

## ACTIVE PHARMACEUTICAL INGREDIENTS (API) MANUFACTURING - CASE STUDY OF PAKISTAN

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(CGP # 05-061)

*(This document is unedited author's version submitted to RASTA)*

### PHARMACEUTICAL SECTOR

#### Manufacturing Process

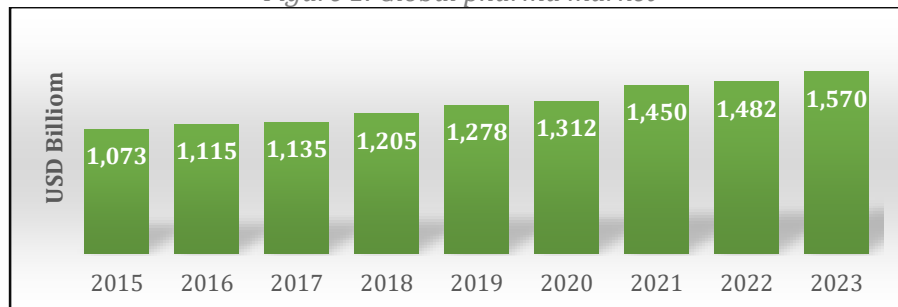


Source: PPMA

### Global Perspective

In recent years, the pharmaceutical industry has witnessed significant expansion. As of 2022, the global pharmaceutical market was valued at USD 1.48 trillion, projected to reach USD 1.57 trillion by the end of 2023, and anticipated to surpass USD 1.7 trillion by 2025. The pharmaceutical industry is characterized by a concentration of established players, with the top 10 firms generating more than a third (35%) of global revenue in 2022. The United States remains the primary contributor to global pharmaceutical revenue, accounting for nearly 45% in the same year.

Figure 1: Global pharma market



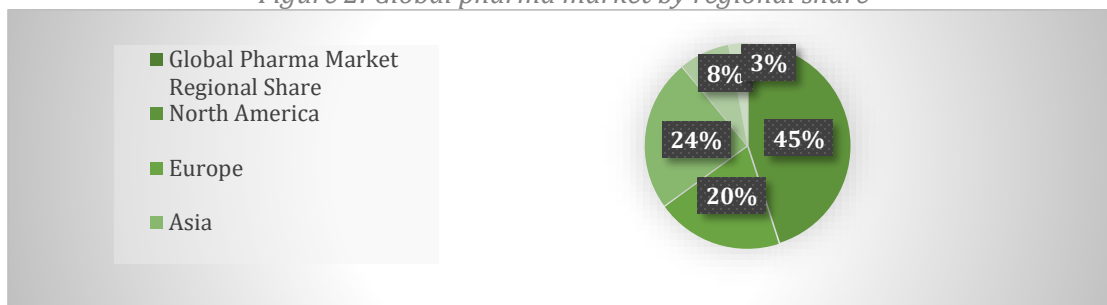
Source: VIS Credit Rating Company Limited (2023).

Table 1: Global top 10 pharmaceutical companies

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. Hoffman-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 Myer Squibb, USA	46.16

Source: VIS Credit Rating Company Limited (2023).

Figure 2: Global pharma market by regional share

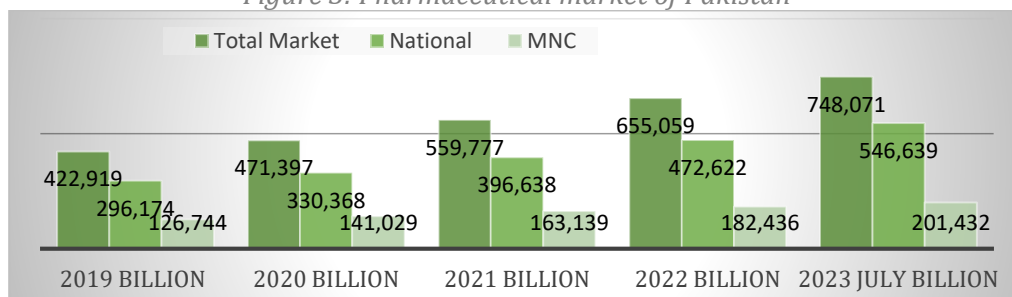


Source: VIS Credit Rating Company Limited (2023).

