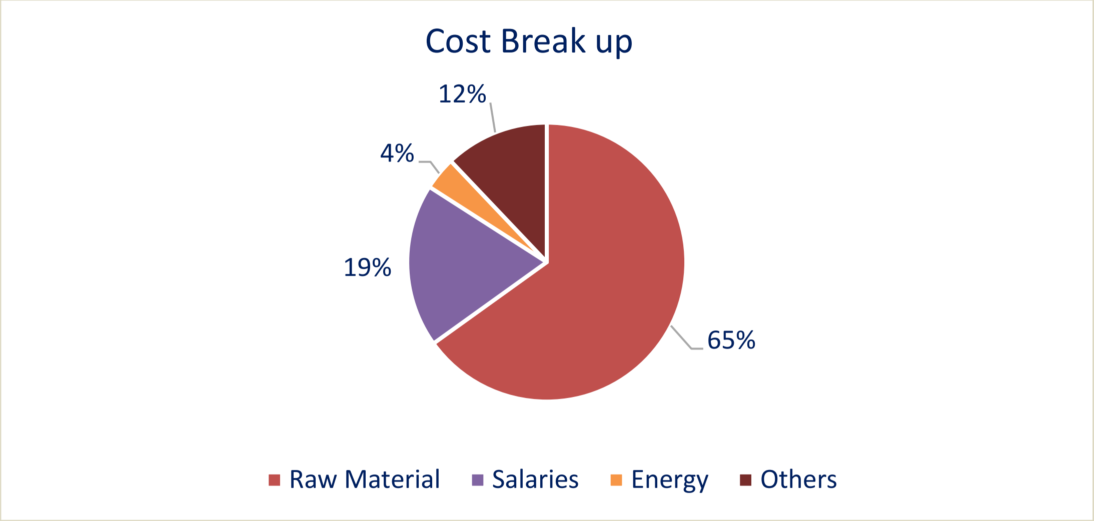
- Rising cost of sales and declining gross margins were observed in FY18 and FY19. Depreciating exchange rate and delay in price hikes by DRAP resulted in lower margins in CY18 and CY19. Positive growth in margins can be seen in FY20 and 9MFY21 with declining cost of sales and improving profit margins. Stable exchange rates provides stability to margins.

- Pharmaceutical business model heavily relies on raw material as it makes up ~65% of its cost of sales while energy cost being the lowest component accounts for ~4%. Salaries and other expenses account for ~31% of cost of sales.

- With DRAP regulating the prices of drugs, the profits margins are sensitive to exchange rates fluctuation and change in cost of raw material. ~95% of raw material (APIs) is imported and posses a major risk for the Industry.

- Companies with larger concentration of non-essential and low priced drugs will have larger impact on revenue from price change every year, all else equal.





Note: Calculations based on PACRA rated and selected PSX listed companies.

