INDUSTRY RISK ANALYSIS

Pharmaceutical

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Assessment of the risks inherent to the industry in which the company operates is one of the essential steps during the credit rating process. The industry risk assessment sets the ceiling for ratings of individual entities within a given industry. It focuses on the degree of cyclicality and the strength of competitive forces along with the extent of capital intensity, vulnerability to technological change, level of regulatory interference and energy sensitivity. All these factors are assessed on a scale ranging from High to Low to assign an overall risk level to each industry.

This document explains VIS approach to assess industry risk of Pharmaceutical sector of Pakistan.

Pharmaceutical Sector in Pakistan

OVERALL INDUSTRY RISK
High
High to Medium
Medium
Medium to Low
Low

The Pharmaceutical sector of Pakistan has grown at a Compound Annual Growth Rate (CAGR) of 10-12% since the last five years; and estimated to be around USD 3.2 billion in 2020, doubled from USD 1.64 billion in 2011. According to Drug Regulatory Authority of Pakistan (DRAP) – the governing body of the sector, the pharmaceutical industry in Pakistan comprises of 620 players. Of the approximate USD 3 billion pharmaceutical market in Pakistan, 80% of medicines (in their final dosage form) are manufactured in Pakistan, while the remaining 20% are imported. The market is highly skewed; the top 50 firms have 80% of the market share while the top 100 firms constitute 97% of the market share, depicting concentration in the industry with more than 500 firms competing for 3% of the market. The industry is also divided between multinational companies (MNCs) and local manufacturers. Over the years, the share of contribution of MNCs has reduced. It was initially dominated by 40 MNCs in the 1990s in terms of numbers as well as market value. The number has reduced to around 25 with local players constituting majority of the share. The industry is further differentiated in terms of product market. The MNCs primarily produce original drugs that have been developed using their own research and for which they have or had a patent. Local firms, on the other hand, produce generic drugs that are primarily sold as generics.

The sector is characterized among health care essentials. The average health care expenditure per capita of Pakistan stands at approximately USD 43/capita, while the global average stands at approximately USD 1,100/capita. With increasing population and awareness towards health and hygiene; the demand outlook of the pharmaceutical industry remains positive.

The industry is import dependent with 95% basic raw material (Active Pharmaceutical Ingredient (API)) requirements being met through imports. Domestic production is currently low in Pakistan while exports are minimal. However, the industry has the opportunity to capitalize on the off-patent generics market in the short-run for exports; wherein the market accounted for approximately 151 billion at end-2020. For the long run; Pakistan may consider entering into the global human vaccine market which was worth USD 33 billion in 2019 and is expected to reach USD 66.6 billion by 2027. Financial performance of the pharmaceutical industry, historically, has not fluctuated with changes in the economic environment. Cyclicality risk therefore is considered low. Growing population and increasing health awareness in the population has provided support to the sector.

Assessment of competitive risk encapsulates the existence of barriers to entry, availability of substitutes and risk in growth trends. Barriers to entry in the pharmaceutical sector are considered low given the market structure characterized with significant number of players. The top heavy structure reflects higher brand loyalty in this sector. However, the industry is more focused towards generic drugs, and research and development investments are minimal. As a result, firms can enter the industry with low investments. This allows entry of new players and therefore risk of effectiveness of barriers to entry is considered high.

Risk of substitution in the pharmaceutical industry is evaluated as low. There is no alternate technology or product that can act as a substitute for pharmaceutical products. Alternative medicines such as herbalism, homeopathy, and acupuncture exist but remains a very small contributor nor does it cover all treatments. Therefore, risk of substitution in the pharmaceutical sector is considered low.