## Pakistan Perspective

Pakistan's pharmaceutical sector has undergone remarkable growth and evolution recently, focusing primarily on drug formulation. Locally manufactured pharmaceuticals, especially generic drugs, dominate the market, satisfying about 70% of the nation's needs, while multinational companies (MNCs) and imports cover the remaining 30%. (economies). Currently, there are 639 pharmaceutical manufacturing units in Pakistan, employing around 240,000 people and exporting products worth over \$200 million to more than 60 countries. The market structure is heavily skewed, with the top 10 firms commanding 49% and the top 25 firms holding 75% of the market share. The sector's current value is Rs. 828 billion and projected to reach close to Rs. one trillion by 2025, driven by increasing local production and healthcare expenditure.

Figure 3: Pharmaceutical market of Pakistan



Source: VIS Credit Rating Company Limited (2023).

Table 2: Pakistan's top 10 companies

TOP 10 COMPANIES SALE VALUE DEC 2023					
Category	Company	Value Rs. (in Billion)	Units (in Million)	Value Share (%)	CAGR 2023vs2019
Total Pharma Market (Dec 2023)		828			16.14
National	Getz pharma	58.2	154.0	7.03	21.07
National	Sami	51.7	205.9	6.24	11.44
Multinational	GlaxoSmithKline	49.9	370.4	6.03	15.77
Multinational	Abbott Lab Pak Ltd	48.0	234.5	5.79	17.51
National	The Searle Company	46.7	247.4	5.64	15.78
National	Martin Dow Limited	34.0	135.6	4.11	23.85
National	Hilton	32.6	76.4	3.93	12.44
National	OBS	29.8	108.9	3.60	16.86
National	High-q Intl	28.7	90.3	3.46	19.32
Multinational	Haleon Pak Ltd.	27.1	136.5	3.27	18.89
Total		406.7		49.10	17.38(avg)

Source: IQVIA (2023).

Table 3: Top 25 companies' sale, December 2023

TOP 25 COMPANIES SALES VALUE DEC 2023					
Category	Company	Value Rs. (in Billion)	Units (in Million)	Value Share (%)	Value Growth (%)
Total Pharma Market		828	3634	100	17.59
National	Getz Pharma	58.2	154.0	7.03	28.83
National	Sami	51.7	205.9	6.24	20.75
Mncs	GlaxoSmithKline	49.9	370.4	6.03	16.92
National	Abbott Lab Pak Ltd	48.0	234.5	5.79	12.43
National	The Searle company	46.7	247.4	5.64	17.18
National	Martin Dow limited	34.0	135.6	4.11	18.97
National	Hilton	32.6	76.4	3.93	30.83
National	OBS	29.8	108.9	3.60	14.14
National	High Q international	28.7	90.3	3.46	32.02
Mncs	Haleon Pakistan Ltd.	27.1	136.5	3.27	18.89
Mncs	Bosch	21.8	94.5	2.63	15.75
National	Highnoon	21.1	84.1	2.55	22.82
Mncs	Sanofi-Aventis Pakistan	19.8	69.6	2.40	17.21
National	CCL	18.9	53.6	2.28	43.34
National	Atco	18.8	119.7	2.27	24.83
National	Barrett Hodgson	16.5	116.7	1.99	17.74
National	Pharm Evo Pvt. Ltd.	13.1	38.7	1.58	28.27
National	Nestle Pakistan Ltd	13.0	50.8	1.57	5.70
National	Nabi Qasim	12.1	69.1	1.46	15.31
National	ICI	11.7	75.2	1.42	11.40
Mncs	Pfizer Inc	11.5	32.7	1.38	7.03
National	Ferozsons	9.9	34.6	1.20	50.58
Mncs	Novartis Ph. Pak Ltd	9.4	19.9	1.13	-1.69
National	Novo Nordisk	8.9	8.7	1.08	19.81
National	Macter	8.9	25.3	1.07	21.74
Total		622.1	2653.3	75.11	

Source: IQVIA (2023).