Source: PACRA Internal Database

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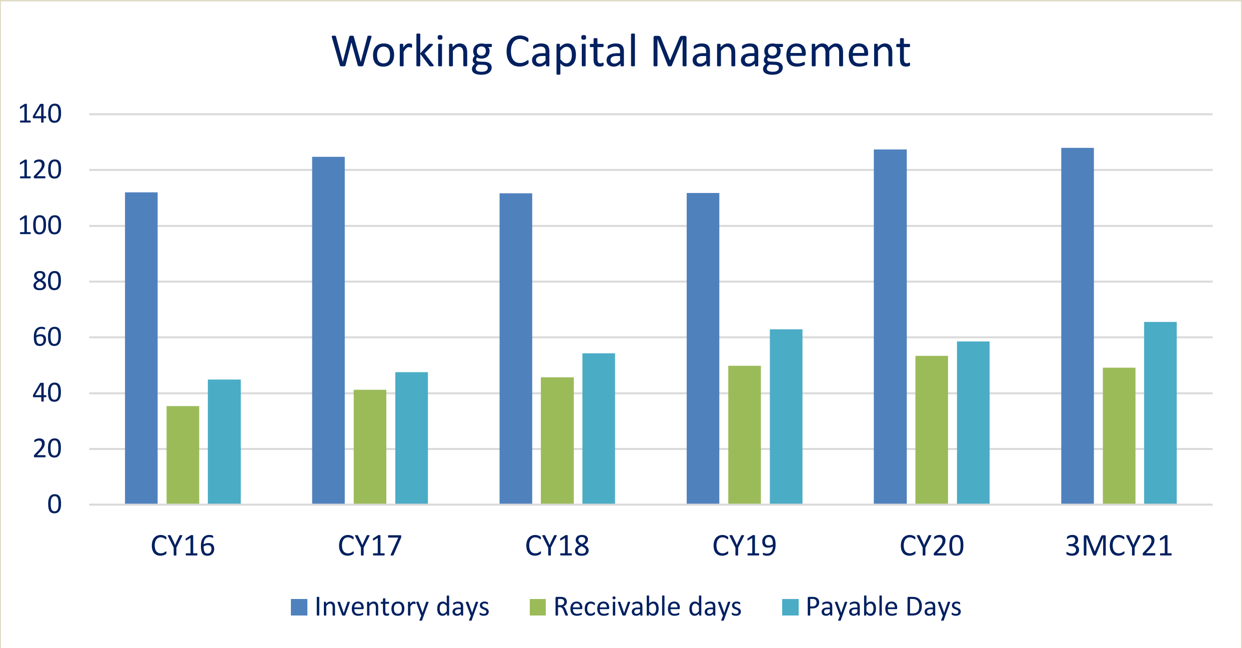
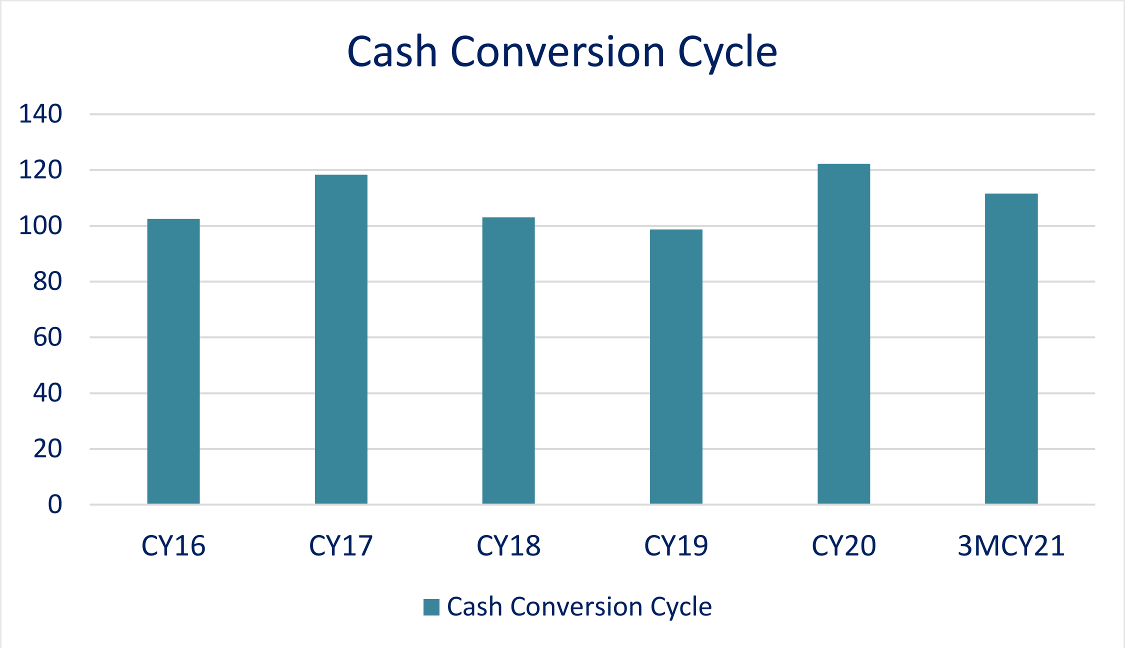
Financial Risk-Working Capital

- Working capital structure of the sector is characterized by high inventory days. Cash conversion cycle of the sector increased significantly to ~122 days during CY20 owing to general business disruptions caused by the pandemic.

- Stricter lock down by the government to contain the spread of COVID-19 during ongoing third wave has the potential to put more pressure on the sector's working capital management.





Note: Calculations based on PACRA rated and selected PSX listed companies.