Growth trend in this sector remain positive, driven by high population growth; dismal health facilities; increasing incidence of diseases; shifts in demand patterns with increasing life expectancy, literacy rates, incomes, and better awareness of health-related issues. A global healthcare data company, IMS/IQVIA, has categorized the pharmaceutical industry of Pakistan among the “Pharmerging” industries. A country is categorized as a Pharmerging market if

capita income is below USD 30,000/year and five-year absolute growth in industry's spending exceeds USD 1 billion. Furthermore, there is an opportunity to capitalize on the off-patent generics market in the export markets. Therefore, given high risk of effectiveness of barriers to entry, low risk of substitution and low risk in growth trends, overall competition risk for the sector is medium.

Industry risk analysis also entails assessing the level of capital intensity, tenure of return on capital, and access to debt/ equity financing. While substantial Research & Development (R&D) expenditure is required in the pharmaceutical sector for production of any new drug together with significant time and approvals involved for regulatory approvals, the industry's focus continues to remain on generic drugs over branded drugs. The level of investment expenditure for establishing a manufacturing facility for the former is considered as medium to low when compared with other industries.

Vulnerability to technological change for Pharmaceutical sector is low as the industry is characterized with very low R&D spends. The industry is concentrated towards drug formulation rather than innovation; with pharmaceutical products primarily ranging from tablets, liquids and syrups, capsules, injections, tinctures, capsules, and ointments. One reason for low R&D investments and innovation is the affordability of new molecules as healthcare expenditure in Pakistan is primarily financed through the private sector. Gradual departure of MNCs has further reduced skills and technology transfer and investments in the product space. Moreover; brand loyalty is considered to be high in the industry which lowers the incentives for new product development. Another important reason behind minimal R&D and innovation in this industry is the role of DRAP. Issues of weak regulation and administration of standards by DRAP; stringent pricing regime; weak intellectual property rights; non-pursuance of Stringent Regulatory Authority (SRAs) approvals for the manufacturing facilities lowers incentives for investments in R&D and innovation. Based on the aforementioned reasons; technological risk is low for the pharmaceutical sector.

The pharmaceutical industry of Pakistan is highly regulated by DRAP in terms of pricing, licensing, and procedural requirements. DRAP is mandated to ensure effective coordination and enforcement of the Drugs Act, 1976 to regulate, manufacture, import, export, store, distribute, and sell therapeutic goods in Pakistan. Price ceilings discourage players for local manufacturing of drugs; thus increasing reliance on imported Active Pharmaceutical Ingredients (APIs) (raw material for drugs) as well as partially manufactured drugs. The same further discourages innovation in the industry. Pricing regulations of 2018 has however allowed pharmaceutical companies to increase the price of essential drugs up to 70% of CPI (subject to cap of 7%) and non-essential drugs up to 100% of CPI (subject to cap of 10%), but inefficiencies of the regulating bodies including pending pricing approvals and notifications for technical testing and assessments by the Drug Pricing Committee (DPC) under DRAP continue to remain major challenges for the industry; along with the lack of indigenous research & development. Accordingly, regulatory risk is high for pharmaceutical sector.

Energy sensitivity as a risk parameter for evaluating industry risk encapsulates the availability and cost of energy as a proportion of their total production costs. Energy requirements for running plants in pharmaceutical industry are considered to be on the lower side when compared with other industries. As a percentage of cost of sales, energy costs account for a lower proportion. Therefore, energy sensitivity has been assigned a low risk rating.

Overall, on account of all the above mentioned risk parameters, industry risk of the pharmaceutical industry is assessed as Medium to Low.

Table 1: Summary of Industry Risk Factors

PHARMACEUTICAL								
Cyclicality	**Competition**				**Capital Intensity**	**Technology Risk**	**Regulatory Framework**	**Energy Sensitivity**
	Risk of Effectiveness of barrier to entry	**Risk of Substitutes**	**Risk in Growth Trends**	**Overall**				
Low	High	Low	Low	Medium	Medium to Low	Low	High	Low

To review industry risk assessment of other industries, refer to Industry Risk Analysis Document

(https://docs.vis.com.pk/docs/Industryrisk062021.pdf).

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