

A Comprehensive Review Of The Global Api Industry: Market Insights And Strategic Outlook

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Abstract:

The global Active Pharmaceutical Ingredient (API) market has witnessed robust growth, driven by an aging population, rising prevalence of chronic diseases, and increasing healthcare expenditure in developed and emerging economies. This growth is further fueled by the demand for innovative drugs, biosimilars, and generics. Historically dominated by the U.S. and Europe, API manufacturing has shifted to Asia, with India and China emerging as key players due to their cost advantages, skilled labor, and government support. India, dubbed the "pharmacy of the world," is a leading exporter, while China dominates global API production by volume.

The API market is not without challenges, including supply chain vulnerabilities, regulatory complexities, and environmental concerns. The COVID-19 pandemic exposed the fragility of global supply chains, prompting discussions on reshoring and diversifying production. Technological advancements in biopharmaceuticals, high-potency APIs (HPAPIs), and continuous manufacturing are reshaping the industry, creating opportunities for growth in personalized medicine and biologics.

The Indian API sector, a fragmented market with over 1,500 manufacturers, is positioned for significant expansion post-COVID. Supported by initiatives like the Production Linked Incentive (PLI) scheme and bulk drug parks, India aims to reduce dependency on imports and strengthen its global position. The domestic market is expected to grow at 11.5 % - 12.5 % CAGR, while exports are forecasted to grow at 9.5 % - 10.5 %.

Globally, the API market, valued at \$181.3 billion in 2020, is projected to reach \$259.3 billion by 2026, driven by increasing demand for oncology drugs, biologics, and generics. India, contributing 8 % to the global API market, continues to gain prominence as patents expire and demand for cost-effective and innovative solutions rises. The future of the API industry hinges on balancing innovation, sustainability, and resilience in the face of evolving healthcare demands.

Keywords: Active pharmaceutical ingredient, Innovative drugs, Generics.

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I. Introduction

The global API market has experienced significant growth over the past few decades, driven by several key factors, including an aging population, increasing prevalence of chronic diseases, and rising healthcare expenditure in both developed and emerging economies. As a result, pharmaceutical companies are under constant pressure to innovate while maintaining cost efficiency, making the sourcing and production of APIs a critical factor in their competitiveness.[1]

At the heart of the API industry is a highly globalized and specialized supply chain. Historically, the API manufacturing landscape was dominated by the U.S. and Europe. However, in recent decades, Asia, particularly India and China, has emerged as a dominant force, becoming the largest producers of both generic and innovative APIs. These countries have capitalized on lower production costs, skilled labor, and government incentives to become integral to the global pharmaceutical supply chain. As of today, India is known as the "pharmacy of the world" for its significant role in global API exports, while China is the largest API supplier by volume.

Despite this, the global API market faces numerous challenges, including supply chain vulnerabilities, quality control issues, environmental concerns, and shifting regulatory landscapes. The COVID-19 pandemic underscored the fragility of the API supply chain, with disruptions leading to shortages of critical medications. This has prompted many pharmaceutical companies and governments to reassess their reliance on overseas manufacturing, leading to discussions on reshoring or diversifying API production.[2]

Technological advancements are also reshaping the API industry. Innovations in biopharmaceuticals, high-potency APIs (HPAPIs), and continuous manufacturing techniques are pushing the boundaries of what is possible in drug development and manufacturing. As personalized medicine and biopharmaceuticals gain

prominence, the demand for specialized APIs, particularly biologics, is expected to surge. This creates both opportunities and challenges for traditional API manufacturers, who must adapt to these changing demands.

The Active Pharmaceutical Ingredient (API) industry refers to the sector responsible for designing, developing, manufacturing, and supplying the active components of medications, which provide the therapeutic effect.[3]

API: An Active Pharmaceutical Ingredient (API) is any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Drug manufacturing process is shown in Figure no 1.



Figure no 1: Drug manufacturing process

Terminologies:

API [4]: It is the basic drug itself with the desired medicinal pharmaceutical properties, also known as bulk drug. It is prepared with specified strength & concentration.

Intermediaries: Most chemical reaction are step wise, that is they take more than one elementary step to complete and the intermediary formed in the process of making an API is called an intermediate.

Excipients: The excipient includes substances other than the drug that help deliver the medication to your system.

Finished dosage/ Formulations: It is the form in which the drug is consumed by us. A dosage form of a drug is usually composed of two things: The API, which is the drug itself; and an excipient, which is the substance of the tablet, or the liquid the API is suspended in.

