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Credit Rating Company Limited

PAKSTAN PHARMACEUTICAL SECTOR REPORT

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INTRODUCTION

Pharmaceutical is a critical sector that impacts public health globally. It plays vital role in healthcare system by researching, developing, manufacturing and marketing drugs for use as medications. Pharmaceutical companies discover and produce a wide range of medicines, from over-the-counter drugs like pain relievers and cold remedies to complex prescription medications for chronic diseases like cancer and heart disease and other life-saving drugs. The global pharmaceutical industry has shown rapid growth over the years and emerged as one of the fastest growing industries in the world though pharmaceutical production and consumption is still unevenly dispersed around the world with the developed countries as the leading producers and consumers of pharmaceuticals.

The modern pharmaceutical industry traces its origins back to the late 19th century, when companies first began researching and mass-producing medicinal drugs. In the early 20th century, breakthroughs like the discovery of penicillin and insulin helped establish drug research as a viable industry. Over the next few decades, advancements in chemistry, biology, and medicine accelerated drug development. Major transformations came in the 1970s with the adoption of recombinant DNA technology, allowing mass production of drugs like insulin that were previously only available in limited quantities. Regulatory changes have also facilitated growth of the industry by speeding up review processes and extending patent protections. In the 1990s and 2000s, the mapping of the human genome enabled more targeted drug therapies, especially in oncology. Other innovations like high throughput screening and combinatorial chemistry enabled rapid drug discovery and optimization. Information technology advancements also allowed companies to digitize and automate more of the drug discovery process. More recently, the industry has seen shifts towards biopharmaceuticals, personalized medicine, and specialty drugs for niche patient populations.

Rising costs of drug development, pressure to lower drug prices, expiring patents on popular drugs, and growing demand for generic drugs are some of the trends shaping the pharmaceutical sector. Recent developments include increased merger and acquisition activity among big pharma companies to boost pipelines, as well as growth of biologic drugs. The global pharmaceutical market is expected to grow steadily over the next decade driven by aging populations and increased access to healthcare in developing countries.

Generic Manufacturing Process

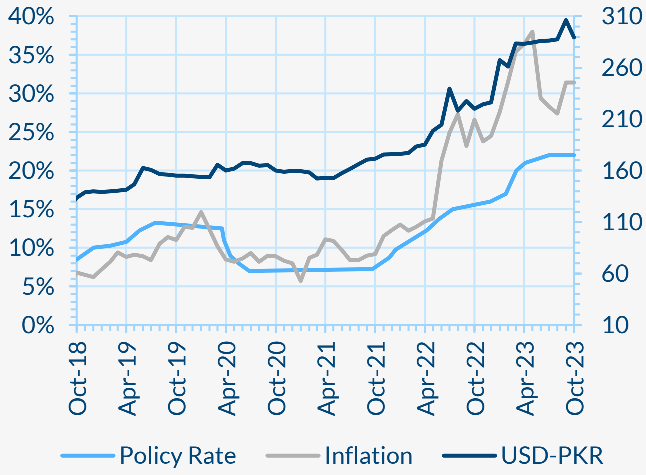
Drugs are rarely administered to a patient solely as a pure chemical substance. For clinical use they are almost always administered as a formulation designed to deliver the drug in a manner that is safe, effective, and acceptable to the patient. Therefore all drugs are made up by mixing of two core components – the Active Pharmaceutical Ingredient (API) and the excipient.

The API is the central ingredient, produced from raw materials with a specified strength and chemical concentration through multiple passes in reactors. An API has to be ultrapure to meet the strict quality criteria for medicines. The excipient includes substances other than the API that help deliver the medication to our system as well as aid in the processing of the drug delivery system during its manufacture; enhance product stability and safety, bioavailability, product identification, and assist in maintaining integrity of the drug product during storage. In the vast majority of cases, excipients have limited (if any) pharmacological activity, unlike the API. The form and dosage of medicine (i.e. packaging) depends on the route of administration of drugs and range from tablets, capsules, solutions, syrups, powder to aerosols, ointments and creams.