Source: PACRA Internal Database, SBP

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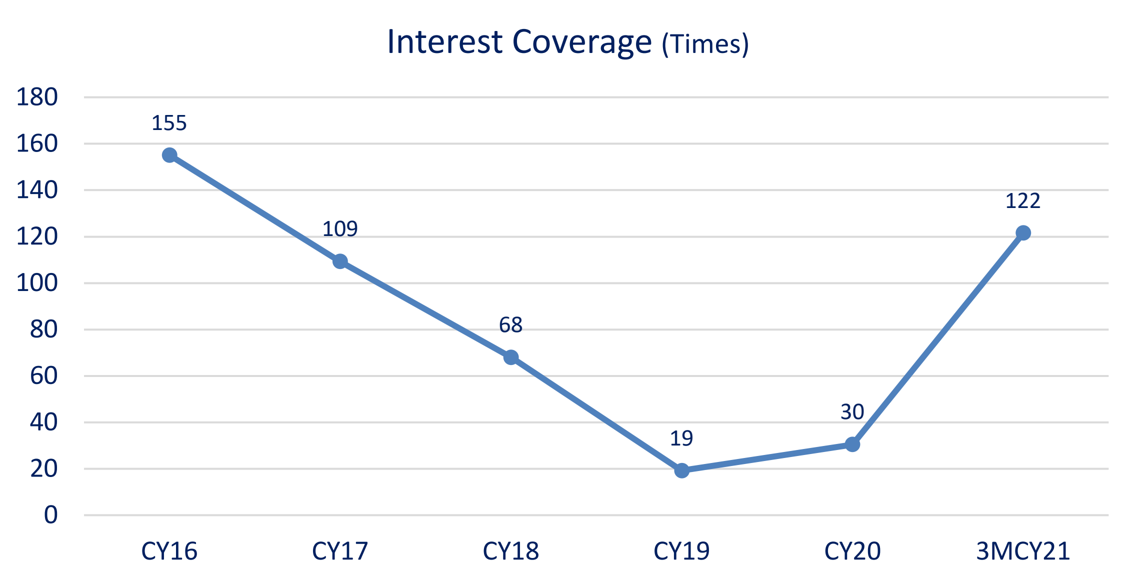
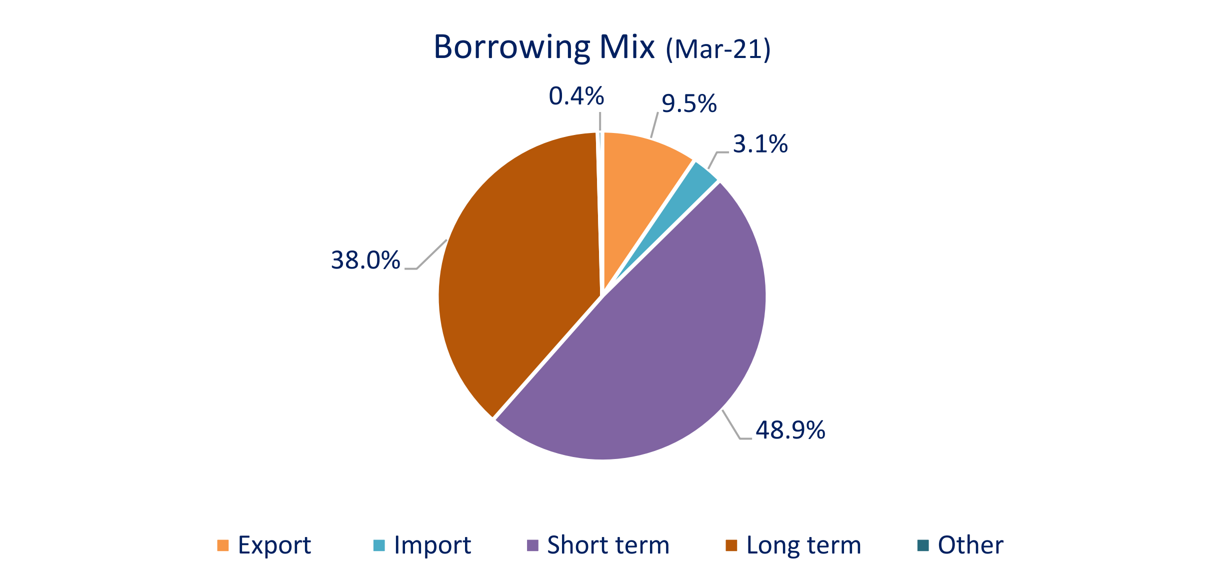
Financial Risk-Borrowings

- Total sector borrowing clocked at PKR~81bln at End-Mar'21. Last year, total borrowing stood at PKR~55bln as of End-Mar'20. The Industry is heavily reliant on import of raw material which constitutes a major portion of its cost. Short term borrowing makes up ~48.9% of the total borrowings of the sector. The major portion of increase in sectors borrowing is being taken up by local manufactures while decrease in debt financing by MNCs is observed.

- Infection ratio for the sector increased from ~5.3% in Jun-19 to ~5.8% in Jun-20. The gearing ratio of industry is low and ranges between ~15%-~25%. Given the nature of operations in the sector, most debt is being utilized in short term borrowing. With an interest coverage ratio as high as ~122x, the overall financial risk of the sector is considered low.





Note: Calculations based on PACRA rated and selected PSX listed companies.