II. Major Segments In Pharmaceutical Industry [5]

Contract Research & Manufacturing Services (CRAMS): Outsourcing services to providers such as contract research organizations (CROs) and contract manufacturing organizations (CMOs) consist of two primary segments: contract manufacturing services, which makes up 60 % of the market, and contract research services, accounting for the remaining portion. India's projected market size for 2024 is approximately USD 12 billion, with an anticipated compound annual growth rate (CAGR) of 10.7 %.[6]

Over The Counter Medicines (OTC): The over-the-counter (OTC) segment includes medicines that can be purchased without a prescription. The largest category within this segment is vitamins and minerals, with a market volume of USD 2.3 billion as of 2023[7]. The overall OTC market size in India is USD 6.1 billion in 2023, with an anticipated compound annual growth rate (CAGR) of 7.5 %.

Vaccines: A biological substance designed to strengthen the immune system and protect against bacterial and viral infections, vaccines are a critical component of public health. India contributes to 60 % of global vaccine production. The Indian vaccine market size was USD 2.7 billion in 2023, with an expected compound annual growth rate (CAGR) of -16.5 %. This decline is primarily due to reduced demand for COVID-19 vaccines, though demand for other vaccines is expected to maintain a steady growth trend.[8]

Active Pharmaceutical Ingredient (APIs): An active pharmaceutical ingredient (API) [9] is the biologically active component of a drug responsible for its intended medical effect. India ranks as the third-largest market for APIs globally, holding an 8 % global share and contributing 57 % of APIs to the World Health Organization's prequalified list. The Indian API market size was USD 20 billion in 2021, with an expected compound annual growth rate (CAGR) of 8.3 %.

Generic Medicines: Generic drugs [10] are affordable versions of branded medications introduced after the expiration of the original drug manufacturer's patent. Key growth drivers include an increase in chronic diseases, such as diabetes and cardiovascular conditions, as well as lifestyle changes. In India, the market size for generics reached USD 24.5 billion in 2022, with an expected CAGR of 7.0 %.

Biosimilars & Biologics: Biologics are drugs derived from living cells or organisms, used to treat severe and life-threatening diseases. Biosimilars, [11] a class of drugs related to biologics, are designed to improve patient access to these treatments. India accounted for 8 % of the global biopharmaceutical market in 2021. The projected market size for biosimilars and biologics in India is USD 12 billion by 2025, with an expected CAGR of 22.0 %.

III. Market Overview Of Global API Industry

The global active pharmaceutical ingredient (API) industry [12] is a cornerstone of the pharmaceutical supply chain, responsible for producing the essential compounds that give drugs their therapeutic effects. As healthcare needs expand globally due to an aging population and the rising prevalence of chronic diseases, the demand for APIs has surged. This industry has evolved rapidly, with significant contributions from synthetic and biologic APIs, which serve a wide range of therapeutic areas. Growth is further fueled by the increasing production of generics and biosimilars, particularly as patents on major drugs expire, as well as the shift toward outsourcing production to more cost-effective regions. However, the industry faces challenges, including regulatory complexities, supply chain vulnerabilities, and environmental concerns. Overall, the API market continues to adapt, driven by innovation, quality demands, and the need for resilience in global healthcare systems. Figure no 2 shows the Global API market in USD Billions.

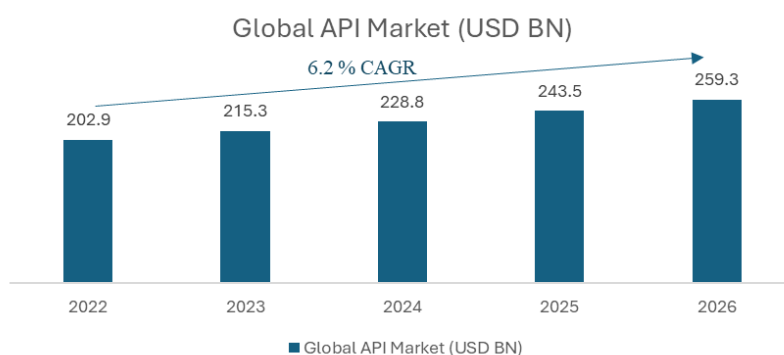


Figure no 2: Global API Market (USD BN)

The global API market [13] was valued at approximately US\$181.3 billion in 2020 and is projected to grow at a compound annual growth rate (CAGR) of 6.2 %, reaching around US\$259.3 billion by 2026. The market is expected to maintain a positive trajectory, driven by the increasing development of innovative therapeutic drugs by pharmaceutical and biotechnology companies. Key factors fueling this growth include the rising prevalence of chronic diseases, the growing demand for personalized medicine, and the emergence of new drug delivery technologies. API market by therapy is represented in Figure no 3.