ECONOMIC OVERVIEW

The Pakistan economy is undergoing severe stress due to a combination of domestic and external factors. GDP growth has fallen to just 0.29% in FY23 down from 5.7% in FY22; however, the same is expected to improve to 3.5% during FY24. Persistently high inflation above 30% continues to erode purchasing power while tight monetary policy is hindering investment and growth. Moreover, import restrictions imposed to preserve foreign exchange reserves have led to shortages and production disruptions across industries. The devastating floods in 2022 damaged agriculture, infrastructure and livelihoods, inflicting losses of over $30 billion as per World Bank estimates.

Though measures like ban on luxury imports, subsidy rollbacks and new taxes to rein in the fiscal deficit taken in earlier part of 2023, brought some relief, however, structural issues plaguing the economy remain unaddressed. The major challenges include need for energy reforms, deterioration of social indicators, rising poverty and poor productivity.

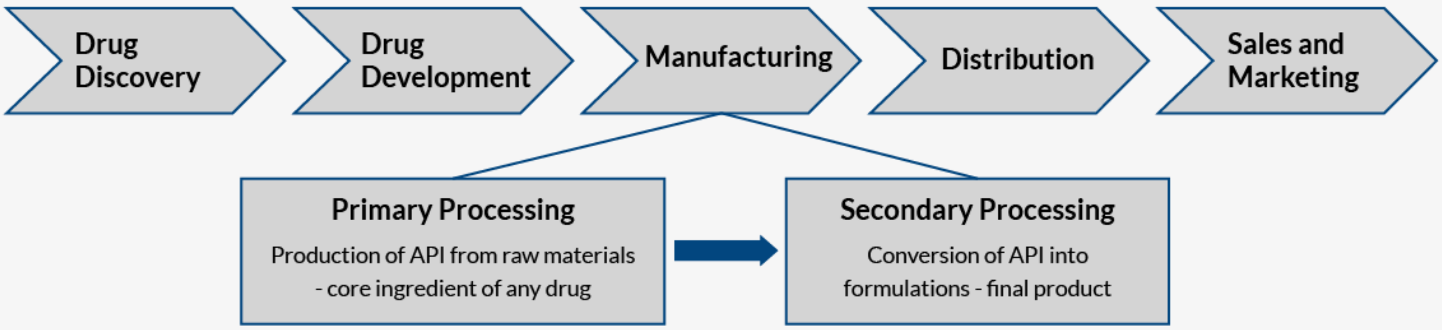


The pharmaceutical sector in Pakistan contributes more than one percent to the GDP and has approximately one percent share in the total exports. It saves more than USD two billion annually though import substitution and contributes some 4.2% to the largest manufacturing sector output. The sector is estimated to employ around 90,000 workers directly and 150,000 indirectly.

Expenditure on healthcare is one of the factor contributing to growth of the pharmaceutical sector. Expenditure on healthcare in Pakistan has been increasing steadily over the years. Yet, it is dismally low on regional as well as global comparison. Pharmaceutical spending shows a strong correlation with income levels. While it may be intuitive to correlate pharmaceutical growth with population, the Pakistani population under 30 years of age is more than 60%, which tends to consume a lower level of medication. Pakistan spent approximately Rs 920 bn on health care in 2022, representing about 1.4% of the GDP. In terms of per capita expenditure on healthcare, Pakistan ranks lowest in the region with average of USD 38 per capita against USD 56.63 in case of India, USD 151 of Sri Lanka, USD 50.66 of Bangladesh. Average per capita expenditure on healthcare in developed economies like USA is around USD 11,702, Switzerland USD 10,309, Norway 7,707, and Canada USD 5,620 leaving huge room for growth of Pakistan pharmaceutical sector.