## ACTIVE PHARMACEUTICAL INGREDIENTS (API) SECTOR

### Global Perspective

The active pharmaceutical ingredients (API) market is anticipated to witness a significant rise, climbing from USD 216 billion in 2024 to approximately USD 306 billion by 2029. Asia Far East accounts for 60.5% of global API production, followed by Western Europe with 27.9%, North America with 4.6%, and the remaining 7% from other regions. Presently, China and India stand as the primary providers of pharmaceutical raw materials and excipients on a global scale. Around 72% APIs are imported by US from China. China is one of the main suppliers supplying 13% of API to US. 83% of medicines in US had no US source of API out of 100 generic medicines. Figure 2 shows

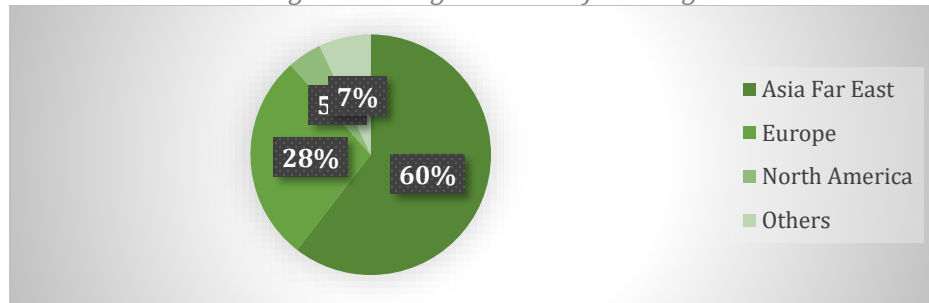
China is the biggest supplier of raw materials for Active Pharmaceutical Ingredients. India accounts for 20% of the global production by volume and 7% for value. According to report by. Figure I indicate China is the largest producer of API however USA is the largest producer of API by value followed by China.

Table 4: API global market

Market-2024	Anticipated Market-2028	Anticipated CAGR
216 billion	306 billion	7.22%

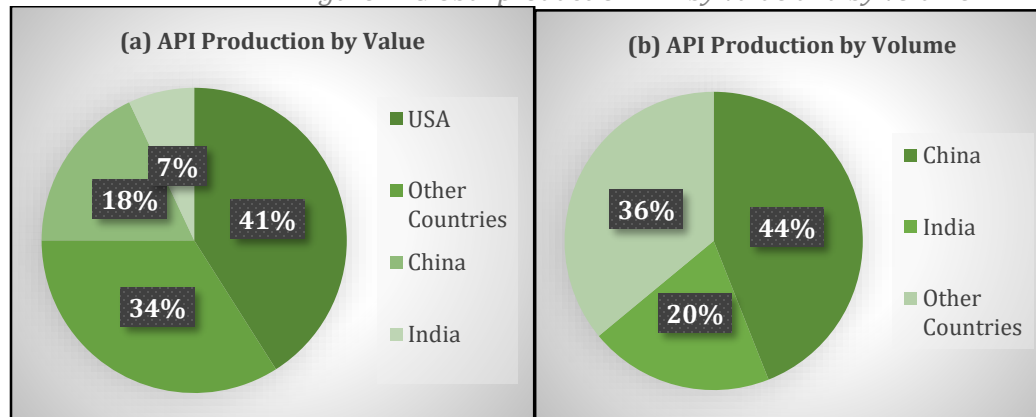
Source: Mordor Intelligence (2023).

Figure 6: API global manufacturing



Source: IQVIA (2020).

Figure 1: Global production API by value and by volume



Source: Cherian et al. 2021.