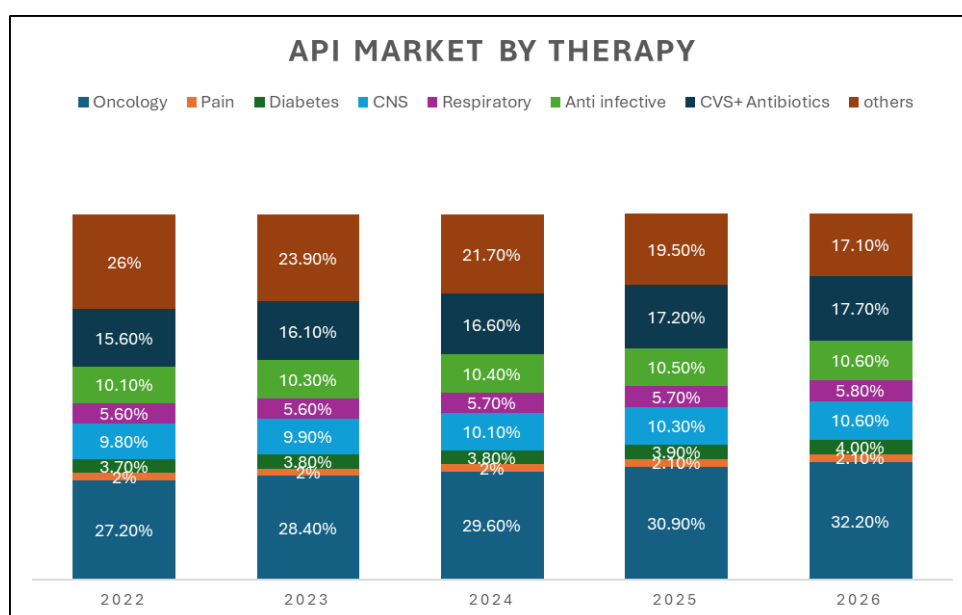


Figure no 3: API Market by therapy

The demand for oncology-related drugs [14] is growing due to the increasing prevalence of cancer in developing countries. According to the ICMR 2021 Report, the number of cancer patients in India is projected to rise from 26.7 million in 2021 to 29.8 million by 2025. This anticipated rise in cancer cases underscores the need for the development of effective drugs, driving the demand for active pharmaceutical ingredients (API) and contributing to market growth. Other segments are also expected to maintain their relevant market share.

IV. Market Overview Of The Indian API Industry

Post Covid: India’s API Industry due for a strong growth [15]

A highly fragmented market

India’s bulk drug industry is highly fragmented, with a significant presence of small, unorganized players and over 1,500 API manufacturing facilities. India produces more than 500 different APIs, supplying 57 % of the APIs on the WHO’s prequalified list. Unorganized companies make up nearly half of the bulk drug sector. As of the end of FY17, the top 14 – 16 API companies held only about 16 – 17 % of the market share.

Operating Trend

India ranks as the world’s third-largest producer of APIs, contributing to 8 % of the global API market. Leading companies in the Indian API sector [16] include Divis Laboratories, Wanbury, Cadila Pharmaceuticals, Supriya Life science, Neuland Labs, Aarti Drugs, and Megafine Pharma, listed in no particular order.

Alongside numerous standalone bulk drug manufacturers, many formulation companies are backward integrated and also produce bulk drugs. The larger API producers operate in both domestic and export markets, with a stronger focus on exports to the U.S., EU, and various emerging markets. Indian API market size in USD billions is depicted in Figure no 4. Table no 1 shows the Growth prospects enhanced Indian API industry and Table no 2 shows Post covid India’s API industry growth. Indian’s API import by country is represented in Figure no 5.