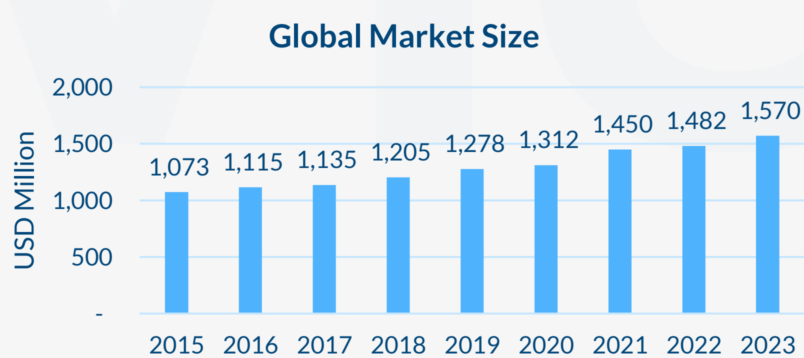
GLOBAL PERSPECTIVE

The pharmaceutical sector is a high-technology and knowledge-intensive industry. The industry has a two-tier structure. The largest firms account for the majority of the R&D investment in the industry and hold the majority of patents. A large number of smaller firms manufacture off-patent products or under license from a patent-holder. Pharmaceutical companies mainly deal in generic, branded, branded generic and over the counter drugs. Firms may also participate in contract development or manufacturing, where a company provides all-inclusive services from drug development to drug manufacturing for another client firm or just drug manufacturing. The typical supply chain followed world-wide is as follows:



Success of pharmaceutical companies depends on drug discovery, which take years of research and resources and subsequently on marketing efforts. The large pharmaceuticals spend heavily on both R&D and marketing. Although virtually all countries have some domestic production of pharmaceuticals, however, bulk of pharmaceutical production occurs in the USA, China, Japan, Switzerland, and the EU (particularly the UK). The second tier of manufacturers – who produce generics or products under license, conduct relatively little R&D of their own, compete mainly on the conventional dimensions of price, service and efficiency.

In recent years, the pharmaceutical industry has experienced massive growth, driven by numerous new market entrants, innovative avenues for pharmacological treatments and therapies, and consumer demands. For 2022, the total global pharmaceutical market was estimated at USD 1.48 trillion and is expected to grow to USD 1.57 trillion by end 2023. The global pharma market will be worth 1.7 trillion USD by 2025 dominated by the United States of America and China, which will represent more than half of the market. North America is expected to retain its leading position in the global pharmaceuticals market with market share of 45% in 2023. Europe on the contrary is expected to see a decline in its market share to 20% of global pharma industry in 2023. Asia Pacific pharmaceuticals market is expected to retain its second position with a market share of 24% in 2023. Latin America and Middle East and Africa (MEA) are expected to retain 8% and 3% market share of global pharmaceuticals market in 2023, respectively.



Global pharmaceutical growth is fueled by increasing and ageing population in key markets. As per World Population Prospects by United Nations, the worldwide population is likely to cross 9.3 billion by 2050 and around 21% of this population is expected to be aged 60 and above. Apart from ageing and rising population, improvement in purchasing power and access to quality healthcare and pharmaceuticals to poor and middle-class families worldwide is also driving the growth of global pharma industry. Another aspect which is leading this growth is rising focus of pharmaceuticals companies to tap the rare and specialty diseases market. Innovations in advanced biologics, nucleic acid therapeutics, cell therapies and bioelectronics and implantable has attracted investments in the industry by even non-pharma companies like Facebook, Qualcomm etc. which is also driving the global pharmaceuticals industry growth. On the other hand, adoption of cost control policies along with tightening of rules by governments in key markets are expected to impact the growth prospect of the global pharmaceuticals industry.

Like many globalized markets, the pharmaceutical industry is also concentrated among established players, with the Top 10 largest pharma firms by revenue representing more than one third (35%) of global revenue for 2022. Likewise, these firms are representative of the largest pharmaceutical markets, led by the United States, which accounted for almost 45 % of global pharmaceutical revenue in 2022. There are, however, trends demonstrating a shifting landscape, with China's growing share of global revenue at almost 10 % (only behind the United States). Though this is partially due to China's massive population growth in recent decades, it has also become a leader amongst pharma emerging markets.

WORLD TOP 10 LARGEST PHARMACEUTICAL FIRMS		
Rank	Company	Revenue 2022 USD Billion
1.	Pfizer Inc., USA	100.33
2.	Johnson & Johnson, USA	94.94
3.	Sinopharm, China	80.19
4.	F. Hoffmann-La Roche Ltd, Switzerland	69.77
5.	Merck & Co., USA	59.28
6.	AbbVie Inc., USA	58.05
7.	Bayer, Germany	53.88
8.	Novartis, Switzerland	50.55
9.	Sanofi-Aventis, France	46.86
10.	Bristol Myers Squibb, USA	46.16

Pharma companies are experiencing a new wave of innovation; with disruptive technology such as AI, 3D printing and precision medicine making waves, the potential for new and lifesaving and life - changing discoveries is at an all-time high. Going forward, focus will be on high growth opportunities, which means that mergers and acquisitions will focus more on oncology and immunology, while other areas including vaccines, cardiovascular diseases and central nervous systems diseases will also be areas of focus.