## Pakistan Perspective

Pakistan has a promising opportunity in the expanding off-patent drugs market, projected to reach USD 700 billion for branded generics and USD 381 billion for generics by 2025. Currently, Pakistan imports 90% of its raw materials for drug manufacturing, indicating significant vulnerability. Despite having over 639 pharmaceutical companies, only 6-7 produce APIs locally. The domestic API market is valued at approximately \$175 million, with only 32 out of 73 enlisted APIs made locally, covering just 10% of the country's API needs. Political tensions with India, a major API supplier, highlight the urgency for Pakistan to enhance local API production.

## FINDINGS

### ***API Policy Implementation***

*Finding:* The API policy, promulgated over two years ago, has seen minimal implementation progress, likely not exceeding 20%. Consequently, promised benefits and infrastructure development initiatives such as setting up of facilitation center, API parks and the feasibility study for a Naphtha Cracking plant remain stagnant. This stagnation has led to a decline in industry growth, causing potential investors to withdraw. Stakeholder interviews have revealed concerns regarding the lack of an ecosystem necessary for API industry development, including low-cost utilities, land availability, electricity supply, production clusters, and API parks etc.

*Issue:* Minimal progress in API policy implementation hindering industry growth in Pakistan.

*Recommendation:* Establishing a Special Task Force for effective Implementation of the API Policy and development of ecosystem for industry development.

### ***Quality Compliance & Accreditations***

*Finding:* A comprehensive review, focusing particularly on successful endeavors in India and Bangladesh, underscores the pivotal role of "Quality, Compliance, International Accreditation, and FDA Approval" for entry into API & Pharmaceuticals export markets. Interviews with industry experts further validate concerns within the pharmaceutical sector regarding the utilization of locally manufactured APIs due to apprehensions related to quality, consistency, compliance, and accreditation. Notably, the import substitution of high-value APIs is impeded by the substantial investment required to enhance infrastructure and cultivate an ecosystem conducive to quality, compliance, and accreditation. Additionally, the competitiveness of the API industry is intricately linked with the scaling up of production and export, necessitating FDA approvals, accreditation, compliance, and adherence to quality standards. Recognizing Pakistan's potential to tap into the USD 193 billion API export market like Bangladesh and India, addressing these barriers is imperative.

*Issue:* Quality, compliance, and accreditation barriers hinder Pakistan's entry into international pharmaceutical & API markets and minimize local consumption.

*Recommendation:* Establish a Quality, Compliance, and Accreditation Upgrade Cell to address industry concerns and facilitate market entry.

### ***Research and Development***

*Finding:* The API industry in Pakistan faces a critical need for robust research infrastructure to meet growing demands. Existing governmental labs like Central Drug Laboratories and research centers, lack resources for rigorous R&D. Significant investment is essential for upgrading equipment, adopting new technology, and enhancing staff capabilities. This investment is crucial to reduce reliance on imported intermediates and to establish basic API manufacturing capabilities. Stakeholder interviews emphasize the necessity of dedicated research centers, citing the success of such centers in India and Bangladesh. With high-value API patents expiring soon, proactive investment in research and development is imperative. Establishing an API research center is not an option but a vital step for Pakistan's pharmaceutical growth.

*Issue:* The insufficient research infrastructure, hindering Pakistan's API industry development and necessitating significant investment in upgrading equipment and staff capabilities.

*Recommendation:* Establish Active Pharmaceutical Ingredients (API) Research & Development Center.

## **FUTURE RESEARCH**

### ***Status of compliance in Pakistan***

Imports of APIs into Pakistan from countries like India, China, and Bangladesh etc. require Drug Master File (DMF) and various certifications. APIs manufactured in these countries are accepted globally due to compliance with international standards and the provision of DMF for regulatory registrations in other countries. APIs manufactured in Pakistan also strive to meet global standards; however, availability of DMF is limited for many APIs. This limitation prevents medicines made with these APIs from being registered internationally, affecting export potential.

### ***Recommendation***

Conduct a comprehensive research study to assess current API compliance challenges in Pakistan, identifying specific gaps in meeting international quality standards. Propose strategic interventions focusing on infrastructure investment, regulatory alignment, and stakeholder collaboration to enhance industry competitiveness, facilitate export potential, and ensure sustained growth in the pharmaceutical sector.