Market size:

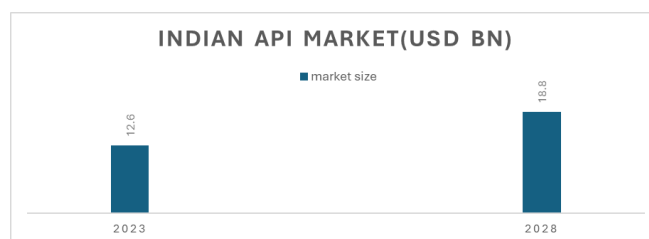


Figure no 4: Indian API Market (USD BN)

Growth prospects enhanced Indian API industry:

Industry segments	Past growth FY15-20	Forecasted growth FY20-FY25	Growth factors
Domestic bulk drugs industry	8.3 %	11.5 %-12.5 %	Growth in formulation drugs, drug parks, PLI schemes
Bulk drugs export	5.6 %	9.5 %-10.5 %	Shift from China market – Alternative supply from China [17]

Table no 1: Growth prospects enhanced Indian API industry

Pre covid: India’s API industry heavily depended on China [18]

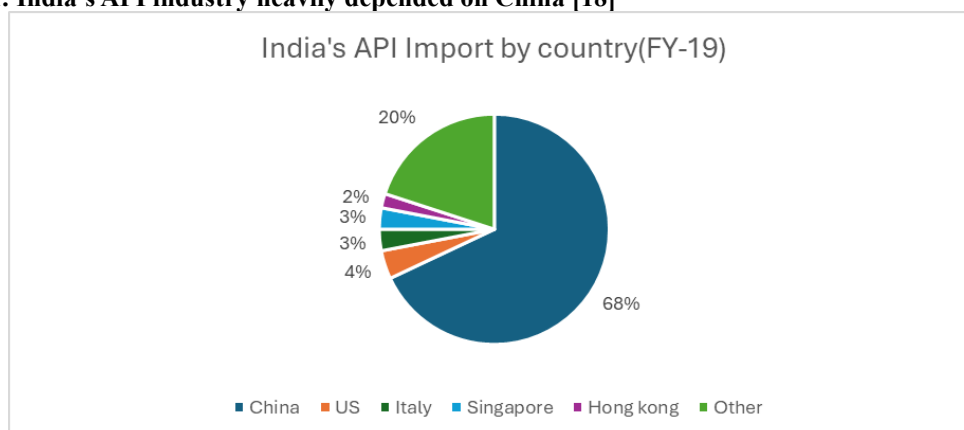


Figure no 5: Indian’s API import by country

Post covid: India’s API industry due for a strong growth[19]

Name of the scheme	Details
Production linked Incentive Scheme (PLI) [20]	<ul style="list-style-type: none"> • Tenure: FY21 to FY30. • Financial outlay: Rs. 6,490 Cr • Scheme applicable for greenfield projects • The net worth of applicant (including that of group companies) as on date of application > =30 % of total proposed investment • Maximum number of selected applicants: 136
Creation of Bulk Drug Parks	<ul style="list-style-type: none"> • Tenure: FY21 to FY25 • Financial outlay: Rs. 3,060 Cr • Three bulk drug parks will be supported under the scheme • Maximum grand-in-aid for one bulk drug park will be limited to Rs. 1,000 Cr Minimum 50 % of land area for bulk drug manufacturing units

Table no 2: Post covid India’s API industry growth

V. Global Formulation Market

Innovators vs Generic [21]

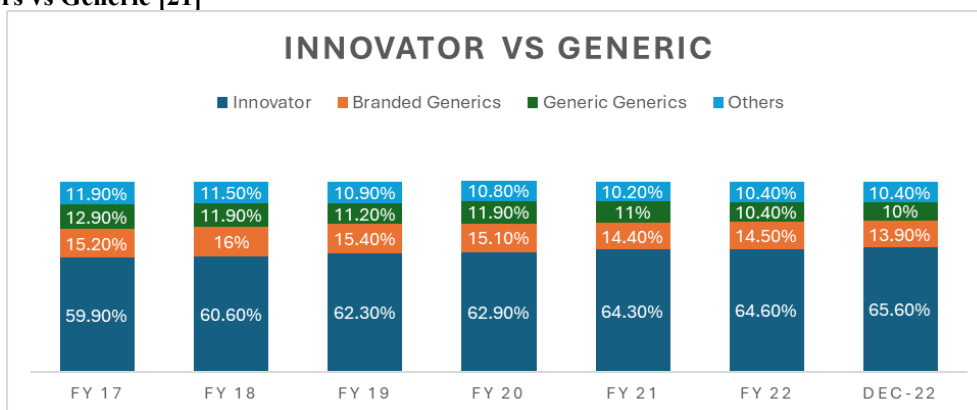


Figure no 6: Market share of Innovators vs Generics (2017-2022)

Patented drugs continue to lead the global formulation market in terms of value. Over the period from Financial Years 2017 to 2022, the value share of innovators and branded generics [22] has consistently ranged between 59 - 65 % and 14 - 16 %, respectively. Additionally, 290 molecules in the US are expected to lose exclusivity between 2022 and 2026, representing a market value of US\$ 188 billion (₹ 14,100 billion) in 2020. Similarly, 313 molecules in the EU5 are set to lose exclusivity during the same period, with a market value of US\$ 38 billion (₹ 2,850 billion) in 2020. Innovators vs Generic global formulation market is represented in Figure no 6.