Global Regulatory Environment

The pharmaceutical industry is heavily regulated world-wide. Pharmaceutical regulations across the world play an important role in ensuring safety, efficacy and affordability of the approved drugs. Both products which are produced domestically and those imported from other countries are regulated.

Every country has its own regulations framed under its own laws. These regulatory controls pursue three primary objectives: (a) preserving the incentives for research and development and the flow of new innovative drugs; (b) ensuring safety of drugs consumed by the public; and (c) controlling the quantity and quality of drug expenditures, thus all aspects of the life-cycle of new drugs as well as existing products, from patent application, to marketing approval, commercial exploitation, patent expiration and competition with generics are controlled. However, pharmaceutical standards and regulatory systems across the world remain in many countries fragile, uneven and highly dependent on aid and technical support from international donors. Strengthening regulatory capacity worldwide remains an important need, as access to quality medicines can only be ensured by the presence of a strong regulatory system. Global coordination however continues to be a challenge in this regard.

PAKISTAN PHARMACEUTICAL MARKET

Pakistan pharmaceutical industry is essentially concentrated on drug formulation rather than innovation. As a formulation industry, its pharmaceutical products mostly include tablets, liquids and syrups, injections, capsules, tinctures and ointments. The value chain of the Pakistan pharmaceutical sector is therefore as under:

Pakistan's pharmaceutical industry is a growing, fast-paced market. The industry meets around 90% of the country's demand of finished dosage forms and 4% of active ingredients. Specialized finished dosage forms such as soft gelatin capsules, parenteral fat emulsions and metered-dose inhalers continue to be imported. There are only a few bulk drug active ingredient producers and the country mainly depends on imports of bulk drugs for its formulation needs resulting in frequent drug shortages. Almost all the raw materials used in making of medicine are sourced from abroad.

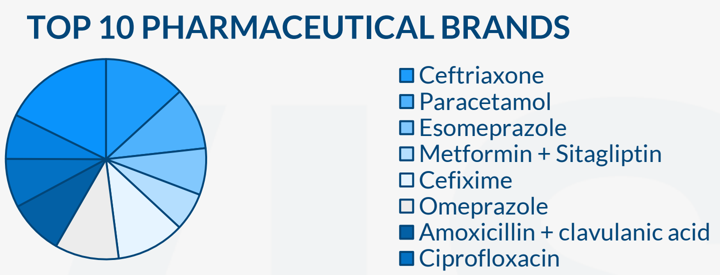
The market is dominated by locally manufactured pharmaceuticals, predominantly generic drug manufacturers, which meet approximately 70 % of the country's needs. Remaining 30% is met by local manufacturing of multinational companies (MNCs) and imports. Domestic pharmaceutical sales have grown 15.3 %, compounded annually in 2019–23, outperforming multinational companies (MNCs), which saw a global growth of 9.34 % CAGR. There has been more growth for local companies as market is basically a low cost generic market. Currently Pakistan has more than 800 pharmaceutical formulation units, including those operated by 25 multinationals present in the country. As of June 2023, the value of Pakistan's pharmaceutical sector was estimated at Rs. 748 bn, with 70 % of the market's domestic need being met by local manufacturers and suppliers. The pharmaceutical market in Pakistan is expected to reach close to Rs one trillion by 2025, driven by increasing local production and healthcare spending.

Pakistan Pharmaceutical Market					Rs million
	2019	2020	2021	2022	2023
Total Market	422,919	471,397	559,777	655,059	748,072
National	296,174	330,368	396,638	472,622	546,639
MNCs	126,744	141,029	163,139	182,436	201,432

The market structure for the Pakistan pharmaceutical industry is also skewed – the top 10 firm have around 47% and the top 25 firms occupy 72 % of the market share. The top 50 companies hold nearly 90 % of the market share. This leaves more than 750 small and medium-sized enterprises competing for the remaining 10 % of the market. Such a highly skewed market sharing has implications for quality and technology levels in the sector, as well as the viability of small and medium firms that are forced to operate on relatively narrow margins.