### ***Deliverable***

*Recommend Solutions and Stakeholder Roles:* Propose actionable recommendations for bridging these gaps. Define roles for stakeholders including DRAP, industry, pharmaceutical companies, R&D institutions, and others to strengthen API quality infrastructure.

*Develop a National Strategic Implementation Framework:* Formulate a strategic framework outlining priorities and timelines for implementation. Address policy and legislative needs to support the growth of the API industry in Pakistan and facilitate export potential

## **RESEARCH METHODOLOGY**

### ***Desk Review***

Comprehensive searches on ResearchGate and other online sources provided insights on Pakistan's API manufacturing industry. This included professional reports, policy papers, and consulting documents, with a global perspective focusing on India and Bangladesh. The study aimed to consolidate data for developing API policies in Pakistan.

### ***API Manufacturing Plant Feasibility Studies***

Qualitative interviews with API industry experts and managers deepened understanding of manufacturing processes. Insights on plant infrastructure, equipment, processes, and challenges were gathered through semi-structured interviews, ensuring confidentiality and ethical standards.

## ***Pharmaceutical & API Market Analysis***

IMS database data for 2022-23 was cleaned and analyzed using Tableau and Power BI tools. The analysis assessed market size, trends, growth rates, and API molecule sales, visualizing data with bar charts for clarity and accuracy.

## ***APIs Import Data Analysis – AI Tool***

Customs data from 2014 to June 2022 was cleaned and visualized using Tableau and Power BI. The analysis explored import trends by molecule, company, and country of origin, ensuring accuracy through cross-validation and dashboards.

## ***Qualitative Analysis***

Utilizing stakeholder interviews, including trade bodies, research institutes, universities, and industry experts, key insights were extracted using advanced AI techniques. Thematic analysis and stakeholder input validated findings, leading to actionable policy recommendations for industry development.

## **CONCLUSION**

The study aimed to explore and unlock opportunities within Pakistan's pharmaceutical and Active Pharmaceutical Ingredient (API) sectors, drawing inspiration from Bangladesh's transformation into a significant API exporter. It identified critical challenges and proposed strategic priorities for developing and promoting the API industry, which forms the backbone of Pakistan's pharmaceutical sector. Key insights reveal that while Pakistan's pharmaceutical sector meets domestic demand, significant potential exists to increase exports from USD 200 million to USD 1 billion within 2-3 years. However, accessing developed markets remains hindered by FDA approval hurdles. The API industry, still nascent, heavily relies on imports, yet local manufacturing capacity can meet domestic needs and target the export market. Currently, Pakistan manufactures 32 APIs, with potential for substantial import substitution if quality, compliance, and supply concerns are addressed. Crucially, the study identifies top-selling APIs in Pakistan and forecasts upcoming opportunities as high-value and blockbuster APIs lose patent protection by 2025 and 2027 respectively. It underscores the need for improved regulatory frameworks and investment in R&D infrastructure to support generic manufacturing.

Policy recommendations emphasize establishing a centralized API research center to enhance R&D capabilities, facilitating technology transfer from multinational pharmaceutical companies for off-patent APIs, and incentivizing local manufacturing through policy interventions. Effective policy implementation, including reducing customs duties, combating dumping practices, and establishing API Mega Parks, is vital but currently hindered by bureaucratic hurdles and lack of coordination among stakeholders. To propel growth, it is imperative to transition regulatory bodies from policing to facilitation, enhance industry-academia collaboration via the Higher Education Commission, and align with international quality standards. Capacity-building initiatives for regulatory staff and improving ease of doing business are also critical to strengthen Pakistan's API manufacturing ecosystem. In conclusion, the study advocates for urgent action to harness Pakistan's pharmaceutical potential by addressing regulatory challenges, enhancing R&D infrastructure, and fostering strategic partnerships. By doing so, Pakistan can capitalize on its existing capabilities to become a competitive player in the global API market while ensuring sustainable growth and innovation within its pharmaceutical sector.

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