Source: PACRA Internal Database, SBP

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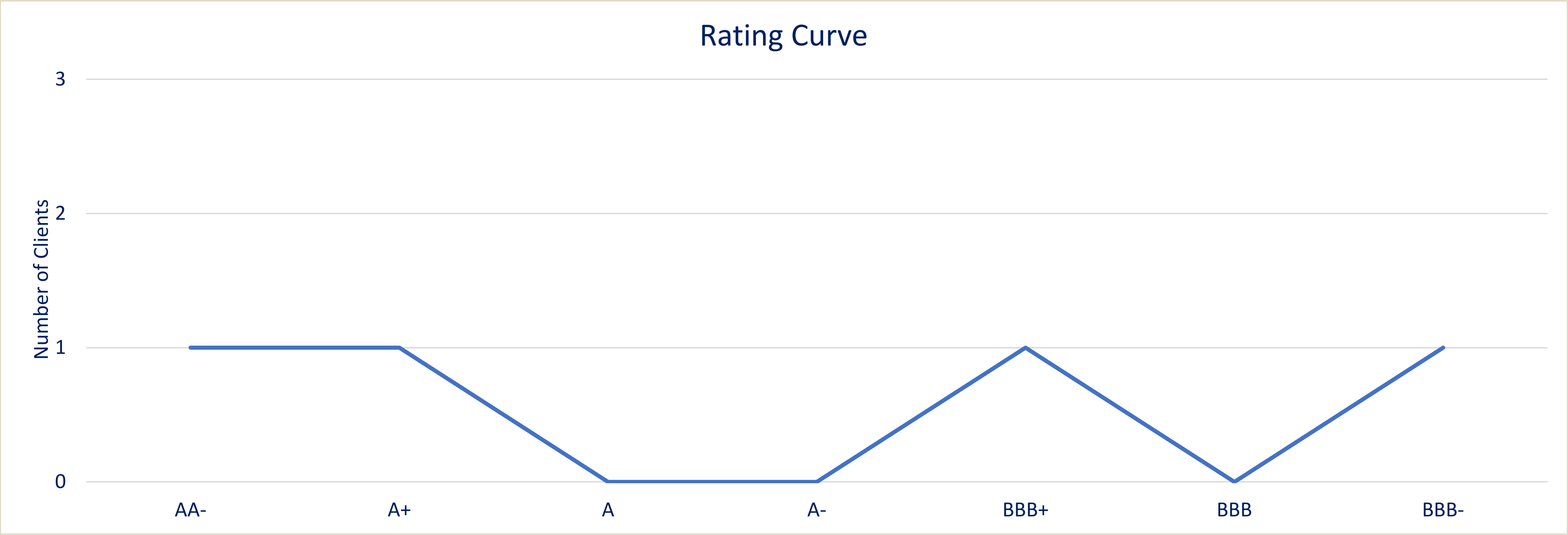
Rating Curve

- PACRA rates 4 clients of the Pharmaceutical industry.
- Rating bandwidth of the sector is AA- to BBB-



Source: PACRA Internal Database

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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.

- Sales of pharmaceutical products are exempted from output sales tax.

		Custom duty	Sales tax	Income tax	Additional Custom duty
API	FY21	11%-20%	17%	11%	2%-7%
	FY20	11%-20%	17%	11%	2%-7%
		Custom duty	Sales tax	Income tax	Additional Custom duty
Excipients	FY21	3%-90%	17%	11%	2%-7%
	FY20	3%-90%	17%	11%	2%-7%
		Custom duty	Sales tax	Income tax	Additional Custom duty
Drugs	FY21	0%-20%	0%-17%	0%-11%	0%-7%
	FY20	0%-20%	0%-17%	0%-11%	0%-7%

Source: FBR

Regulation

- 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 Drugs Regulatory Authority of Pakistan 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-CY18, the country has 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 will have 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

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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 industry

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

- 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

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

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Outlook: Stable

- Pharmaceutical sector is one of the highly regulated sectors of the economy. The companies operating in the sector require approval for almost everything from approval for import of products to price determination/revisions. 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 over the years and is expected to grow further on the back of rising population, currently low per capita healthcare spending and increasing awareness amongst the rising middle class of the country. Increased revenue on the back of vaccines and COVID-19 related drugs will also provide positive impetus to the sector. After the amendments in DRAP pricing regulations, long delays in price revision will be avoided, which will further augments the sector's revenue.

- Profit margins of the sector have remained strong despite the outbreak of pandemic. Stable exchange rates and historical low interest rates have further increased the margins in recent years. As the companies in the sector are not involved in any kind of price competition, margins of the sector are expected to remain intact keeping other factors constant.

- Working capital need of the sector are driven by high inventory days. As working capital financing constitutes the largest portion of the sector borrowings, it reflects that most of the borrowed capital is utilized to finance day to day operations rather for research and development to increase local manufacturing.

- Owing to disruption in global supply chain and increased demand of pharmaceutical products amid COVID-19 pandemic, exports have grown significantly. Exports are expected to increase as the COVID-19 pandemic situation persists.

Source: PACRA Internal Database

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