Top 10 Pharmaceutical Companies in Pakistan - June 2023		
S.No	Company	National/MNC
1.	Getz Pharmaceutical	National
2.	GlaxoSmithKline	MNC
3.	Sami	National
4.	Abbott Laboratories	MNC
5.	The Searle Company	National
6.	Martin Dow Limited	National
7.	Hilton Pharmaceutical	National
8.	High-Q International	National
9.	OBS	National
10.	Bosch Pharma	MNC

Like-wise, market share of pharmaceutical companies, share of the brands is also highly skewed. Among thousands of medicines marketed in Pakistan, share of the top 10 brands has consistently been around 22% of the total industry sales as under:



Marketing efforts and delivery channels play a crucial role in growth of a pharmaceutical company. In Pakistan, retail pharmacies have major share followed by whole sales and direct sales to doctors in the delivery system as under:

SHARE OF VARIOUS SALES CHANNELS	
Retail Pharmacies	61%
Whole Sales	16%
Direct to Doctors	10%
Private Hospital Pharmacies	7%
Hospital vicinity	3%
Chain Pharmacies	3%
e- Pharmacies	Negligible

Even though Pakistan has managed to establish itself progressively as a manufacturing platform for pharmaceuticals, the country remains a small player in the international trade. Pharmaceuticals ranked as the 17th largest export sector for Pakistan in 2022, with a world export ranking of 62. Globally, the sector witnessed a growth of 9.34 % CAGR in 2019–22, whereas Pakistan's exports have steadily increased at the CAGR of 12% over the years reaching USD 328 million in FY2023 as under:

Pakistan Pharmaceutical Exports					USD million
Financial Year	2019	2020	2021	2022	2023
Exports	212	210	270	269	328

Strict regulatory requirements for exportable pharmaceutical goods have also shaped the industry's performance in Pakistan. Investment in R&D and improving manufacturing processes to the global standards is therefore an important factor in capturing export markets, particularly, US and European markets. The industry is trying to upgrade itself and presently the majority of industry is following local Good Manufacturing Practices (GMP) laws, in accordance with international guidelines. Currently two Pakistani pharmaceutical firms comply with US Food and Drug Administration (FDA) regulations, while Pakistan Drugs Testing and Research Center (PDTRC) is the first and only WHO-PQ laboratory in Pakistan.

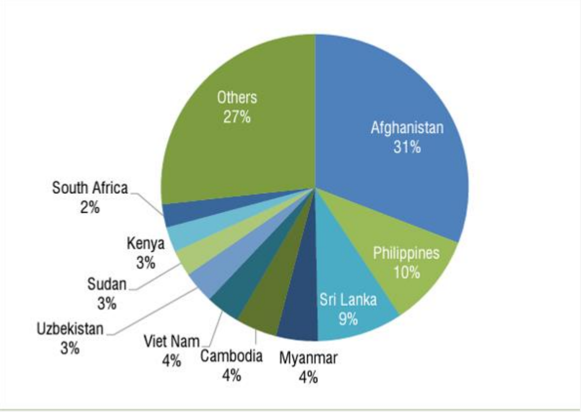
Due to inadequate implementation of international standards, Pakistani pharmaceutical exports are mostly oriented towards the less and semi-regulated markets of Asia and Africa. Accordingly exports of the selected Pakistani pharmaceuticals are concentrated in a limited number of markets. The top export markets for Pakistan has not varied much. Afghanistan, Sri Lank, Philippines, Vietnam, and South Africa are the biggest markets for Pakistani pharmaceuticals. However the domestic industry has recently penetrated non-traditional markets such as Africa and East and Central Asia, but the value of the commodities traded remains limited.