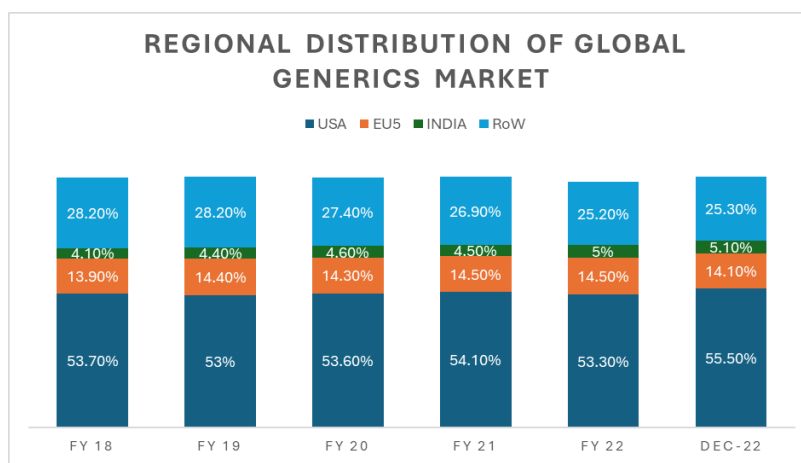


Figure no 7: Regional distribution of Global generics market

The global generics market [23] has seen steady growth at a 3.2 % CAGR from FY 2017 to FY 2022, reaching a total market value of US\$ 326.2 billion. The US and EU5 (the five largest EU markets) are the two dominant players in the generics sector, with market sizes of US\$ 82.2 billion each. Regional distribution of global generics market is represented in Figure no 7.

Regional Distribution of the Global Generics Market [24] (US\$ Billion)

From FY 2018 to FY 2022, the distribution of the global generics market by region shows the following:

- USA: Dominated the market, contributing 28.2 % to 25.2 % of the total market size between FY 2018 and FY 2022.
- EU5: The EU5 markets held steady at 25.3 % to 25.5 % of the global generics market during the same period.
- India: India registered impressive growth, with a CAGR of 12.6 % over FY 2017 - 2022, reflecting its increasing importance in the global generics market.
- Rest of the World (RoW): Contributed around 14 % to 14.5 % over the five - year period.

Market Evolution (FY 2018 to FY 2022):

- In FY 2022, the market value in India increased significantly, as reflected in the CAGR of 12.6 %.
- The USA's share, while still the largest, slightly decreased from 28.2 % in FY 2018 to 25.2 % in FY 2022, indicating growth in other regions, especially India.

VI. Conclusion

The global API market has emerged as a critical component of the pharmaceutical industry, experiencing robust growth fueled by rising healthcare demands, an aging population, and an increasing prevalence of chronic diseases. The industry's evolution has been marked by a significant geographical shift in manufacturing, with India and China dominating the landscape due to their cost advantages, skilled workforce, and supportive government policies. However, the industry faces multifaceted challenges, including supply chain vulnerabilities, regulatory pressures, and environmental concerns. The COVID-19 pandemic further highlighted the importance of supply chain resilience, prompting countries to reconsider their dependence on external sources and explore reshoring and diversification strategies. Technological advancements in biopharmaceuticals, HPAPIs, and personalized medicine have opened new opportunities while presenting challenges for traditional manufacturers. As the API market continues to grow, driven by innovation and increasing demand for generics, biologics, and oncology-related drugs, the focus will remain on balancing cost efficiency, quality assurance, and sustainability. The Indian API industry, with its expanding role as a global supplier and its shift toward reducing reliance on imports, particularly from China, is well-positioned for strong growth. Government initiatives, such as the Production - Linked Incentive (PLI) Scheme and the development of bulk drug parks, are poised to strengthen India's standing in the global API market. In conclusion, the API industry's growth trajectory remains promising, driven by evolving healthcare needs, innovation, and strategic adjustments to address challenges, ensuring its integral role in the global pharmaceutical supply chain.

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