Raw materials in the Pakistan pharmaceutical industry mainly consist of Active Pharmaceutical Ingredients and excipients. However, import of pharmaceuticals takes all forms including APIs, excipients, intermediate drugs and ready to use drugs. Import of pharmaceuticals during the last 5 years were as under:

Pakistan Pharmaceutical Imports					USD million
Financial Year	2019	2020	2021	2022	2023
Import (USD Million)	1,093	997	1,390	4,063	1,329

Pakistan Pharmaceutical Regulatory Environment

Pharmaceutical industry in Pakistan is governed under The Drugs Act, 1976. The Drug Regulatory Authority of Pakistan (DRAP) is the apex regulatory body for pharmaceutical industry and is responsible for enforcement of The Drugs Act, 1976 by way of controlling licensing, registration, advertisement, import, export and research in pharmaceuticals in Pakistan. Therapeutic goods regulated by the DRAP include pharmaceutical and biological drugs for human or veterinary use; medical devices and medical cosmetics and health &



OTC (non-drugs) also known as alternative. DRAP ensures that therapeutic goods, approved and available in market, meet prescribed standards of quality, safety and efficacy.

As an apex body DRAP controls the registration of new medicines (both local and imported) and new manufacturing sites. Also, all pharmaceutical imports are subject to NOC from DRAP and it also determines Maximum Retails Price (MRP) of all medicines marketed in Pakistan. Other functions performed by DRAP include, vigilance, market surveillance and control, regulatory inspection, laboratory testing, clinical trials oversight, pharmacovigilance, lot release of biologicals etc. The industry is also regulated by the Ministry of Health Services, Regulations & Coordination, whereas Pakistan Pharmaceutical Manufacturing Association (PPMA) and Pakistan Tibbi Pharmaceutical Manufacturing Association (PTPMA) are the major associations in the industry.

SECTOR DYNAMICS

The Pakistan pharmaceutical industry is characterized by low entry barriers and significant regulations.

- Key success factors include drug development capabilities, advanced manufacturing facilities, manufacturing quality, distribution network reach, skilled workforce, brand reputation and cost efficiencies.
- Patent protections are relatively weak, allowing imitation of patented drugs. This drives domestic competition but deters innovation.
- Government policies like price controls and regulatory changes significantly influence the sector outlook.
- Though there is no evidence of sector cartel, however, product differentiation provides pricing power to the top companies.
- Large MNCs enjoy premium positioning but local firms compete well on costs.

SECTOR ISSUES

The Pakistan pharmaceutical sector has certain characteristics that have impeded its progression to a mature pharmaceutical sector. These characteristics to a large extent explain the mixed performance of the sector, which while growing at compound annual growth rates averaging above 15% over the last five years, has been unable to translate it into global success.

- Firstly, the sector composition is skewed in favor of large companies with the top 10 firms enjoying large market share, which reduces competition, innovation and investment in R & D.
- Secondly, prices are heavily controlled with excessive government regulations. Since 2010, this has caused several MNCs to exit from Pakistan. MNC departure has reduced efficiency, skills and technology transfer, investment, quality and capacity upgradation.
- Thirdly, the issue of weak regulation and enforcement of standards by DRAP has led to coexistence of multiple quality standards of manufacturing facilities.
- Fourthly, due to existing pricing regime and weak intellectual property rights, MNCs in Pakistan target the local market, do not export from Pakistan, and have not pursued Stringent Regulatory Authority (SRA) approvals for their manufacturing facilities which has lowered incentive for MNCs to register innovative (new) medicines.
- As healthcare expenditure in Pakistan is primarily financed privately, the affordability of new medicines is also a factor. Moreover, healthcare access disparity due to poverty and rural-urban divide limits domestic market expansion.

- Lengthy registration process for new and generic drugs, weak enforcement of quality standards and Good Manufacturing Practices (GMP) and absence of clear intellectual property rights are some of the other issues facing the industry.

SECTOR OUTLOOK

The pharmaceutical sector outlook in Pakistan remains positive driven by population growth, increasing health awareness, rising personal income and heavier disease burden. Pakistan is also strategically positioned to capitalize on the shifts in global supply and demand patterns. Nonetheless, the ongoing trend of relying on imports for 95% of raw materials is unsustainable as a permanent strategy for the industry. Prioritizing investment in research and development and exploring new export markets remains key. For now, the industry remains vulnerable to exchange rate volatility. Margins, therefore, are likely to remain constrained in the wake of limited pricing power.

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